

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Ownership, Management, and Control of
Pharmacies and Other Business Entities

Section Affected: Amend Section 1709, Article 2 of Division 17 of Title 16, California
Code Regulations

Problems Addressed

The California State Board of Pharmacy (board) is the state agency vested with the authority to regulate the pharmacy industry, including pharmacies and pharmacists. (Business and Professions Code (B&P) section 4000, *et seq.*) The board's mandate and mission is to protect the public. (BPC section 4001.1.) Additionally, existing law establishes to whom the board is authorized to issue a license, the requirements regarding ownership of the licensee, and provide notifications to, when changes take place, that affect the licensee.

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 regulated 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 pharmacy license when the ownership structure of the pharmacy included a trust, as occurs in many current estate plans, etc.

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 the information of any person with management or control over the license.

The board proposes to amend 16 CCR 1709, to clarify and make specific the standards of pharmacy and ownership disclosure, as they relate to pharmacy ownership, management, and control, including through trusts.

This proposal will modify the requirements relating to the ownership of, and the management and control over, pharmacies and other business entities. It will primarily implement the statutory changes made, in 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.

Specifically, the proposal would:

- Change the term “permit” to “license”
- Specify that a license shall not be transferred from one owner to another.
- Specify the reporting time frame as identified in BPC section 4201.
- Identify the board’s ability to issue a license to an entity controlled by a trust; 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 it is to be provided.

Benefits

Protection of the public is the board’s highest priority in exercising its licensing, regulatory and disciplinary functions. The proposed changes ensure the board is able to continue to track the beneficial ownership of a pharmacy or other regulated business entity, even when it is owned by a trust, and ensure that previously disciplined owners or other prohibited forms of ownership (i.e. prescriber owned), are not occurring.

By regulating the ownership, management and control of pharmacies and other regulated business entities, the board seeks to better protect the drug supply. Individuals with ownership, management and control over a business licensed by the board have the ability to affect the quality, security and safety of the pharmaceutical drug supply, as well as the distribution of drugs without a valid prescription. By identifying individuals who may pose a risk, in those positions, the board seeks to prevent their ownership and, thereby, prevent consumers from being exposed to such risks.

Specific Purpose of Proposed Changes and Rationale

The purpose of the board’s proposal makes the following changes:

Amend Section 1709. Article 2. Division 17. Title 16 of the CCR

The board proposes amending the regulation title from “Names of Owners and Pharmacist-in-Charge” to read “Ownership, Management, and Control of Pharmacies and Other Regulated Business Entities.” This change is necessary to more thoroughly and accurately describe the content of the regulation section.

Subdivision (a) is being amended to replace the term “permit” with “license issued by the board.” This change is made to align the regulation with BPC sections 4037, 4110, and 4201, which specify that the board issues a “license” to a business entity. In the first sentence “show” was amended to “reflect” for grammatical clarity. Additionally, “(individual, partnership or corporation)” was removed. This change was made because the description of the forms of possible ownership are unnecessary, as well as incomplete, because it did not include other forms of business entity, including trusts.

The board determined that it was unnecessary to define the various form of ownerships, in this section, as they are already described in BPC section 4035 and would be

duplicative. Finally, three changes were made for grammatical clarity: “and” was added to the second sentence to read “in its initial application and on the annual renewal...” to resolve any doubt that the requirement applied both upon application, as well as at the time of the annual renewal; and “Board” was changed to “board.” Also, “of the change” was added for clarity, since it’s unclear when the 30 days would begin running, thus causing potential confusion.

Subdivision (b) would be renumbered to (b)(1) and would be amended to replace the term “permit” with “license” to align the regulation with BPC sections 4037, 4110, and 4201, which describe that a pharmacy or other business entity is licensed by the board. Also, “of the transfer” was added for clarity, since it’s unclear when the 30 days would begin running, thus causing potential confusion.

Subsection (b)(2) will add “Any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued, shall require written notification to the board within 30 days of the transfer.” This subsection is added for clarity as a result of the changes made by SB 1193 to BPC 4201 requiring the disclosure of information related to any person with management or control over the license. Additionally, the board mirrored the language in (b)(1), with respect to the written notification being provided to the board within 30 days of the transfer. Maintaining the same process for reporting changes to the board eliminates possible confusion on the reporting process.

Subdivision (c) will be amended to add: “A license issued by the board shall not be transferred from one owner to another.” In many locations of the board’s law, including in BPC sections 4201(f)-(h) and 4205, licenses issued by the board are not transferrable. The duplication, in regulation, is necessary for clarity to the regulated public, as it includes the transfer prohibition in the same regulation section as the notification requirements. It also resolves any potential confusion with the board’s authority in section BPC sec. 4110, subd. (a), to specify, by regulation, when a pharmacy license may be transferred.

