

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office by October 14, 2019.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Section 4005 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, 4208, and 4210 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy (board) proposes to amend 16 CCR section 1706.2 to consolidate all board license types into two broad categories to simplify the regulation.

Existing 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. Additionally, 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 cure

deficiencies in an application.

As currently written, the 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. 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 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. Consolidating the licensing types to only two categories will provide clarity to the regulated public as it increases readability of the regulations. It will also improve the board's efficiency by not having to update the regulation via a regular rulemaking action each time a new license category is created, and by allowing the board to find applications abandoned for newly created license categories.

Anticipated Benefits of Proposal

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). 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 deem 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.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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.

Cost Impact on Representative Private Person or Business:

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. The cost would vary from \$140 to \$2,380 depending on the type of license the individual or business is applying for as set by Business and Professions Code section 4400 and/or California Code of Regulations section 1749.

Effect on Housing Costs: None

Effect on Small Business:

While the board does not have nor does it maintain data to determine if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. 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, the proposed regulation will simplify the regulatory language, thereby providing clarity to the regulated public and ensuring that the instances where an application will be deemed abandoned are clearly specified based on the license type (premises or individual).

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

Results of Economic Impact Assessment/Analysis:

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; and
- (3) It is unlikely that the proposal will expand businesses currently doing businesses within the state.

The board determined that by deeming 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.

Benefits of Regulation:

This regulatory proposal benefits the health and welfare of California residents because by deeming 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. 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. 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. This regulatory proposal does not affect worker safety or the state's environment.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations during the written comment period at the address listed for the Contact Person.

Initial Statement of Reasons and Information

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has made available all the information upon which the proposal is based.

Text of Proposal

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <http://www.pharmacy.ca.gov>.

Availability and Location of the Final Statement of Reasons and Rulemaking File

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Lori Martinez
Address:	2720 Gateway Oaks Drive, Ste 100 Sacramento, CA 95833
Phone No.:	(916) 518-3078
Fax No.:	(916) 574-8618
E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Drive, Ste 100 Sacramento, CA 95833
Phone No.:	(916) 518-3090
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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.