TITLE 16. BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Central Fill Pharmacies

Section Affected: Amend Title 16, California Code of Regulations (CCR) section 1707.4

Background and Statement of the Problem

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

Existing regulation at Title 16, CCR section 1707.4, which has not been updated in over twenty years, generally provides authority for a pharmacy licensed by the Board to process a request for refill of a prescription received by another pharmacy within California under specified conditions, including:

1. The pharmacy that refills the prescription either has a contract with or has the same owner as another pharmacy that received the prescription.
2. The prescription container meets specific labeling requirements and includes the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy that receives the refilled prescription.
3. The patient is provided with written information about which pharmacy to contact if the patient has any questions.
4. Both pharmacies maintain records as specified.
5. Both pharmacies are responsible for ensuring the order is filled correctly.
6. The originating pharmacy is responsible for compliance with maintaining medication profiles, conducting patient consultations, and reviewing medication profiles and drug therapy records prior to prescription drug delivery.

In October 2023, the Board decided to review these requirements and determine whether changes were necessary. The Board and stakeholders had robust discussions and several presentations were given, across multiple public committee and Board meetings. The discussions and presentations addressed several provisions in the draft regulations, including final product verification and the use of technology in central fill pharmacies.

The proposed amendments to the regulation are intended to clarify the current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. Specifically, references to "refill" are being removed, clarifying language is being added

to ensure that the central fill pharmacy is licensed by the Board and operated within California, and to ensure that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, language is being added to allow originating pharmacies to perform final product verification before dispensing and allow for the final product verification to be done by viewing images in lieu of a physical visual inspection. Finally, a definition of central fill pharmacy is being added.

Anticipated benefits from this regulatory action:

The Board's highest priority in exercising its licensing, regulatory, and disciplinary functions is protecting the public. The Board has determined that this regulatory proposal will benefit the health and welfare of California residents.

This proposal clarifies current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. Specifically, clarifying language is being added to ensure that the central fill pharmacy is licensed by the Board and operated within California, and that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, the amendments allow originating pharmacies to perform final product verification before dispensing and permit final product verification to be done by viewing images in lieu of a physical visual inspection. The amendments to this regulation will benefit licensees and consumers by increasing transparency to consumers, and ensuring patients know that a Central Fill facility filled their prescriptions and who to contact with any questions— thereby benefitting the health and welfare of California consumers—and allow pharmacies flexibility regarding labeling and product verification.

This regulatory proposal does not affect employee safety or the state's environment.

Specific purpose of, and rationale for, proposed changes

The Board's proposal makes the following changes to section 1707.4:

The regulation's title has been amended from "Procedures for Refill Pharmacies." to "Procedures for Central Fill Pharmacies." The purpose of this change is to ensure the title identifies the subject of the section, central fill pharmacies. The title change is necessary to improve clarity and allows for easy reference to the appropriate regulatory section for central fill facilities.

The reference to "refill" was removed throughout the section (and accompanying nonsubstantive grammatical changes were made). The purpose of this change is to eliminate language that appeared to restrict central fill pharmacies from filling new prescriptions, which was never the intent of the section. A central fill facility prepares and packages prescriptions for other pharmacies to dispense to patients. The change is necessary to ensure the type of prescription (new or refill) a central fill pharmacy can fill is not restricted, provided the other requirements of the regulation are met.

Subsection (a) is added and reads “(a) For purposes of this section, a central fill pharmacy is defined as a California-licensed pharmacy that, pursuant to a contract or on behalf of a pharmacy under common ownership, prepares and packages prescriptions for another pharmacy to dispense to the patient.” The purpose of this subsection is to provide the specific definition of “central fill pharmacy” and the specific activities performed by such a pharmacy. This definition is necessary to ensure that the regulated public knows what constitutes a central fill pharmacy.

Subsection (b) is added and reads “For the purposes of this section, the originating pharmacy is defined as the pharmacy that received the patient’s initial prescription and dispenses the medication to the patient.” The purpose of this subsection is to define “originating pharmacy” as used within the section. This definition is necessary to ensure that the regulated public understands the meaning of the phrase and its use within the section.