Additionally, the second sentence will be amended for grammatical clarity and now reads “The following shall constitute a change of ownership and shall require a new application for licensure:” As previously explained, what constitutes a “transfer” is confusing, since the board’s position is that a license cannot be transferred, in its entirety, the board determined that the revised sentence provided additional clarity that a new license application must be provided. The subdivision was split into new subdivision (c)(1) to follow the format of subdivision (b) and (d).

Subdivision (c)(1) will be added to read “any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee’s holding 50% or more of the beneficial interest in that license.” This text was relocated from subdivision (c) and is not new language. A new final sentence will be added to subdivision (c)(1) to clarify that once a transfer is proposed, where the transferee will

hold 50%, or more, of the beneficial interest in the license, a new license application for that entity is required, and that the application is required before the transaction takes place.

This section also helps distinguish the process when a smaller portion of the beneficial interest is transferred to a new person, which is currently regulated by the provisions of subdivision (b) and is not being substantively changed. BPC section 4201(j) requires that the board be notified within 30 days of any proposed change in ownership. This section is added to align the regulation with the statute and ensure that the board is notified of proposed ownership changes (actual or beneficial) in advance of the transfer of ownership being completed. This is necessary for the board to review and ensure that the current owners are not under disciplinary action and that the new owners are not prohibited from owning a pharmacy due to previous discipline or prescriber ownership.

Subdivision (d) will add: “If any beneficial interest of a business entity licensed by the board is held in trust, the applicant, licensee, or any person with management or control of the business entity shall do the following:” This subdivision is added to require the acts specified in subdivisions (d)(1) – (d)(5)(F), if any beneficial interest of the entity is held in trust. These acts are required to ensure that the board has the most current information on file and ensure clarity for the regulated public of the notification requirements.

Subdivision (d)(1) will add: “In addition to the requirements in subdivision (a), as part of their application and renewal, report the name of any other person in any position with management or control of the business entity;”. This subdivision is added to ensure that applicants and licensees disclose any person with management or control over the pharmacy, as required in BPC section 4201(a). This disclosure is necessary to ensure that the board has the most current information, on file, for the licensee, ensure prohibited ownership (i.e. previous discipline or prescriber ownership) is not occurring, and identify if changes in management or control have occurred without notification, to the board, to ensure compliance with pharmacy law.

Subdivision (d)(2) will add: “As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to, the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.” The section is necessary to clarify the reporting requirements for the ownership of the trust. It is necessary to have the full name of the trust to confirm the authenticity of the trust documents submitted. Additionally, the submission of the trust document and amendments is necessary to identify the beneficial owners and persons with management and control of the trust, as some beneficial owners and persons with management and control of the trust may be prohibited from owning a pharmacy, under pharmacy law.

Finally, specifying that the trust documents are confidential financial documents is necessary to reassure the applicant or licensee that the documents, themselves, may be withheld from release to the public under the Public Records Act. The board

frequently has conversations with applicants and licensees who resist disclosing documents because they worry that the documents will be, thereafter, released to the public. Generally, the board will withhold similar documents in response to a Public Records Act request, pursuant to Government Code sections 6254, subdivisions (k) and (n), and 6254.15; Evidence Code sections 1040 and 1060.

Subdivision (d)(3) will add: “As part of annual renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.” The submission of any trust amendments is necessary to identify the beneficial owners and persons with management and control of the trust, as some beneficial owners and persons with management and control of the trust may be prohibited from owning a pharmacy under pharmacy law (i.e. previous discipline or prescriber ownership), and identify if any changes in owners, management and/or control occurred, without notification to the board, to ensure compliance with pharmacy law.

Subdivision (d)(4) will add: “Include in the application and annual renewal, the name, address, phone number and any email address for each grantor, settlor, trustee, and trust protector, as applicable.” The disclosure of each identified individual, and their contact information, is necessary to identify the beneficial owners and persons with management and control of the trust, as some beneficial owners and persons with management and control of the trust may be prohibited from owning a pharmacy under pharmacy law (i.e. previous discipline or prescriber ownership), and identify if changes in owners and/or management or control occurred without notification to the board to ensure compliance with pharmacy law. The phone number and email address are required to enable the board to fully consider the information; the board may need to ask follow-up questions or confirm the identity of an applicant using this information. The identified individuals (grantor, settlor, trustee and trust protector), are designated here because they are the individuals that have been identified, in the trust, who could have influence or control over the pharmacy; and, therefore, the board must vet to determine whether they are prohibited from holding such roles.

