

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

Amend Title 16, Section 1709, of the California Code of Regulations,
to Add Trusts to the Types of Entities that Can
Own, Manage and/or Control a Pharmacy

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) proposes taking the rulemaking action described below. 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 no later than September 7, 2021.

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 the interested person's 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 non-substantive 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 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 (BPC) authorizes the board to adopt these regulations. The proposed regulations implement, interpret, and make specific BPC sections 4035, 4058, 4101, 4110, 4111, 4112, 4113, 4120, 4130, 4131, 4201, 4207, 4302, 4305, 4307, 4308, and 4330.

Goals and objectives of the proposed regulations:

The board proposes to amend California Code of Regulations (CCR), title 16, section 1709, to reflect statutory changes regarding ownership structures for pharmacies and other business entities, including as they relate to trust ownership of a pharmacy.

Summary of existing law and regulatory changes to be made:

The board tracks the beneficial interest of business owners, whether the owners are a natural person or an entity. Previously, pharmacy law did not recognize a "trust" as a "person" to whom the board was authorized to issue a license. This prevented the board from issuing a license, usually pharmacies, when the ownership structure included a trust.

Senate Bill (SB) 1193 (Hill, Chapter 484, Statutes of 2016) amended, among other things, BPC Sections 4035 and 4201 to make the following changes:

- BPC section 4035 – Added “trust” to the definition of “person;” and
- BPC section 4201 – Added requirements to disclose information of any person with management or control over the license to the Board.

This proposal will make the board’s regulation text at section 1709 more specific with respect to the statutory changes made as a result of SB 1193. Specifically, the proposal would:

- Change the term “permit” to “license”;
- Specify that a license shall not be transferred from one owner to another without written notification to the board;
- Specify the reporting time frame as required by BPC section 4201; and
- Identify the board’s ability to issue a license to an entity controlled by a trust and specify the requirements for disclosure and notice to the board, including identifying who must be identified (by role), when disclosure or notice is required, what information is required, and how notification is to be provided.

Informative Digest/Policy Statement Overview

The board proposes clarifying and making specific the disclosure and notice standards for applicants and licensees relating to ownership, management, and control of pharmacies and other business entities licensed by the board.

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 law establishes which businesses, in the pharmacy industry, must be licensed, and to whom the board is authorized to issue a license and to whom it cannot issue a license. Existing law provides the notification requirements when a change in ownership of the license takes place. The existing regulation explains when notice is required and when a new application for a license is required.

Pharmacy law requires owners and other individuals, with management and control over a license issued by the board, to meet certain criteria to hold the license or the position, respectively. To fulfill its regulatory functions, the board monitors the persons who have a beneficial interest in, as well as the management and control over, pharmacies and other business entities, whether the persons are a natural person or an entity. Previously, pharmacy law did not recognize a “trust” as a person to whom the board was authorized to issue a license. This prevented the board from issuing a license to a pharmacy, or other business entity, when the ownership structure included a trust.

This proposal will modify requirements relating to the ownership of, and the management control over, pharmacies and other business entities regulated by the board. It will, primarily, implement the statutory changes made by SB 1193, by specifying what information businesses, that are beneficially owned by a trust, must disclose upon application for a license and when any such ownership changes.

Anticipated Benefits of Proposal

This proposal is necessary to implement the new statutory requirements enacted in SB 1193. These changes will help ensure that the board is able to monitor the beneficial ownership of a pharmacy, or other regulated business entity under its supervision, when it is owned by a trust, and help ensure that previously disciplined owners or prohibited forms of ownership (i.e. prescriber ownership) are not occurring. It will also provide clarity to applicants and licensees about what, when and how they must disclose ownership interests, thus increasing transparency in the board's regulatory functions. Ultimately, it will protect the public by prohibiting individuals or entities, who are not qualified from operating a pharmacy or other regulated business entity, and by preventing hidden ownership.

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: The proposed regulations do not result in a fiscal impact to the state. The Board has been providing licensure to trust-ownership business entities under current law since 2017. This proposal aligns the Board's regulations with existing practice, as authorized under current law.

The Board typically receives and process approximately 30 to 35 license applications from trust-owned business entities per year and currently has approximately 100 licensed trust-owned pharmacies.

