Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Wholesaler/3PL Self-Assessment

Section Affected: Amend Section 1784 of Article 10 of Division 17 of Title 16, California Code Regulations

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). Additionally, existing law establishes that the board is authorized to license wholesalers and third-party logistics providers (BPC sections 4160 and 4161).

In 2007, the board established via regulation a self-assessment process for a wholesaler to use as a tool to confirm compliance with provisions of specific state and federal law. Included in the regulation is the requirement to complete the self-assessment, the frequency of completion, and some other general requirements. In addition, the self-assessment form is incorporated by reference. The self-assessment form is a compilation of Pharmacy Law, which changes with some regularity.

To update and streamline the form, the board is seeking to further refine the regulations to specify the form's requirements.

In this rulemaking, the Board proposes to amend Section 1784 of Article 10 of Division 17 of Title 16 of the CCR to update, and establish the requirements for, the following self-assessment form in regulation: Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 09/18).

Existing law at 16 CCR section 1784 requires the designated representative-in-charge (DRIC) of a wholesaler licensed under BPC sections 4160 and 4161 to complete a self-assessment before July 1 of every odd numbered year; and within 30 days whenever:

(1) A new wholesaler license has been issued, or
(2) There is a change in the DRIC.
(3) There is a change in licensed location of a wholesaler to a new address.

Previously, the board licensed third-party logistics providers (3PLs) as wholesalers; however, effective November 2013, federal provisions within section 585, subdivision (b), of the Federal Food, Drug, and Cosmetic Act (21 United States Code Section 360eee-4, subdivision (b)(2)) no longer allows states to license 3PLs as wholesalers. As 3PLs are a member of the drug supply chain, the board successfully obtained legislation to establish 3PLs as a separate licensing category (Assembly Bill 2605, Bonilla, Chapter 507, Statutes of 2014).

AB 2605 added or amended, among others, the following sections:

- **BPC section 4022.7**:
  - Established the definition of a designated representative-3PL.
  - Established the definition of a responsible manager, who is also a designated representative-3PL.
- **BPC section 4045**:
  - Established the definition of a "third-party logistics provider." A 3PL provides or coordinates the warehousing of, or other logistics services for, a prescription drug or device on behalf of another person. The 3PL does not, however, take ownership, nor have responsibility to direct the sale or disposition of, the drug or device.
- **BPC section 4053.1**:
  - Established the board's authority to issue a license to a designated representative–3PL and specified that person's role as providing sufficient and qualified supervision of a 3PL's place of business by ensuring the safe handling, storage, warehousing, distribution, and shipment of drugs and devices.
  - Established the minimum qualifications to obtain said license.
- **BPC section 4160**:
  - Established the board's authority to issue a 3PL license and specifies that the location must operate with a designated representative-3PL present.
  - Established that, no person may act as a 3PL without, first, obtaining a license from the board.
- **BPC section 4161**:
  - Established the board's authority to issue a nonresident 3PL license for those performing the services outside California for drugs that ultimately come into California.
  - Requires board licensure for anyone operating as a nonresident 3PL.

To address the new license category, this proposal will add the requirement for 3PLs to complete the self-assessment, which continues the requirements that applied previously when these entities were licensed as wholesalers. The proposal will also update the self-assessment form up to include law and regulation changes since 2014, which is the last time the form was updated.

Benefits

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. Additionally, the proposal will require that 3PLs and the responsible manager complete the self-assessment biennially. This addition will ensure regulatory consistency between wholesalers and 3PLs. The self-assessment form aids licensees in assessing their compliance with federal and state law and regulations. The proposal updates the form to include law and regulations adopted since 2014, and exclude law and regulations that have been superseded or repealed since 2014. As the designated representative-in-charge (DRIC) or responsible manager (RM) completes the self-assessment form, biennially, they will identify any areas where the wholesaler or 3PL may be out of compliance. This awareness can increase self-correction and makes the wholesaler and 3PL site inspection process

more meaningful by providing useful information to the DRIC or RM about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety and will improve facility operations with respect to employee safety and the state's environment. The proposal will not impact the state's environment.

Specific Purpose of Proposed Changes and Rationale

The Board's proposal makes the following amendments:

Amend Section 1784 of Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend the title of the section to include third-party logistics providers and responsible managers. The title of the section will now read "Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager." The new title will provide clarity to the regulated public with respect to whom the section applies. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate to include their reference here. The title change also identifies the individual that must complete the self-assessment based on the license type. A 3PL cannot not employ a DRIC and a wholesaler cannot not employ an RM, as such it is necessary to clarify the responsible party for each license type.