Subdivision (d)(5) will add: “The application and annual renewal shall also include the name, address, phone number and any email address for each named beneficiary of the trust who is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary shall be identified;”. The name of the beneficiaries is required because a trust beneficiary has a beneficial interest, even though that interest does not vest until the death of the settlor. Additionally, it is possible for a pharmacy to transfer ownership, within the trust, to a beneficiary without the board being notified. For these reasons, the board is requiring that beneficiaries over the age of 18 years (and the guardians of those under 18) be disclosed to the board, to prevent possible prohibited ownership (i.e. previous discipline or prescriber ownership).

Subdivision (d)(6) would add “Notify the board in writing within 30 days of all the following:” This subdivision is being added to ensure that the changes defined in subdivisions (d)(6)(A) – (F) are reported, to the board, within 30 days, as required by BPC section 4201(j). Applicants are required to report, in writing, because it is more

manageable (prevents mistakes, creates a record for the file) for the board to complete its review if the report comes in written form, whether directly or via electronic communication. Filing the report, within 30 days, appears to be a reasonable period of time, because it is consistent with the other reporting timelines relating to ownership changes; it is also not too short a timeline for reasonable business people to comply. Any time period, longer than 30 days, for the board to learn of these changes (identified below) and begin a review process seems to unnecessarily delay the review process, which could put the public at risk. Thirty days is also consistent with the notification requirements in subdivisions (a) and (b), of this section, and makes implementation and compliance easier, by having a single time period within which to report to the board.

Subdivision (d)(6)(A) will add: “A change in the trustee, protector or any other person with management or control of the business entity.” A change to the trustee, protector, or any other person with management or control of the entity will impact the beneficial ownership of the pharmacy; therefore, BPC section 4201(j) requires that the board be informed of the change. It is necessary for the board to confirm that the change in the individual does not violate pharmacy law and create a prohibited ownership structure (i.e. previous discipline or prescriber ownership) that could pose a risk to the public.

Subdivision (d)(6)(B) will add: “Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary’s(ies’) shall be identified;” A change to the beneficiary will impact the beneficial ownership of the pharmacy; therefore, BPC section 4201(j) requires that the board be informed of the change. It is necessary for the board to confirm that the change does not violate pharmacy law and create a prohibited ownership structure (i.e. previous discipline or prescriber ownership) and could pose a risk to the public.

Subdivision (d)(6)(C) will add: “The revocation of the trust.” The revocation of a trust will impact the beneficial ownership of the pharmacy; therefore, BPC section 4201(j) requires that the board be informed of the change. If board records indicate that the ownership of the pharmacy is the trust and the trust is revoked, a change of ownership will need to occur. It is then necessary for the board to confirm that the revocation of the trust does not result in a violation of pharmacy law and create a prohibited ownership structure (i.e. previous discipline or prescriber ownership) or other ownership situation that could pose a risk to the consumer.

Subdivision (d)(6)(D) will add: “The dissolution of the trust.” The dissolution of a trust can impact the beneficial ownership of the pharmacy; therefore, BPC section 4201(j) requires that the board be informed of this change. If board records indicate that the ownership of the pharmacy is the trust and the trust is dissolved, a change of ownership will need to occur. It is then necessary for the board to confirm that the dissolution does not result in a violation pharmacy law, by creating a prohibited ownership structure (i.e. previous discipline or prescriber ownership), or otherwise pose other risks to the consumer.

Subdivision (d)(6)(E) will add: “Any amendment(s) to the trust since the original application.” Any amendments to the trust could impact the beneficial ownership of the

pharmacy; therefore, BPC section 4201(j) requires that the board be informed of the change. It is necessary for the board to confirm that the amendments do not violate pharmacy law, by creating a prohibited ownership structure (i.e. previous discipline or prescriber ownership), or otherwise pose other risks to the consumer.

Subdivision (d)(6)(F) adds “Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.” Changes to the legal character of the trust could impact the beneficial ownership of the pharmacy; therefore, BPC section 4201(j) requires that the board be informed of the change. It is necessary for the board to confirm that the change does not result in a violation of pharmacy law by creating a prohibited ownership structure (i.e. previous discipline or prescriber ownership), or otherwise pose other risks to the consumer.

Subdivision (e) adds “An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.” This is added to identify the appropriate statutes, for clarity to the public, when the board may deny an application or suspend, or revoke a license. It is not intended to restrict the board from denying or taking any other action under any other provision of law.

The reference statutes were amended to add and remove appropriate sections to ensure that the statutes are up to date and accurate in compliance with the section 11346.2(a)(2) of the Government Code. BPC sections “4035, 4037, 4110, 4131, 4205, 4207, 4302, 4307, 4308, and” were added and BPC sections 4124, 4133, 4141, 4149, 4160, 4161, 4196, 4304 were removed to accomplish the update.

