

**Board of Pharmacy**  
**Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Renewal Requirements

Section Affected: Amend Section 1702 of Article 1 of Division 17 of Title 16,  
California Code Regulations  
Amend Section 1702.1 of Article 1 of Division 17 of Title 16,  
California Code Regulations  
Repeal Section 1702.2 of Article 1 of Division 17 of Title 16,  
California Code Regulations  
Amend Section 1702.5 of Article 1 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 premises or facilities and the individuals who work within the premises. (Business and Professions Code (B&P) section 4000, et seq.) The board's mandate and its mission is to protect the public. (B&P section 4001.1.) Pharmacy law specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions and generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

Existing pharmacy regulations at 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 establish the license renewal requirements for board licensees. These regulatory sections are necessary to provide clarity to the regulated public with respect to the requirements and criteria used by the board to deem an application for renewal complete. As currently written, the regulation sections require frequent amendments to incorporate each new licensing program as they are established. Amending regulations is a time intensive process and the board has not been able to update the regulations as frequently as necessary. Since 2014, the board's regulatory jurisdiction has increased in size. In 2018 alone, the board's licensing types grew from 25 to 39. This proposal will simplify the regulatory language and consolidate the renewal of license types into two categories: (1) a premises or facility license; and (2) a license issued to an individual, with an exception for the pharmacist and advanced practice pharmacist licenses, as these licensing programs have specialized continuing education requirements that are addressed in other regulation. Consolidating the regulations for renewals into only two categories will provide clarity to the regulated public by increasing the readability of the regulations and ensure consistent application of the renewal requirements.

Additionally, as currently written, the regulations do not require all premises or facility license types to report disciplinary action taken by other government agencies to the board; this is only required of nonresident pharmacies and nonresident wholesalers. The board is authorized to discipline a licensee based on discipline imposed by other entities (B&P section 141.) The proposed regulations will allow the board a mechanism

to identify such discipline for all premises or facility license types. If a licensee has been disciplined by another agency, the board must be made aware of this discipline in order to investigate and ensure that the licensee does not pose a risk to the safety of California residents by continuing to operate.

### **Benefits**

This regulatory proposal benefits California residents because the proposed regulation will simplify the regulatory language, which will provide clarity to the regulated public. A premises/facility cannot operate with an expired license and an individual cannot work with an expired license. These regulations will ensure that the requirements for a complete renewal application are clearly specified based on the license type (premises/facility or individual). By separating the license types into two categories (premises/facility or individual), the board can ensure consistent application of the renewal requirement across all license types and allow for inclusion of future license types automatically as the board's regulatory jurisdiction grows. Renewing licenses consistently ensures that all board licensees meet the minimum standards for renewal and individuals can continue to work and premises/facilities can continue to distribute and/or furnish prescription medication to California residents. Additionally, the disclosure of discipline by all premises or facility licensees will allow the board to investigate the disciplinary action and ensure that the licensees are operating in accordance with pharmacy law, which will ensure the health and welfare of California residents.

### **Specific Purpose of Proposed Changes and Rationale**

Existing pharmacy law at 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 establish the license renewal requirements for board licensees. These regulations are necessary to provide clarity to the regulated public with respect to the requirements and criteria used by the board to deem an application for renewal complete. As currently written, the regulations identify specific license types within each section. Therefore, new regulatory language is required to incorporate or address each new licensing program as it is established. Consequently, the board has determined that the renewal requirements should be consistent across all individual license types, so it is assured of consistency with a more comprehensive regulation.

The board's proposal makes the following specific changes:

### **Amend Section 1702 of Article 1 of Division 17 of Title 16 of the CCR**

Subsection (a) is amended to correct a typographical error and remove the "s" after "pharmacist."

Subsection (d) is added and reads "As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with all continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.5." This change is necessary because an applicant renewing their pharmacist license is required to submit satisfactory proof that the applicant has

completed the required continuing education pursuant to B&P section 4231 and CCR section 1732.5. To the extent that the regulation duplicates the information from statute and other regulation sections, such duplication is necessary to ensure that the regulated public can readily and easily find the renewal requirements in one place, rather than having to review multiple sections of law.

