TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

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

Sections Affected: Title 16, California Code of Regulations (CCR) section 1784

Updated Information

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

The 45-day public comment period began on September 17, 2021, and ended on November 1, 2021. The board's notice stated that the board did not intend to hold a hearing on the matter unless requested. The board did not receive a request for a hearing during the comment period and one was not held.

During the 45-day comment period, the board received no comments. At the January 27, 2022 board meeting, the board amended the regulation text and self-assessment form to add the pharmacy law changes that occurred between September 2018 and January 1, 2022. The changes are as follows:

Modified Text

Section 1784

The board amended subdivision (c) to change the revision date of the self-assessment form incorporated by reference from 09/18 to 12/21. Following adoption by the board, staff made non-substantive changes to the subdivisions (c)(6)(A), (c)(6)(C), and (c)(7) by removing gendered language and replacing it with gender-neutral terms in accordance with Assembly Concurrent Resolution No. 260 of 2018, in which the Legislature resolved that "state agencies should … use gender-neutral pronouns and avoid the use of gendered pronouns when drafting policies, regulations, and other guidance." Corresponding verbs were changed to the plural form for grammatical consistency. Because these changes are grammatical, they are without regulatory effect.

The board notes that the proposed language to 1784(c) has been added to provide clarity on completion of the self-assessment form. Future amendments to the form will be noticed to the public via the rulemaking process.

Self-Assessment Form

Throughout the form, the board removed or added, “Yes, No, N/A” as needed above the check boxes to ensure the boxes are identified at the top of each page and beginning of each section. Items were renumbered as needed to adjust for added and/or removed text. Additionally, spacing between words or letters was added or removed for consistency throughout the document. Further, grammatical changes were made to correct punctuation or spelling throughout the document, and statutes and regulations identified on the form were updated to ensure reference to the appropriate code sections throughout the form. Finally, the revision date was amended at the bottom of each page from 09/18 to 12/21 to reflect the last update. Each occurrence of these nonsubstantive changes has not been identified below as the edits are described above and do not have regulatory effect.

Page 1

The first sentence of the second paragraph was amended to add the term “form” to clearly identify the self-assessment form within the paragraph. Additionally, the term “includes” was stricken after “DR” for consistency with the remaining abbreviations in the section.

Page 2

The term “other” where staff are listed for clarity that other licensed staff (outside the designated representative-in-charge (DRIC) or responsible manager (RM). This clarifies that the DRIC and/or RM do not need to be listed a second time as they are listed earlier on the form.

Page 3

Section 1.1 was amended to add WLS/3PL (Wholesaler/Third-Party Logistics Provider) before the term license. This addition provides additional clarity on what “license” the form is referring to. While the form is specific to WLS/3PL licenses, the addition just provides additional clarity.

Section 2.1.6 was amended to strike “USP 1990 22nd Edition” and add “the standards set forth in the latest edition of the USP” to reflect the amendments made to CCR section 1780(b) in April 2021.

Section 2.2 was amended to add “adulterated” to the list for type of drugs that should be placed in a quarantine area. The amendment aligns the language with the language of CCR 1780(e).

Page 4

Section 2.4 was amended to add “and devices” to mirror the language in section 2.3 for consistency. Additionally, the terms “dangerous” and “or devices” were added below section 2.4 where the list of personnel is identified for consistency.

Following adoption, section 2.4 was amended to change “or devices” to “or dangerous devices” to mirror the language in Business and Professions Code (BPC) section 4116 for consistency in both sentences identified above. This amendment is non-substantive as it conforms with statute and does not have regulatory effect.

Section 2.7 was amended to add the terms “dangerous” and “or devices” for consistency. Additionally, minor grammatical corrections were made.

Following adoption, section 2.7 was amended to change “or devices” to “or dangerous devices” to mirror the language in BPC section 4116 for consistency. This amendment is non-substantive as it conforms with statute and does not have regulatory effect.

Page 5

Section 2.8 was added and reads, “The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices.” A space is also provided for the DRIC/RM to record that date of approval. These additions are necessary to include changes made to BPC 4163(c) effective January 1, 2020.

The note section has been amended to add “storage, distribution, and disposal of” to clarify that the additional requirements for controlled substances apply to these topics as well and not just wholesaling of controlled substances. This addition provides additional clarity to the DRIC/RM about the information available in section 11.

The title of Section 3 was amended to add “Designated Representative-Reverse Distributor” as this new licensee category was established effective January 1, 2018. A Designated Representative-Reverse Distributor in charge of a reverse distributor is still referred to as a DRIC; however, they oversee a reverse distributor instead of a wholesaler.

Section 3.1 was amended to add “of the facility” to the end of the sentence. This change provides clarity that the records and inventory being referred to are those of the facility.

Page 6

Section 3.4 was amended to change “the appointment” to “a proposed” as a new DRIC/RM is subject to approval by the board. As such, “appointment” is the not the

correct terminology as if the new DRIC/RM is not approved, a new individual must be selected.

Section 3.5 was amended to change “his or her” to “their” to use a gender-neutral pronoun.

Page 7

The note section has been amended to add “storage, distribution, and disposal” to clarify that the additional requirements for controlled substances apply to these topics as well and not just wholesaling of controlled substances. This addition provides additional clarity to the DRIC/RM about the information available in section 11.

Page 15

Section 11.30 was added and reads, “Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency.” The requirement was established via 21 USC 832(a)(3) in 2018. The legal citations are added as USC 832(a)(3), USC 802(57), and CFR 1301.74(b) to clearly identify where the requirements can be found for further reference. Following adoption, “21” was added before each legal citation to appropriately cite the “Title” of the legal reference.