Because the regulations implement the Board's current policies and procedures related to issuing a license and regulating a trust-owned pharmacy consistent with existing statutory authority, no fiscal impact is anticipated.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

Business Impact:

The board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses and/or employees, including the ability of California

businesses to complete 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, while the proposed regulation requires the disclosure of additional information, by the applicant and/or licensee, the proposed regulation clarifies existing licensing standards and specifies what and when information must be disclosed and reported to the board.

Cost Impact on Representative Private Person or Business:

The regulations do not result in an economic impact to the state. Because the Board currently provides licensure to these entities under current law no additional costs are anticipated.

The Board notes applicants for a new business license currently incur nominal additional costs to make copies of the trust documents and the time to report the additional information on the application documents.

Additionally, for existing business licensees who wish to transfer business ownership into a trust, the estimated cost, to the business, will be determined by the ownership structure of the existing licensee and the ownership, management and control within the trust.

If the existing licensee ownership and the ownership, management and control within the trust are identical, the cost to the business entity to report the changes and update the licensee ownership, management and control, with the trust, would be \$130 [BPC section 4400(o)] for a change of permit, plus the cost of paper and time to complete the application.

Note: A change of permit is the process of updating the ownership or officer structure of an existing license, when a change of ownership has not occurred. If the ownership and/or management and control structure, within the trust, is different than the existing licensee ownership, the cost to the business entity to report the changes and update the licensee ownership, management, and control, within the trust, would vary according to BPC section 4400 and 16 CCR 1749, based on the license type for a new license, as these changes would alter the ownership of the existing license. BPC section 4201(f) – (h) specifies that a license is non-transferable, so a new license must be issued if the ownership is changed.

However, because business entities currently incur these costs and because the proposed regulations do not result in additional costs, the board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

Business Report:

The proposed action will require a business to make a report under certain circumstances. The board has made a preliminary finding that the reports are necessary for the health, safety, or welfare of the people of the state that the regulation apply to businesses.

Effect on Small Business:

The board does not have, nor maintain, data to define if any of its licensees (pharmacies or other licensed entities) are a “small business,” as defined in GC section 11342.610. While the board is unable to determine if any of its licensees are considered a small business, based on its experience in dealing with applicants and licensees for pharmacy or other related business licenses, the board determined that this regulatory proposal is more likely to affect a small business, as a small business is more likely to have an ownership structure that includes a trust. The board, however, made an initial determination that the proposed regulatory action will not have a significant adverse impact directly affecting small businesses. While the proposed regulation requires the disclosure of additional information, by the applicant and/or licensee, the proposed regulation clarifies existing licensing standards and specifies the information that must be disclosed, at the time of application, and when the information must be reported to the board.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that it is:

- (1) Unlikely that the proposal will create or eliminate any jobs within California;
- (2) Unlikely that the proposal will create new, or eliminate existing, businesses in California; and/or
- (3) Unlikely that the proposal will expand businesses currently doing businesses within the state.

Benefits of Regulation:

This regulatory proposal benefits the health and welfare of California residents. The proposed regulation implements SB 1193, which gave the board authority to issue licenses to entities owned by trusts. The proposed regulation will make it less likely that prohibited forms of ownership, management, and/or control (i.e. prescriber owned, control by those previously disciplined) will occur. This will provide increased protection to the residents of California by making it less likely that prohibited individuals are able to obtain ownership, management and/or control over a licensee distributing dangerous drugs and devices within California, which could impact patient and public safety. Finally, the proposed regulation increases

transparency and clarifies the application process with respect to the disclosure requirements relating to ownership, management and control of an entity licensed by the board. The regulatory proposal is not anticipated to benefit worker safety or the state's environment.

Consideration of Alternatives

The board must determine that no reasonable alternative, which 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 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, any document incorporated by reference therein, the Initial Statement of Reasons, and all of the information upon which the present proposal is based, may be obtained upon request from the Board of Pharmacy, at 2720 Gateway Oaks Dr., Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at the web address noted below.

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 Dr., Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3078
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E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Debbie Damoth
Address: 2720 Gateway Oaks Dr., Ste. 100
Sacramento, CA 95833
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Website Access

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