Subdivision (a)

Subdivision (a) is amended to add "and third-party logistics provider" after wholesaler in the first sentence. This change will require the existing requirement that applies to a wholesaler to complete the self-assessment, to now apply to 3PLs for consistency between the two similar licensing categories. The subdivision is further amended to relocate "the designated representative-in-charge of" from the first sentence to the second sentence. Additionally, "the wholesaler, or by the responsible manager of the third-party logistics provider" was added to the second sentence. These changes specify the individual that must complete the self-assessment based on the license type. A 3PL cannot not employ a DRIC and a wholesaler cannot not employ a RM, as such it is necessary to clarify the responsible party for each license type. The DRIC and RM are responsible for overseeing the operation of the licensed facility and as such, are responsible for ensuring that the facility is operating in compliance with state and federal law.

Subdivision (b)

Subdivision (b) is amended to add "or responsible manager" after DRIC. As a 3PL cannot employ a DRIC, this addition is necessary to ensure that the appropriate responsible party is identified for 3PLs.

Subdivision (b)(1) is amended to remove "wholesaler permit" and add "license." This change is necessary to include the 3PL license type. This subdivision is further amended to remove "or" at the end of the sentence and add a period for proper punctuation. The removal of the term "or" is necessary to provide clarity that the self-

assessment needs to be completed anytime any of the three criteria are met. The term "or" is not grammatically appropriate here given there are three criteria and not two.

Subdivision (b)(2) is amended to add "or responsible manager" and add "or responsible manager of a third-party logistics provider" following DRIC and wholesaler respectively. This change is necessary to include the 3PL license type. As a 3PL cannot employ a DRIC, these additions are necessary to ensure that the appropriate responsible party (RM) is identified for 3PLs. Additionally, as 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate to include their reference here.

Subdivision (b)(3) is amended to add "third-party logistics provider" after wholesaler. This change is necessary to include the 3PL license type. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate to include their reference here.

Subdivision (c)

Subdivision (c) is repealed and replaced with the following:

> "Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 09/18) which is hereby incorporated by reference. The form shall include the information required by this section."

This change is necessary to include the 3PL license type and the responsible manager. As a 3PL cannot employ a DRIC, these additions are necessary to ensure that the appropriate responsible party (RM) is identified for 3PLs. Additionally, as 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate to include their reference here. Furthermore, the self-assessment form title has been updated to reference the revised form, which includes both the wholesaler and third-party logistics providers in the title. Finally, the revision date on the self-assessment form was updated to 09/18 to correctly reference the appropriate self-assessment form within the regulation for clarity to the regulated public. The final sentence within the subdivision identifies the beginning of the requirements within the self-assessment from. The specific requirements of the self-assessment form are identified is subdivisions (c)(1) – (c)(7). The phrase "to evaluate compliance with federal and state laws and regulations has been stricken as duplicative with subdivision (a).

Subdivisions (c)(1) through (7) articulate the required components of the self-assessment form. The components represent the elements that will make the assessment sufficient, mostly for the board to evaluate whether the DRIC/RM 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) adds “The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:” This information is needed on the self-assessment form to positively identify the licensee. While the self-assessment forms are maintained by the licensee at the facility, should an inspector take a copy of the self-assessment form during an inspection, it is necessary to ensure that identifying information for the licensee is on the form.

Subdivision (c)(1)(A) – (c)(1)(E) is added to clearly state the requirement that the DRIC/RM is responsible for providing identifying information about the premises, and that the identifying information shall include:

(A) Name, license number of the premises, and the license expiration date;
(B) Address, phone number, website address, if applicable, and type of ownership;
(C) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;
(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and
(E) Hours of operation of the licensee.

This information was added based on requirements in the existing form. This information provides clarity to the regulated public that the board is requiring the DRIC/RM to provide the information listed and makes it clear to board inspectors and the DRIC/RM which premises the form pertains to and keeps all the identifying information about the location in one place. The board requires the DRIC/RM to be aware of such information.

It is necessary to have the DRIC/RM record the name and license number for the licensed facility to ensure that the license is current and ensure that should an inspector take a copy of the self-assessment form during an inspection, identifying information for the licensee is on the form. It is necessary to require the DRIC/RM to record the address, phone number, website, and ownership type to ensure the DRIC/RM is aware of the license’s current information and can ensure that this information matches board records. If the information is not current, the DRIC/RM can take appropriate steps to update the board’s records prior to their license renewal becoming due. This will allow for timely processing of their renewal payment when it’s submitted and prevent license renewal holds, which would prevent the licensee from conducting business.