Adoption

During the January 27, 2022 board meeting, the board voted to initiate a 15-day public comment period, which commenced on February 15, 2022, and concluded on March 2, 2022. During the 15-day comment period, the board received one comment. At the March 16, 2022 board meeting, the board considered the comment submitted and determined that no additional modifications to the text or form were appropriate. The board voted to adopt the modified text as noticed for public comment on February 15, 2022.

Following adoption by the board, staff made non-substantive changes to the self-assessment form to ensure all statutes and regulations identified on the form have consistent formatting and sections are appropriately referenced. On page 4, section 2.4 was amended to add legal citations to BPC 4116 and 4167, which address access to dangerous devices. In addition, on page 5, the ampersand was deleted from the legal citations in sections 2.9 and 2.10 for consistency with the remaining legal citations throughout the form. Additionally, minor typographical and grammar edits were made. These edits were all non-substantive as they did not have any regulatory effect.

Finally, on page 17, the legal reference in section 15.3 (4059.5[a]) was deleted as it is not the correct legal citation for this section. On page 19, sections 16.8.1, 16.8.2, and

16.8.3 were amended to remove the underlining of the numbers 1, 2, and 3, as those numbers are existing text. On page 21, the "(Date)" was added to the Designated Representative-In-Charge / Responsible Manager Certification after "Any deficiency identified herein....." for clarity to the signer what should be entered in the blank. This is a non-substantive change as it does not have any regulatory effect.

Incorporation by Reference

Existing regulation incorporates a form (17M-26) by reference. This rulemaking continues the incorporation by reference of that form, retitled Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 12/21). Continued incorporation is appropriate because the 20-plus page form is cumbersome and contains formatting that would not be publishable in the CCR.

Nonduplication Statement - 1 CCR § 12

As stated throughout the Initial and Final Statements of Reasons, the proposed forms being incorporated by reference in these regulations partially duplicate or overlap federal and state statutes and regulations. By the very nature of the incorporated forms being "Self-Assessments," which are essentially compliance checklists, references to applicable law are essential. By repeating (and citing to) key language from these statutes or regulations within these forms, the forms themselves become significantly clearer, and enable a user to find the area of law for further research if questions arise. To ensure accuracy, duplication or overlap is necessary to effectively implement the self-assessment forms in a way that satisfies the "clarity" standard of Government Code section 11349.1, subdivision (a)(3).

Local Mandate

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

Small Business Impact

While the board does not have nor does it maintain data to define if any of its licensees are "small businesses" as defined in Government Code section 11342.610, the board determined that any adverse economic impact will not be significant. While the board does not have specific data to determine if its licensees are a "small business" as defined in Government Code section 11342.610, the board anticipates that 3PLs are, by their nature, rather large businesses. The proposal makes the regulatory oversight of 3PLs, previously licensed as wholesalers, consistent with the standards for wholesalers.

Completion of a self-assessment form is required by existing regulation biennially and based on certain events; the completed forms are also required to be maintained. The updates will change some of the questions on the forms, but do not ask significantly more questions; it is therefore not anticipated that the licensee will use more time completing, or more space storing, the self-assessment form. As the requirement to

complete and maintain these forms already exists in regulations, this proposal, that updates the form used and places some of the requirements, currently contained only in the form, into regulations will not have an impact on businesses.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The board considered the 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 but not making substantive changes to the regulation text. The board determined that this alternative would not have been as effective, because by putting requirements in the regulation, some routine maintenance of the form itself could be implemented in the future with a rulemaking under 1 CCR 100, such as updating changed statutory references. These nonsubstantive regulatory updates will be more efficient.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period on September 17, 2021, which ended on November 1, 2021, the board received zero comments. The board amended the regulation text to address changes in pharmacy law and voted to initiate a 15-day comment period.

15-Day Public Comment Period

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

Summary and Response to 15-day Comments:

Written Comments from Duane Allison, Eversana,

Comment 1: The commenter recommended that form 17M-26 be amended to remove the VAWD (Verified-Accredited Wholesale Distributors) abbreviation to update the form to the current NABP (National Association of Boards of Pharmacy) Drug Distributor Accreditation Certificate and add the Facility NABP e-profile number.

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that this comment was outside the scope of the comment period. Additionally, the board noted that while NABP has updated that Drug Distributor Accreditation Certificate, it still acknowledges the term VAWD. Further, the board noted that the board's system is not integrated with NABP's system and mandating disclosure of the e-profile number is not necessary.

Comment 2: The commenter requested that section 2.4, which requests the list of personnel with keys that have access to the dangerous drugs (Rx Drugs) be replaced with a list of personnel that have access to the controlled substance cage or vault area. The commenter stated that the list of personnel with access to Rx Drugs would include almost the entire facility staff and not be practical for organizations with over 350 personnel.

Response to Comment 2: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the requirement to limit access to all prescription drugs is a requirement in existing law, specifically, California Code of Regulations section 1780(c). The law does not limit that access to controlled substances only, as such staff with access to prescription drugs must be listed.

Comment 3: The commenter stated that it is impossible and impractical for all incoming shipments to be received by the DRIC or manager as shipments are received over the course of the day from 8am to 10pm. The commenter indicated that the form should be revised to state "shipments received by personnel under the supervision and training of the DRIC or Manager".

Response to Comment 3: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that this comment is outside the scope of the comment period; in addition, it is not a requirement for incoming shipments to be received by the DRIC or responsible manager depending on the license type. The requirement, as specified in Business and Professions Code section 4059.5(a), is that incoming shipments be received by a pharmacist or a designated representative. The designated representative does not need to be the DRIC of the facility.

At its March 16, 2022, meeting, after reviewing and considering all comments in the record, the board voted to adopt the regulation text as noticed for public comment on February 15, 2022. Additionally, the board delegated to the Executive Officer the authority to make technical and non-substantive changes as necessary to complete the rulemaking file.