The original subsection (d) has been renumbered to subsection (e). This section is further amended to require the applicant for renewal to provide all of the information required under penalty of perjury. The requirement to provide the information under penalty of perjury is to ensure truthful responses because the potential consequence should make the individual providing the information take compliance seriously. In addition, in the event enforcement action is necessary, the individual providing the information may be held accountable for failing to be truthful.

### **Amend Section 1702.1 of Article 1 of Division 17 of Title 16 of the CCR**

The board is proposing to amend the title of this section from “Pharmacy Technician Renewal Requirements” to “Renewal Requirements for Individual Licensees Other Than Pharmacists,” which more comprehensively states to whom the renewal requirements apply. For additional clarity, the sentence “This section applies to the renewal of any license held by an individual licensee other than an individual licensed as a pharmacist or an advanced practice pharmacist” was also added. The renewal requirements for all of the current individual licensees (pharmacy technicians and the designated representative series) are the same, and therefore making one regulation that applies to those individual licensees who are not pharmacists or advanced practice pharmacists will enhance public protection by ensuring that licensee renewal requirements are clear and consistent. In addition, if and when a new license type is created and implemented, the board can simply update the regulation with new reference citations as a change without regulatory effect under CCR Section 100 to update the regulation with new reference citations when new license types are created. The Section 100 process is simple and will save the board time in updating the regulation. This will ensure that any new license types are not left out of the regulation and the licensees understand what renewal requirements apply to them. It is also consistent with the board’s efforts to change other regulations to apply to the two license categories rather than list out each license name/type.

Subsection (a) is further amended to change “applicant” to “applying” for clarity. Without the change, the sentence is not grammatically correct.

Subsection (d) is further amended to require the applicant for renewal to provide all of the information required under penalty of perjury. The requirement to provide the information under penalty of perjury is to ensure truthful responses because the potential consequence should make the individual providing the information take compliance seriously. In addition, in the event enforcement action is necessary, the individual providing the information may be held accountable for failing to be truthful.

Within this entire regulation section, the term “pharmacy technician” has been amended to “licensee.” This change is necessary for consistency with the change in the title and will require the existing minimum requirements to apply to all individual licensees

(pharmacy technicians and the designated representative series), other than pharmacist and advanced practice pharmacist.

### **Repeal Section 1702.2 of Article 1 of Division 17 of Title 16 of the CCR**

Consistent with the change to section 1702.1, the board is proposing to repeal this section. Section 1702.2 identifies the renewal requirements for Designated Representatives. This license category is an “individual” license type. Since 2014, two new designated representative license types have been established (Designated Representative – 3PL and Designated Paramedic). This is an example of why the board is proposing this rulemaking. By folding Designated Representatives into the individual license category, the two new license types are automatically included into the designation. To ensure that all designated representative license types have clear and consistent renewal requirements, the renewal requirements for this license type have been consolidated within the changes identified in section 1702.1 of this proposal.

### **Amend Section 1702.5 of Article 1 of Division 17 of Title 16 of the CCR**

The board is proposing to amend the title of this section from “Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy” to “Renewal Requirements for Premises or Facilities,” which more comprehensively describes to whom the renewal requirements apply. For additional clarity, the sentence “This section applies to the renewal of any license held by a premises or facility” was also added. The ordinary meaning of the word premises is “a building or part of a building usually with its appurtenances.” (<https://www.merriam-webster.com/dictionary/premises>.) The term “premises” is also a commonly used word within pharmacy law meaning the building licensed by the board (i.e. pharmacy, hospital, wholesaler, etc.). (See e.g. B&P section 4107 [premises is a location with its own address and an independent means of ingress and egress].) This change will make the section apply to all premises or facility licensees and will include any possible future license types in this category. This change will provide increased clarity to the regulated public by including all site license types in one regulation section and the necessary consistency to treat similar license types uniformly.