It is necessary to have the DRIC/RM record the current DEA (federal Drug Enforcement Administration) number, expiration date and the most recent DEA inventory to ensure the DRIC/RM complies with DEA requirements. Further, this information allows the board to confirm the DEA registration, expiration date and date of DEA inventory to ensure compliance with federal requirements.

It is necessary to have the DRIC/RM record the Verified-Accredited Wholesale Distributor (VAWD) accreditation number and expiration date, if applicable, to ensure the DRIC/RM records all the identifying information about the location in one place and ensure that the DRIC/RM is aware of the accreditation of the licensed facility.

The hours of operation are necessary for the board to properly monitor and enforce regulations. As the board conducts random unannounced inspections, knowledge of the hours of operations eliminate the potential for the board to attempt an inspection at a time in which the business is closed. Documentation of this information requires deliberate review by the DRIC/RM and should highlight if the licensee is noncompliant with either reporting required changes to the board (for example a new address) or DEA inventory requirements. Currently, these requirements only exist on the self-assessment form and the requirements are being added into regulation to ease the administrative process of updating the self-assessment form. Subdivision (c)(2) adds "The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license." This provision ensures that the DRIC/RM 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) adds a requirement that the DRIC/RM report, by responding "yes", "no" or "not applicable" (N/A), if the licensed premises is in compliance with the laws and regulations that apply to each specific setting. This change was necessary to require the DRIC/RM to acknowledge compliance and/or noncompliance with various provisions of state and federal law. Each noted "yes", "no" or "not applicable" identifies to both the DRIC/RM, as well as board staff, that this self-review and evaluation has been completed and areas of noncompliance are noted. This element requires deliberate assessment by the DRIC/RM 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 designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law." This addition will provide clarity to the DRIC/RM that the board requires a written corrective action or action plan to address all areas of noncompliance identified by the DRIC/RM. This addition further ensures that the DRIC/RM has created a plan for the licensed premises to remediate areas of noncompliance and makes if more likely that the licensed premises will become fully compliant. Currently, this requirement only exists on the self-assessment form and the requirements are being added into regulation to ease the administrative process of updating the self-assessment form. Board staff regularly inspect wholesalers and third-party logistics providers 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. The corrective action or action plan is simply a written statement detailing how the DRIC/RM will address areas of noncompliance or what they have already done to address it and is written on the self-assessment form or can be attached to it.

Subdivision (c)(5) adds the specific requirement that the DRIC/RM shall initial each page of the self-assessment form. This requirement further reinforces the requirement that the DRIC/RM complete the self-assessment and not another member of the licensee's staff. The requirement of an initial on the form may prevent other personnel from completing the self-assessment form on behalf of the DRIC/RM and will document that the DRIC/RM completed the required information on each page of the self-assessment. This requires deliberate action by the DRIC/RM and helps to convey the significance of their role in ensuring compliance with state and federal law. Currently, this requirement only exists on the self-assessment form and the requirements are being added into regulation to ease the administrative process of updating the self-assessment form

Subdivision (c)(6) adds the specific requirement that the DRIC/RM certify, under penalty of perjury, on the final page of the form, that they completed the self-assessment form. This addition provides clarity to the regulated public that the board requires a certification that affirms the DRIC/RM completed the self-assessment. The DRIC and RM are responsible for overseeing the operation of the licensed facility and, as such, are responsible for ensuring that the facility is operating in compliance with state and federal law. Currently, this requirement only exists on the self-assessment form and the requirements are being added into regulation to ease the administrative process of updating the self-assessment form.

Subdivision (c)(6)(A) – (c)(6)(D) adds the following:

(A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;
(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;
(C) He or she understands that all responses are subject to verification by the Board of Pharmacy; and
(D) The information provided in the self-assessment form is true and correct.

This information is added to provide clarity to the regulated public and the DRIC/RM of their responsibilities after completion of the self-assessment. The certification also requires the DRIC/RM to provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California and that the information provided in the self-assessment form is true and correct making such statements legally enforceable. By requiring attestation under penalty of perjury, the board is communicating to the DRIC/RM the gravity of falsifying the information. 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. Therefore, should the DRIC/RM falsely certify to the completion of the self-assessment, they will be disciplined by the board. Currently, these requirements only exist on the self-assessment form and the requirements are being added into regulation to ease the administrative process of updating the self-assessment form.

