Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Abandonment of Applications

Section Affected: Amend Section 1706.2 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 sites (premises) 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.)

Existing pharmacy law at 16 CCR section 1706.2 establishes the provisions under which the board may determine that an application has been abandoned by the applicant. This regulatory section is necessary to provide clarity to the regulated public with respect to the criteria used by the board to deem an application abandoned. Once an application is abandoned, the board ceases expending staff time and resources on attempting to cures deficiencies in an application.

As currently written, this regulation requires frequent amendments to incorporate each new licensing program as they are established. This is a time- intensive process and the board has not been able to update the regulation as frequently as necessary. This forces the board to have to wait until a regular rulemaking action is completed before it can treat new license types the same way as existing license types, for purposes of abandonment. Since 2014, the board's regulatory jurisdiction has increased in size (from 25 to 39 licensing types in 2018). This regulatory proposal will simplify the regulatory language and consolidate the license types into two categories: (1) a premises license and (2) an individual license, with an exception for pharmacist examination and licensure and pharmacy intern applicants, as these licensing programs have specialized requirements.

Benefits

This regulatory proposal benefits California residents because the proposed regulation will simplify the regulatory language which will provide clarity to the regulated public. These regulations will ensure that the instances where an application will be deemed abandoned are clearly specified based on the license type (premises or individual). The regulation will improve the board's efficiency. The board will no longer need to update its regulations to specify each new premises or individual license type. Instead, each time a new license type is created in statute, the proposed regulation will automatically apply for purposes of determining abandonment. Additionally, this will help to ensure that applicants are responding timely to application deficiencies. Finally, this proposal will allow the board to deem an application abandoned in lieu of retaining the pending applications indefinitely.

Allowing the board to consider applications abandoned under certain conditions in lieu of continuing to contact applicants for deficiency items, allows the board to more easily focus its efforts on processing new applications, as well as spending more time working with applicants who are attempting to correct their deficiencies. The board will be able to answer questions and provide guidance to applicants seeking clarity with meeting the minimum qualifications for licensure.

Specific Purpose of Proposed Changes and Rationale

The board's proposal makes the following changes:

Amend Section 1706.2 of Article 1 of Division 17 of Title 16 of the CCR

The board broadly regulates two types of licensees: premises and individuals. Subsection (a) is amended to remove "to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes" from the section and replace with the term "premises" before the word license at the beginning of the section. 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 commonly used within pharmacy law meaning the building or site licensed by the board (i.e. pharmacy, hospital, wholesaler, etc.). (See e.g., B&P section 4107 [premises is a building with its own address and independent means of ingress and egress.]) This change will make the section apply to all applicants for a premises license. Additionally, this proposal will remove the existing list of license types and will embrace all current premises license types and any possible future premises licenses. This change will provide increased clarity to the regulated public by including all site license types. It will also ensure clarity to the reader as the language is more concise when the long incomplete list of license types is consolidated.

Subsection (b) is amended to remove "a pharmacy technician or a designated representative license" and add "an individual license not included in subdivision (c), (d), or (e). The board combined the pharmacy technician and designated representative license types under the umbrella term of "individual license" for clarity. This section applies to all applicants for an individual license. Additionally, the section specifies that the applicants for an individual license not included in subsections (c), (d), or (e), would fall under this section. This will provide clarity to the regulated public by allowing for clear identification of the section within the regulation that applies to them. The board retained the existing language to ensure that each application is treated on a case-by-case basis. Prior to withdrawing an application, board staff review each application individually to confirm that the applicant has not completed their deficiency items and has not contacted the board in an effort to meet the requirements for licensure. A case-by-case-review is necessary to ensure that each application is reviewed on its own merit and that the application is not withdrawn after 60 days if the applicant is making an effort to complete the licensing requirements.

Subsection (c), is amended to add "(1)" after subsection (f) within the section. This change is necessary to make the regulation consistent with the regulatory change in Title 16 CCR section 1749 on April 20, 2018. This section was further amended to add "shall" after "eligibility" and reads: "An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to…" This change is necessary for clarity and consistency with existing language in new subsection (c), formerly (d). Adding "shall" does not change the intent of the regulation text; in fact, it was previously left off in error.

Subsection (e), is amended to read "for an intern" instead of "for a intern" for grammatical correctness.

These changes in totality will also provide increased clarity to the regulated public by including all license types within the regulation. Additionally, not including the long list of license types within the regulation text, will provide increased clarity and ensure that the language is concise.