Subsection (c) [previously subsection (a)] is amended to add “central fill” and “located in California and”. The purpose of these additions is to align the subsection’s language with the terminology used in proposed subsection (a). These changes are necessary to ensure compliance with California laws and regulations, and to do so, the Board must be able to inspect central fill facilities, which requires that the facilities be located within California. Another amendment is capitalizing the “B” in “Board”. This change is non-substantive because it is a grammatical change as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the Board’s regulations. Inconsistent capitalization may result in misinterpretation and confusion. Additionally, the subsection is amended to add “medication”, remove “a” and add “another”, and strike “within this state”. The purpose of these changes is to enhance clarity for the regulated public. The term “prescription” is defined as “an oral, written, or electronic transmission order” (BPC 4040). As such, it was necessary to add “medication” as the central fill pharmacy does not receive the specific prescription document from the patient and is providing the prescription medication to another pharmacy. Changing “a” to “another” is necessary to help delineate between the originating and central fill pharmacies in the process. Finally, it is necessary to strike “within this state” to ensure central fill pharmacies are permitted to enter into a contract with a non-resident pharmacy provided that the other requirements of this section are met.

Subsection (c)(1) [previously subsection (a)(1)] is amended to change the term “prescription” to “medication”. The purpose of this change is to ensure appropriate use of terminology throughout the regulation text. As mentioned previously, the term “prescription” is defined as “an oral, written, or electronic transmission order” (BPC 4040). As such, it is necessary to change the term used to “medication”, as the central fill pharmacy does not receive the specific prescription document from the patient and is providing the prescription medication to another pharmacy.

Subsection (c)(2)(A) [previously subsection (a)(2)(A)] is amended to add BPC section 4076.5, which specifies the authority for the Board to establish prescription medication label requirements and the requirement that all prescription medication contain a standardized, patient-centered label. The purpose of this addition is to ensure that all labels are standardized and patient-centered. This addition is necessary because standardized and patient-centered labels are required by BPC section 4076.5 and the

information printed on the label must include the elements required by BPC section 4076.

Subsection (c)(2)(B) [previously subsection (a)(2)(B)] is amended to add “as applicable” to the beginning of the subsection. The purpose of this addition is to provide clarity with respect that the requirement to include the name and address of the appropriate pharmacy based on the flexibility granted within the subsection. This change is necessary because the label requires only the name of one pharmacy, and the phrase indicates that, in these specific circumstances, facilities can determine which facility’s information to include based on their business needs as determined by the facilities under common ownership or pursuant to a contract between the filling facility and the dispensing facility. Another change is removing “prescription” and adding “medication” in its place. The purpose of these changes is to enhance clarity for the regulated public. As mentioned previously, the term “prescription” is defined as “an oral, written, or electronic transmission order” (BPC 4040). As such, it was necessary to add “medication” as the central fill pharmacy does not receive the specific prescription document from the patient and is providing the prescription medication to another pharmacy. “Refilled prescription” was removed and “medication to dispense” was added in its place. The purpose of this change is for consistency throughout the regulation and to eliminate language that appears to restrict central fill pharmacies from filling new prescriptions, which was never the intent of the section. This change is necessary for consistency with the terminology of prescription and medication. Finally, the subsection is amended to add “Nothing in this subsection should be interpreted as preventing inclusion of the name and address of both pharmacies.” at the end of the subsection. The purpose of this addition is to clarify that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on written information provided to patients if pharmacies so choose. This change is necessary to allow facilities the flexibility to determine which pharmacy’s name and address to include on the label as determined by the facilities under common ownership or pursuant to a contract between the filling facility and the dispensing facility. The Board noted that the pharmacy identified on the prescription label must have sufficient staff and access to all information necessary to assist a patient.

Subsection (c)(3) [previously subsection (a)(3)] is amended to add “indicating that the prescription was filled at a central fill pharmacy, and written information”. The purpose of this change is to increase transparency to patients. This change is necessary to ensure that patients are aware that a central fill pharmacy filled their prescription medication and ensure that the patient is aware of who to contact should they need assistance with their prescription medication.