Subdivision (c)(7) adds the requirement for a certification and acknowledgement by the owner, partner, or corporate officer of the licensed premises. The certification specifies that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the premises license issued by the board. This requires that the owner, partner, or corporate officer 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 owner, partner, or corporate officer of the premises the gravity of falsifying information. 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 DRIC/RM, the premises license may be disciplined if an owner, partner, or corporate officer falsely certify to the reading and reviewing of the self-assessment. This requirement also ensures that the owner, partner, or corporate officer 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) is amended to remove the term “wholesale” from the subdivision for consistency with the changes throughout the section. As section 1784 will now apply to both wholesalers and third-party logistics providers, the term “wholesale” is no longer appropriate as it would exclude 3PLs.

Subdivision (d) is further amended to add “completed in its entirety” to the first sentence 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 licensed premises. When only portions of the self-assessment are completed, the DRIC/RM has not fully assessed the licensee’s compliance, and a full and meaningful assessment is necessary to make it more likely the licensee is compliant.

Subdivision (d) is also amended to add “The completed, initialed, and signed original must be readily available for review during any inspection by the board.” to permit the licensee to scan the original, completed self-assessment and keep it on file at the licensed premises 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 match with the respective parties’ initials or signatures, it can still hold licensees accountable if they fail to comply.

Subdivision (e) is amended to add “or third-party logistics provider” and “or responsible manager, respectively" to the subdivision for consistency with the changes throughout the section. As section 1784 will now apply to both wholesalers and third-party logistics providers, the inclusion of the 3PL license type and the responsible manager is necessary and appropriate to this subdivision. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. As a 3PL cannot employ a DRIC, these additions will also ensure that the appropriate responsible party (RM) is identified for 3PLs.

Subdivision (f) is added to require any identified areas of noncompliance to be corrected as specified in the certification. This addition explicitly advises the DRIC/RM and owner, partner, or corporate officer that identified areas of noncompliance must be corrected within the certified timeframe. Failure to do so would result in a violation of this section and could result in administrative or disciplinary action being taken against the license by the board.

The reference statutes were amended to add appropriate sections. Sections “4022.7, 4044.5, 4045, and 4053.1” of Business and Professions Code were added as references.

Changes to Form 17M-26 Incorporated by Reference

On every page of Form 17M-26, the footer at the bottom left corner which reads “17M-26 (Rev. 10/14)” was amended to reflect the updated revision date (“17M-26 (Rev. 09/18)”). Conforming changes were made throughout. The reference to “RPH” within the footer of each page has been amended to “RM.” Section 1784 specifies that the self-assessment form must be completed by the DRIC or RM, not an RPH. While a licensed pharmacist (RPH) may complete the self-assessment form, they would be performing the duty in their capacity as the DRIC, so therefore, they would initial each page as the DRIC. The amendment will also ensure that the appropriate responsible party (RM) is identified for 3PLs.

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 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 self-assessment form, minor changes were made to correct punctuation and typographical errors, make grammatical corrections (changing e-mail to email, etc.), and correct capitalization for consistency. Additionally, line items have been renumbered as appropriate to account for the addition or deletion of requirements.

Title Page – Page 1

- The title of the self-assessment form has been amended from “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment” to “Wholesaler/Third-Party Logistics Provider Self-Assessment” to accurately identify to whom the self-assessment form applies. The new title will provide clarity to the regulated public. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate for wholesalers and 3PLs to use the same self-assessment form.

- The referral to the legal references page has been updated from page 21 to page 22. This page number may change once the self-assessment form is finalized and the rulemaking file completed to account for the removal of stricken text and the deletion of blank space that exists in the proposed document. Keeping this page reference current is necessary for clarity and to provide the regulated public with an accurate location to obtain further explanation of the legal references used throughout the self-assessment form.

- A legend has been added to page one to define the abbreviations used throughout the document with respect to the licensing categories. The added text reads as follows:

  > “For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:
  > - WLS= Wholesaler
  > - 3PL= Third-Party Logistics Provider
  > - DRIC = Designated Representative-in-Charge
  > - RM = Responsible Manager
  > - DR includes Designated Representative, Designated Representative-3PL and Designated Representative Reverse Distributor”

  Adding this legend assists the regulated public and consumers who may use the form with decoding the abbreviations used throughout the form. This will ensure clarity to the public and a consistent understanding among the licensees.