As part of the requirements for initial licensure as a premises or facility, an applicant must disclose any disciplinary actions taken by a government agency. Prior to issuance of a California license, the Board obtains a National Practitioner Data Bank (NPDB) Practitioner Self-Query that reports adverse licensure actions, adverse clinical privilege actions, Medicare/Medicaid exclusions, and/or judgment or conviction reports found for the applicant. This information is very valuable when making a licensing decision; however, it only provides information at the time of licensure. Currently, except for nonresident pharmacies and nonresident wholesalers, there are no regulations that require disclosure of new disciplinary action taken since a license was issued or since a license was last renewed. The board may discipline a licensee based on discipline imposed by another entity. (B&P section 141.) The proposed regulations would allow the board a mechanism to identify such discipline for all premises or facility license types. This will increase public protection by ensuring that the board is aware of any

out-of-state discipline that may impact a licensee's ability to safely distribute medication within California.

Subsection (a) is amended to add "premises or facility" and remove "nonresident wholesaler or as a nonresident pharmacy" from the first sentence. This will ensure that the regulation language applies to all premises or facility licenses that the board currently issues and may issue in the future. Additionally, the subsection is further amended to add "issuance or" to the first sentence and remove the second sentence in its entirety. The change is a rewording for readability within the section and is not a substantive change.

### **Underlying Data**

1. Relevant Meeting Materials from Board of Pharmacy Licensing Committee Meeting held April 19, 2018 (Meeting Materials Pages 1, 7-8).
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held May 2-3, 2018 (Meeting Materials Pages 1, 10-11, Minutes Pages 1, 18-19).

### **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 absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, the proposed regulation will simplify the regulatory language, thereby providing clarity and consistency to the regulated public with respect to the requirements and criteria used by the board to deem an application of renewal complete. The proposed regulations require all premises or facility licensees to report discipline by another government agency at the time of the license renewal; however, this is done by marking an indicator on the application for renewal and will not impose an economic or fiscal impact on the licensee.

### **Economic Impact Assessment**

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

- (1) It will not create or eliminate any jobs within California;
- (2) It will not create new, or eliminate existing, businesses in California; and,
- (3) It will not expand businesses currently doing businesses within the state.

As the board's licensing program authority has increased, the board has not been able to update these regulations at the same pace. The proposed regulations provide clarity to all licensees with respect to the requirements necessary for a renewal to be deemed complete by the board and will ensure consistent application of the renewal requirements. While this may allow a business or individual to renew their license timely, the regulatory proposal does not actually create the business or the job,

eliminate businesses or jobs, or expand businesses currently doing business in the state.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation will simplify the regulatory language which will provide clarity to the regulated public. A premises/facility cannot operate with an expired license and an individual cannot work with an expired license. These regulations will ensure that the requirements for a complete renewal application are clearly specified based on the license type (premises/facility or individual). This will help to ensure that licensees are submitting complete applications, which will allow for the timely renewal of licenses. Renewing licenses timely ensures that individuals can continue to work and premises/facilities can continue to distribute and/or furnish prescription medication to California residents. If a business is able to continue services, it benefits the health and welfare of California residents by providing continued access to pharmacy related care. Additionally, it will ensure that the board is aware of any disciplinary action taken by other government agencies against a board licensee. This disclosure will allow the board to investigate the disciplinary action and ensure that the licensees are operating in accordance with pharmacy law, which will ensure the health and welfare of California residents.

This regulatory proposal does not affect worker safety or the state's environment. The proposed regulation simplifies the existing regulatory language and consolidates the license types into two categories: (1) an individual license and (2) a premises or facility license to provide clarity to the regulated public and ensure that the renewal requirements for all licensees clearly specified based on the license type.

### **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 amending the regulation. The board determined that this alternative was unacceptable because it is necessary to provide clarity to the regulated public so that they may be aware of the requirements to renew their individual or premises/facility license. This alternative would also not reduce the burden on the board in having to undertake a regular rulemaking action each time a license type is established. Additionally, the board would not be notified of disciplinary action taken against licensees other than nonresident pharmacies and nonresident wholesalers. This would not meet the board's statutory mandate of consumer protection.

2. The board considered amending the regulation text to include a list of license types. This alternative was unacceptable because the regulation would require frequent amendments as the board's regulatory authority increases and a large list within the body of the text would reduce clarity within the regulation.