Subsection (c)(4)(C) [prior subsection (a)(4)(C)] is amended to remove “refill request” and add prescription in its place. The purpose of this change is for consistency throughout the regulation and to eliminate language that appears to restrict central fill pharmacies from filling new prescriptions, which was never the intent of the section. This change is necessary for consistency with subsections (c)(4)(A) and (c)(4)(B).

Subsection (c)(5) was amended to add “receives” and remove “to”, and strike “is provided”. The purpose of these changes is to specify that both the pharmacy filling the

prescription and the pharmacy dispensing the prescription are responsible for ensure accuracy of the prescription. These changes are necessary for grammatical clarity that both the filling pharmacy and the dispensing pharmacy are responsible for ensuring that the order was properly filled. Additionally, this subsection was amended to add "Pharmacists working at the originating pharmacy may perform final product verification prior to dispensing, including through review of images of the final product in lieu of physical visual verification." The purpose of this addition is to establish a permissive requirement. This is necessary to allow the originating pharmacy to perform final product verification prior to dispensing and allow for the final product verification to be completed by viewing images of the product in lieu of a physical visual inspection. Finally, this subsection was amended to add "A pharmacist shall not be required to perform final product verification where product verification by a pharmacist is performed at the time of stocking the automated dispensing device, if the dispensing device is not further accessed by pharmacy personnel, and the medication is dispensed into a labeled container (with a label that meets the requirements set forth in section 1707.5 of this Article)." The purpose of this addition is to establish an exemption from product inspection. This exemption is necessary to prevent duplicative product verification that would be unnecessary given that the product was previously verified and dispensed by an automated device without human intervention.

Prior subsection (b) is stricken from the section. The purpose of this change is to remove language that is no longer necessary. This change is necessary because the language no longer applies. Central fill pharmacies would not receive new prescriptions from patients or their agents, transmitted directly to them by prescribers.

Underlying Data

1. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held October 18, 2023 (Meeting Materials Agenda Item VII and Additional Information, Meeting Minutes)
2. Relevant Meeting Materials and Minutes from the Board Meeting held November 1-2, 2023 (Meeting Materials Agenda Item XIII(d), Meeting Minutes)
3. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held January 22, 2024 (Meeting Materials Agenda Item V, Meeting Minutes)
4. Relevant Meeting Materials and Minutes from the Board Meeting held February 8, 2024 (Meeting Materials Agenda Item IX(b), Meeting Minutes)
5. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held April 10, 2024 (Meeting Materials Agenda Item XII and Additional Information, Meeting Minutes)
6. Relevant Meeting Materials and Minutes from the Board Meeting held April 24-25, 2024 (Meeting Materials Agenda Item XIII(h), Meeting Minutes)
7. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held July 18, 2024 (Meeting Materials Agenda Items VIII and IX, Meeting Minutes)
8. Relevant Meeting Materials and Minutes from the Board Meeting held July 31-August 1, 2024 (Meeting Materials Agenda Items XIII(e) and (f), Meeting Minutes)

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The proposed amendments to the regulation are intended to clarify the current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. The amendments also provide increased flexibility regarding labeling and product verification. This regulation will benefit licensees and consumers and will not have any adverse effects.

Economic Impact Assessment

The Board has determined that this proposal will not:

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

The Board determined this proposal will not create or eliminate jobs or businesses. This proposal clarifies current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language.

Specifically, clarifying language is being added to ensure that the central fill pharmacy is licensed by the Board and operated within California and that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, amendments allow originating pharmacies to perform final product verification before dispensing and permit final product verification to be done by viewing images in lieu of a physical visual inspection.

The amendments to this regulation will benefit licensees and consumers by increasing transparency to consumers, ensuring patients know that a Central Fill facility filled their prescriptions and who to contact with any questions—thereby benefitting the health and welfare of California consumers—and allow pharmacies flexibility regarding labeling and product verification.

This regulatory proposal does not affect employee safety or the state’s environment.

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 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 restricting the originating pharmacy to in-state licensees; however, the Board determined that a central fill pharmacy should not be restricted to filling in-state prescriptions only, provided all other requirements are met.

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

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