- The term “wholesaler” has been amended to “licensed premises” at two locations for consistency. License premises was selected as the phrase encompasses both wholesaler and 3PL facilities. As the self-assessment will now apply to both wholesalers and third-party logistics providers, the term “wholesale” is no longer appropriate as it would exclude 3PLs.

- The term “permit” has been amended to “license” as it is more accurate to call it a license and not a permit. 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 increases clarity to the regulated public.

Page 2

- The third line down from the top on page two requires that the name of the designated representative-in-charge or pharmacist be listed. The phrases "designated representative-in-charge" and "pharmacist (RPH)" have been removed and "RM" has been added. This language accurately reflects the individuals responsible for the operation of the wholesaler or 3PL. A pharmacist can be responsible of the operation of a wholesaler; however, in this case, the pharmacist would be acting in the capacity of a DRIC. The change is necessary for consistency within the regulation and the self-assessment form and pharmacy law.

- The fourth line down from the top of page two has been amended to change "DRIC" to simply "DR" as this is the licensing category for both the DRIC and the RM. The board does not issue a DRIC license. Additionally, the DR licensing category contains three different designated representative classes as identified in the legend on page one of the self-assessment form. The change is necessary for consistency within the regulation and the self-assessment form and pharmacy law, specifically, BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, and 4053.2.

- The sixth line down from the top of page two has been amended to remove the phrases "wholesaler" and "designated representative." The removal of the phrase wholesaler is required as 3PLs will now be required to complete the self-assessment form. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate for wholesalers and 3PLs to use the same self-assessment form. The DR licensing category contains three different designated representative classes as identified in the legend on page one of the self-assessment form. These changes are necessary for consistency within the regulation and the self-assessment form and pharmacy law, specifically, BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, and 4053.2. Finally, "RPH" is added after pharmacist to clearly define what RPH stands for in the list following this information. RPH is not defined earlier in the document and this is added for clarity to the regulated public and/or consumers that may look at the form.

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

Section 1 – Ownership/Location

- Subsection 1.1 has been amended to change the phrase "wholesaler permit" to "license" in order to include the 3PL licensing category. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate for wholesalers and 3PLs to use the same self-assessment form. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

Section 2 – Facility

- Subsection 2.5 has been amended to change the phrase "designated

representative" to "DR" to include the three different possible designated representative license types. This change is necessary for consistency within the regulation and the self-assessment form and pharmacy law, specifically, BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, and 4053.2.

- Subsection 2.6 has been amended to change the phrase "wholesaler" to "licensed" in order to include the 3PL licensing category. As 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations, it is appropriate for wholesalers and 3PLs to use the same self-assessment form. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

- Subsection 2.7 has been amended to add "third-party logistics provider" to the list of business types within the subsection in order to include the 3PL licensing category. As 3PLs perform similar functions as wholesalers it is appropriate for 3PLs to be included in this list. Including 3PLs provides clarity to the regulated public and ensures that the reference is consistent with BPC section 4040.5.

- As indicated above, subsections 2.8 and 2.9 were amended to make a grammatical correction (changing e-mail to email) for consistency and is nonsubstantive.

- As indicated above, the Note, after section 2.9 was amended to renumber the section identified as appropriate to account for the deletion of a section. This change is nonsubstantive.

Section 3 – Designated Representative-in-Charge/Responsible Manager/Owner Responsibilities

This section title has been amended to include the responsible manager. The responsible manager is employed by the 3PL to oversee the operations of the facility. It is necessary to accurately identify the individual that must complete the self-assessment for clarity to the regulated public. The responsible manager is basically the designated-representative-in-charge of the 3PL facility; however, they have different job titles.

Each subsection throughout this entire section has been amended to change the reference to "designated representative-in-charge" to "DRIC/RM" to accurately identify the responsible parties. These changes ensure consistency throughout the form and provide clarity to the regulated public. In addition, the following changes are being made:

- Subsection 3.2 has been amended to remove the phrase "wholesaler" in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection. The last sentence of this subdivision was amended to change designated representative-in-charge" to "DRIC" for consistency within the form. This sentence does not include the RM as pharmacy law does not allow for a

pharmacist to be a RM. Separately, the word “is” is being removed from the phrase “at least 18 years of age and is responsible.” This change is to correct the grammar of the sentence and is non-substantive.

- Subsection 3.3 has been amended to remove the phrase “or pharmacist” for clarity within the self-assessment form. A pharmacist can be responsible of the operation of a wholesaler; however, in this case, the pharmacist would be acting in the capacity of a DRIC.