Factual Basis/Rationale

The board monitors the beneficial interest of owners in pharmacies and other business entities, whether those owners are a natural person or an entity. This is done through a careful analysis of all information submitted in support of an application or renewal and often identifies inconsistencies with respect to the ownership reported. For some, what is initially reported as (what appears to be) a simple, two or three-level ownership structure, turns out to be multiple levels of ownership, with multiple owners and business entities involved. To determine who has the ownership, control, and/or management over the dangerous drugs or dangerous devices, so that it may intervene if someone has access or authority over those drugs, the board must know who all the persons, who might exercise any degree of control over the dangerous drugs and dangerous devices, are.

Existing regulation, 16 CCR 1709, specifies the reporting of a transfer in the beneficial interest in the business and specifies the threshold of when a change of ownership must be submitted to the board. SB 1193 amended the board’s statutes to allow the issuance of a license to a pharmacy owned by a trust. This proposal updates the existing regulation to include the specific disclosure requirements for pharmacies owned by a trust. These changes will ensure clarity to the regulated public, with respect to the

disclosure of ownership and the necessary reporting, ensure that the board is able to continue to track the beneficial ownership of a pharmacy, when it is owned by a trust, and ensure that previously disciplined owners or prohibited forms of ownership (i.e. prescriber owned) is not occurring.

Underlying Data

1. Senate Bill (SB) 1193 (Hill, Chapter 484, Statutes of 2016)
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held March 30, 2016 (Meeting Materials Pages 1, 5-6 and Attachment 6, Minutes Pages 1, 13-15).
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 27-28, 2016 (Meeting Materials Pages 1, 5-6 and Attachment 7, Minutes Pages 1, 46-47).
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held June 22, 2016 (Meeting Materials Pages 1, 4 and Attachment 4, Minutes Pages 1, 6-9).
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 27-28, 2016 (Meeting Materials Pages 1, 4-5 and Attachment 4, Minutes Pages 1, 14-17).
6. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held September 27, 2016 (Meeting Materials Pages 1, 2 and Attachments 1-2, Minutes Pages 1-4).
7. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 26-27, 2016 (Meeting Materials Pages 1 and Attachment 2, Minutes Pages 1, 59-62).

Business Impact

The board has made an initial determination that the proposed regulatory action will have no significant statewide adverse impact directly affecting businesses and/or employees, including the ability of California businesses to compete with businesses in other states. 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 regulated 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, as a component.

The board, however, made an initial determination that the proposed regulatory action will not have a significant adverse impact directly affecting small businesses. These initial determinations are based on the absence of testimony, to that effect, during the development of the proposed regulation, which occurred over several months during stakeholder meetings held by the board. 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 exactly what must be disclosed, upfront, rather than requiring back and forth requests, between

board staff and the applicant, to obtain information. For those who own the property through a trust, the regulation specifies what events will trigger reports that must be made to the board.

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

The board determined that applicants for a new business license may be subject to a nominal additional cost due to the new reporting requirements. This cost would be the cost of paper to make copies of the trust documents and the time it will take 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 \$130.00 [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, with 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, no economic impact is anticipated.

It is the board's determination that this proposal will primarily affect independently owned pharmacies, as independently owned pharmacies are more likely to be personally owned and not incorporated. Currently, there are approximately 6,500

pharmacies licensed in California and of those, approximately, 2,700 are considered independently owned. Of those 2,700 licensees, approximately 215 licensees (approximately 8%) have submitted applications to include a trust as part of their ownership structure since 2015.

This regulatory proposal benefits the health and welfare of California residents, as the proposed regulation will help ensure that previously disciplined owners or prohibited forms of ownership (i.e. prescriber owned), are not occurring. This will provide increased protection to the residents of California, by ensuring that prohibited individuals are not able to obtain ownership, management and/or control over a licensee distributing dangerous drugs and devices within California, which could impact patient safety.

This regulatory proposal does not affect worker safety because the proposed regulation implements SB 1193, which gave the board authority to issue licenses to entities owned by trusts. The proposal is specific to the ownership, management, and control of business entities and does not affect worker safety in California.

The regulatory proposal does not affect the state's environment. The proposed regulation implements SB 1193, which gave the Board authority to issue licenses to entities owned by trusts. The proposal is specific to the ownership, management, and control of business entities and does not affect the environment in California.

Fiscal Impact Statement

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 processes 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.

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 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. One alternative would be to not implement the new requirements of SB 1193. This is not a reasonable alternative, as the regulation would result in additional work for applicants, licensees, and the board, and, potentially, make it easier for non-qualifying individuals to obtain licensure and ownership, control or management of the pharmaceutical drug supply, to the detriment of consumers.
2. A second alternative the board considered was to receive the certification of trust. This alternative is not reasonable because without reviewing the trust document in its entirety, the board would have no assurance that applicants are providing all the relevant information related to ownership. As such, the board would not be able to ensure that only qualifying individuals are obtaining licensure, in the manner discussed above.