Factual Basis/Rationale

B&P section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

The board issues licenses within two general categories: licenses for buildings or facilities (i.e., premises) and licenses for individuals. The following B&P sections define the premises or individual licensing categories and specify the minimum qualifications required for licensure:

B&P Section	Premises or Individual Licensing Category/Minimum Qualifications
4022.5, 4053	Designated Representative and Designated Representative-in-charge
4029	Hospital Pharmacy
4030, 4208	Intern Pharmacist
4034, 4201	Outsourcing Facility
4034.5	Emergency Medical Services Automated Drug Delivery System
4037, 4110, 4201	Pharmacy
4041, 4042, 4201	Veterinary Food-Animal Drug Retailer
4043, 4160, 4201	Wholesaler
4044.3	Remote Dispensing Site Pharmacy

B&P Section	Premises or Individual Licensing Category/Minimum Qualifications
4045, 4160, 4201	Third-Party Logistics Providers
4112, 4120	Non-Resident Pharmacy
4115, 4202	Pharmacy Technician
4127.1	Sterile Compounding Pharmacy
4127.15	Hospital Satellite Compounding Pharmacy
4141, 4205	Hypodermic Needles or Syringes
4161	Non-Resident Wholesaler or Non-Resident Third-Party Logistics Provider
4180, 4203, 4203.5	Clinics
4190, 4204	Surgical Clinic
4200	Pharmacist
4202.5	Designated Paramedic
4210	Advanced Practice Pharmacist

Existing pharmacy law establishes the provisions under which the board may determine that an application has been abandoned by the applicant. As currently written, the regulation identifies each license type within the language. As such, the language requires frequent amendments to incorporate each new licensing program as they are established. Amending a regulation is a time intensive process for the board, board staff, the public, and other government agencies. In the last two fiscal years (FY), FY 16/17 and FY 17/18, statute has established three and four licensing programs, respectively, within the board's regulatory authority. Given the length of the rulemaking process, the board would still be amending the regulation for one FY when it would need to start pursuing another amendment for the next year. Consequently, the regulation as currently written becomes confusing and inefficient when new licensing programs are established, and the regulation does not include them by name.

Therefore, in addition to this regulation, the board is adopting similar changes to other regulations that name out each license program. This change will create consistency, by imposing the same abandonment of application criteria to all license types, current and future. Applicants applying for licensure under a new license type will know at inception what the requirements for their license type are by grouping the license types into these two categories.

Further, the change will enhance public protection by making the board's efforts more efficient. By incorporating all the license types, current and potential, the board will not have to continuously update the regulation and will be able to focus on processing new applications, as well as working with applicants who are attempting to correct their deficiencies. This will ensure that any new license types are not left out of the regulation and give the board the ability to focus on processing those applications. At most, the board anticipates submitting 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 regulatory proposal will simplify the regulation language and consolidate the license types into two categories: (1) a premises license and (2) an individual license. This change

is necessary to provide clarity to the regulated public and ensure that the instances where an application will be deemed abandoned are clearly specified based on the license type (premises or individual). This proposal will allow the board to deem an application abandoned in lieu of retaining the pending applications indefinitely.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Licensing Committee Meeting held January 16, 2018 (Meeting Materials Pages 1, 3 and Attachment 3, Minutes Pages 1, 9-10).
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 6-7, 2018 (Meeting Materials Pages 1, 4-5 and Attachment 3, Minutes Pages 1, 21-23).
3. List of Board of Pharmacy License Types, revised March 2018.

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 a few months. Additionally, withdrawing an application under specific conditions will allow the board to be able to respond timely to inquiries and provide applicants with improved customer service.

Economic Impact Assessment

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

(1) It is unlikely that the proposal will create or eliminate any jobs within California;
(2) It is unlikely that the proposal will create new, or eliminate existing, businesses in California;
(3) It is unlikely that the proposal will expand businesses currently doing businesses within the state; and
(4) It benefits the health and welfare of California residents.

The board determined that by having an application abandoned under certain conditions in lieu of continuing to contact applicants for deficiency items, the board will be able to focus on processing new applications, as well as working with applicants who are attempting to correct their deficiencies. In these cases, the board will be better able to respond timely to inquiries and provide applicants with improved customer service. This streamline of application processing may result in applicants being able to resolve their application deficiencies earlier, which would allow the license to be issued sooner. While this will allow the business to open earlier or the individual to begin working earlier, the regulatory proposal does not actually create the business or the job. If a business is able to open sooner, it benefits the health and welfare of California residents by providing earlier access to pharmacy related care.

If an individual or business decided to again pursue licensure after the application was deemed abandoned, the estimated costs to the individual or business would be a new application fee as set by Business and Professions Code section 4400 and/or California Code of Regulations section 1749.

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) a premises license and (2) an individual license to provide clarity to the regulated public and ensure that the instances where an application will be deemed abandoned are clearly specified based on the license type (premises or individual).

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 criteria used by the board to deem an application abandoned and, subsequently, withdrawn by the board. This alternative would also preserve the current inefficient process of the board developing and submitting regular rulemaking actions each time a new license type is established in statute.
2. The board considered amending the list of license types within the regulation text. 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. This alternative is less efficient for the board then the proposed action.