- Subsection 3.4 has been amended to remove the phrase “a “Change of Designated Representative-in-Charge,” which is” for clarity. There are two forms available on the board’s website depending based on the type of change as required by BPC sections 4160(f) and 4160(g). The board determined that listing the form title within the self-assessment form was not necessary as there are now two and the forms and the specific notification requirements are required by statute. Removing the name of the form simplifies the self-assessment form and provides clarity to the regulated public by not providing an inaccurate title.

- Subsection 3.5 has been amended to change the phrase “wholesaler” to “licensed premises” in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

Section 4 – Designated Representative/Pharmacist

This section has been stricken from the self-assessment form. This section applies to two specific individual licensing categories and does not apply to the wholesaler or the third-party logistics provider. The requirement to notify the board of a name or address change for an individual license falls on the individual, not the business. For this reason, the board determined that this section was not appropriate to be included in the form and should be removed.

Moving forward, all the sections will need to be renumbered accordingly. For ease of reading and to reduce confusion, the sections will be listed in number order based on the previous section number with the new section number in parenthesis.

Section 5 (now Section 4) – Ordering Drugs by this Business for Future Sale/ Transfer or Trade

- Subsection 5.3 (now 4.3) has been amended to change the phrase “wholesaler” to “licensed premises” in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

Section 6 (now Section 5) – Receipt of Drugs by this Business

- Subsection 6.1 (now 5.1) has been amended to remove the phrase “wholesale” in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection. This subsection was further amended to change the phrase “designated representative” to “DR” to include the three different possible designated representative license types. This change is necessary for consistency within the regulation and the self-assessment form and pharmacy law, specifically, BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, and 4053.2.

Section 7 (now Section 6) – Drug Stock

- Subsection 7.2 (now 6.2) has been amended to remove the phrase “wholesale” in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesale from this subsection.

Section 8 (now Section 7) – Sale or Transfer of Drugs by this Business

- Subsection 8.6.1 (now 7.6.1) has been amended to change the phrase “wholesaler” to “WLS/3PL” in order to include the 3PL licensing category and for consistency with the legend on page one of the self-assessment. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For these reasons, it is necessary to include the reference to both wholesalers and 3PLs within this subsection.

- Subsection 8.10 (now 7.10) has been stricken and new language added. The previous section identified requirements from the Prescription Drug Marketing Act of 1987. This act was replaced by the federal Drug Supply Chain Security Act (DSCSA) that was enacted by Congress in November 2013. The new language reads “For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c]).” This language has been added to ensure compliance with the requirements created under the DSCSA that governs the traceability of drug products through the drug distribution supply chain. These are federal requirements that board licensees must comply with and board inspectors will be confirming compliance when inspecting, as such, including the reference within the self-assessment form reminds the licensees and the DRIC/RM of the requirement so that they can take corrective action to be compliant should a deficiency be identified.

- Subsection 8.11 (now 7.11) removes the outdated reference to the Prescription Drug Marketing Act of 1987. The act was replaced by the federal Drug Supply Chain Security Act (DSCSA) that was enacted by Congress in November 2013 and, as such, it is necessary to remove the outdated law reference from the self-

assessment form.

Section 12 (now Section 11) – Controlled Substances

The legal reference within subsection 12.23 (now 11.23) has been corrected. The previous version of the self-assessment form included the legal reference to section 1304.03 with the references under HSC; however, 1304.03 is a reference to a federal regulation within the CFR (Code of Federal Regulations). For accuracy, consistency, and clarity, the reference was moved to the other CFR references within the same subsection.

Section 16 (now Section 15) – Record Keeping Requirements

- A new subsection was added as subsection 15.2 and reads "Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])." This language has been added to ensure compliance with the requirements created under the DSCSA that governs the traceability of drug products through the drug distribution supply chain. Maintaining these records is a federal requirement that board licensees must comply with and board inspectors will be confirming compliance when inspecting, as such, including the reference within the self-assessment form reminds the licensees and the DRIC/RM of the requirement so that they can take corrective action to be compliant should a deficiency be identified.

- Subsection 16.2 (now 15.3) has been amended to remove the "Note" referencing the maintenance of a drug pedigree as part of the record of purchase and sale for three years. This reference was removed as these records are included with the records required by DSCSA and are already included in the new subsection 15.2, as identified above. This reference is duplicative and unnecessary. This subsection was also amended to correct the legal reference cites as section 4059.5(a) was out of order and 4081 was duplicated. These changes were made for consistency in the order of the references and to provide clarity to the regulated public.

- Subsection 16.12 (now 15.13) has been amended to replace the reference to "or pharmacist" with "/responsible manager" to accurately identify the appropriate individuals responsible for overseeing the wholesaler or 3PL. A pharmacist can oversee a wholesaler; however, they would be acting as the DRIC, so the reference to the pharmacist in this subsection is not consistent with pharmacy law and must be removed. These changes are necessary to ensure consistency with pharmacy law and the self-assessment form. Additionally, the citation in this subsection to Business and Professions Code section 4162(a)(4) has been corrected to refer to subdivision (a)(5). The proposed amendment realigns the reference with the correct subdivision, which was renumbered as a result of the enactment of AB 2605 (Bonilla, Chapter 507, Statutes of 2014).

- Subsections 16.14 and 16.15 (now 15.15 and 15.16) have been amended to change the term “business” to “licensed premises” for consistency within the subsection. The term “licensed premises” is a specific terminology used within pharmacy law which means the actual licensed location. The use of this terminology within this section is necessary for clarity to the regulated public. A business could have multiple licensed locations, so it is necessary to be specific within the requirement that the licensed premises needs to retain the appropriate records, not the business, which could be headquartered at a different location. Additionally, the citation in subsection 15.15 of the proposed form to Business and Professions Code section 4315(e) has been corrected to refer to subdivision (f). The proposed amendment realigns the reference with the correct subdivision, which was renumbered as a result of the enactment of SB 960 (Morrell, Chapter 247, Statutes of 2014).

Section 17 (now Section 16) – Reporting Requirements to the Board

- Subsections 17.1 and 17.2 (now 16.1 and 16.2) have been amended to add “/responsible manager” to accurately identify the appropriate individuals responsible for overseeing the wholesaler or 3PL. As a 3PL cannot employ a DRIC, this addition will ensure that the appropriate responsible party (RM) is identified for 3PLs. Additionally, the term “pharmacist” was removed from subsection 17.2 (now 16.2). A pharmacist can oversee a wholesaler; however, they would be acting as the DRIC, so the reference to the pharmacist in this subsection is not consistent with pharmacy law and must be removed.

- Subsection 17.8 (now 16.8) has been amended to remove reference to a 2006 effective date as it is outdated. The requirement to maintain a tracking system has been in place since 2006 and remains law. The board determined that it was no long appropriate to reference a 12+ year old effective date and that the requirement to develop the tracking system is out dated as the wholesaler should already have the tracking system in place. The language is specific to wholesaler because the tracking system requirement does not apply to third-party logistics providers, per BPC section 4164(b), as such only the wholesaler is reference within this subsection.

- Subsection 17.9 (now 16.9) has been amended to remove the phrase “wholesaler” in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

- A new subsection was added as subsection 16.12 and reads “Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.” BPC section 4169.1 was added to the BPC effective January 2018 by Assembly Bill 401 (Statutes of 2017, Chapter 548). This subsection is added for clarity to the regulated public regarding the requirement to notify the board of suspicious orders. Additionally, as the self-assessment form is a tool

used to confirm compliance with state and federal pharmacy law, the inclusion of this subsection is appropriate.

Section 18 (now Section 17) – Additional Licenses/Permits Required

- Subsection 18.1 (now 17.1) has been amended to remove the phrase "wholesale" in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from this subsection.

Designated Representative-in-Charge Certification

The certification has been amended to replace the reference to "pharmacist" with "responsible manager" to accurately identify the appropriate individuals responsible for completing and certifying completion of the self-assessment. A pharmacist, who can oversee the wholesaler, can complete and certify on the self-assessment form; however, they would be acting as the DRIC, so the reference to the pharmacist in the certification is not consistent with pharmacy law and must be removed. These changes are necessary to ensure consistency with pharmacy law and the self-assessment form. DRIC#/RM# has been removed as duplicative. The license number of the DRIC/RM should already be identified on page one of the self-assessment form.

The sentence "Any deficiency identified herein will be corrected by" has been added, with an underlined blank to be filled out by the DRIC/RM. This is being added for the DRIC/RM to provide an expected timeline for resolution of the noncompliance issues. Board staff regularly inspect wholesalers and third-party logistics providers for compliance with laws and regulations; having the expected timeline for resolution will allow for a more meaningful inspection. The inspector and DRIC/RM can quickly identify possible noncompliance areas based on the resolution timeline.

Additionally, the certification has been further amended to change the phrase "wholesale business" to "licensed premises" in order to include the 3PL licensing category. 3PLs perform similar functions as wholesalers and are required to comply with the same laws and regulations. For this reason, it is necessary to remove the specific reference to wholesaler from the certification.

Acknowledgement by Owner, Partner or Corporate Officer Certification

The certification has been amended to replace the term "pharmacy" with "premises" for clarity. The self-assessment form applies to wholesalers and third-party logistics providers and these entities are not pharmacies. As such, the use of the term "pharmacy" is not appropriate within this certification. The board selected the term "premises" for consistency and to include both wholesalers and 3PLs.

Legal References

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. 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 DRIC/RM completes the self-assessment form and the most accurate information is available on the Internet. The phrase "(see Laws and Regulations)" was removed as it is not a direct location of the pharmacy lawbook and would be incorrect if the website is updated.

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.

Underlying Data

1. Assembly Bill 2605 (Bonilla, Statutes of 2014, Chapter 507).
2. Assembly Bill 401(Aguiar-Curry, Statutes of 2017, Chapter 548)
3. Federal Food, Drug, and Cosmetic Act (Drug Quality and Security Act) https://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf
4. 21 USC Chapter 9, Subchapter V, Part H: Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act) http://uscode.house.gov/browse/prelim@title21/chapter9/subchapter5/partH&edition=prelim
5. 21 Code of Federal Regulations, Chapter 2 – Drug Enforcement Administration, Department of Justice (https://www.govinfo.gov/app/collection/cfr/2018/)
6. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 26-27, 2016 (Meeting Materials Pages 1, 7-8 and Attachment 15, Minutes Pages 1, 80-82).
7. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held November 8-9, 2017 (Meeting Materials Agenda Item X, Minutes Pages 1, 14-15).

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees including the ability of California businesses to compete with businesses in other states. This determination is based on the fact that completion of the self-assessment form is already required by regulation. This proposal is updating the required self-assessment form to a current version to ensure that the pharmacy law references within the form are current and complete. Additionally, the proposal is updating the regulation to more clearly specify the requirements to currently only exist on the self-assessment form. The proposal is establishing the requirement for 3PLs to complete the self-assessment; however, 3PLs must already comply with the laws and regulations within the self-assessment form as they are existing law, as such, completing the form will not have an adverse economic impact on businesses.

Economic Impact Assessment

The Board has determined that it is:

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

The board determined that this proposal will not impact jobs or businesses because the proposal removes old, out-of-date legal references and adds citations to new laws and regulations. Additionally, the proposal changes the way in which the board will update the required self-assessment form in the future. Finally, while the proposal is establishing requirements for 3PLs to complete the self-assessment form, 3PLs should already be in compliance with the laws and regulations within the form, so simply completing the form itself will not have an impact.

This regulatory proposal benefits the health and welfare of California residents. Existing pharmacy law requires that licensed wholesalers complete a self-assessment every odd-number year. This proposal updates the regulation to the current version of the self-assessment form. Additionally, the proposal adds the requirement for licensed 3PLs to complete the self-assessment form. Using a current version of the self-assessment form will help educate DRICs and RMs, which helps ensure that wholesalers and 3PLs are operating in compliance with state and federal laws and regulations, which will help ensure the health and welfare of all CA residents.

This regulatory proposal benefits worker safety because it will help educate DRICs and RMs, which helps ensure that wholesalers and 3PLs are operating in compliance with state and federal laws and regulations. Operating in compliance with state and federal law will make the wholesaler and 3PL sites safer work places.

The regulatory proposal does not impact the state's environment. The proposal will help educate DRICs and RMs, which ensures that wholesalers and 3PLs are operating in compliance with state and federal laws and regulations.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The board considered the following alternatives:

(1) The board considered not updating the self-assessment form specified within the regulation and not updating the specific requirements within the regulation. The board determined that this alternative was unacceptable because the board would be requiring that an outdated form be completed. This would cause confusion to the regulated public with respect to repealed and existing state and federal law. Additionally, 3PLs would not be required to complete an easy self-check for compliance.

(2) The board considered updating the form and the requirements for 3PLs, but not updating the specific requirements within the regulation. The board determined that this alternative was unacceptable as the administrative workload to promulgate the regulation exceeds 12 months. As a result of this timeframe, the board would still be processing one rulemaking when it would become necessary to begin another rulemaking for the same section.