

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Ownership, Management and Control of Business Entities

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1715.6

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

A nonsubstantive change was made to subsection (b)(2) in that the Board inadvertently failed to underline “shall require written notification to the board within 30 days” even though the language is identified as new within the initial statement of reasons.

A nonsubstantive change was made to eliminate subsection (e) from the language. The language was determined to be duplicative and not necessary for the regulation text.

Finally, nonsubstantive changes were made to the authority and reference section to underline the comma after 4305 and remove the underline to “, and”.

The 45-day public comment period began on July 23, 2021 and ended on September 7, 2021. The Board’s notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period comments were received, which the Board reviewed at the September 23, 2021 Board meeting. At the meeting, the Board adopted the regulation text as noticed on July 23, 2021.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

The board does not have, nor does it maintain, data to define if any of its licensees (pharmacies or other licensed entities) are a “small business,” as defined in

Government Code 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.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. 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 only the certification of trust document, rather than the entire trust document. This alternative is not reasonable because without receiving and reviewing the trust document in its entirety, the board would have no assurance that applicants or licensees 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.

Objections or Recommendations/Responses to Comments

During the public comment period from July 23, 2021 to September 7, 2021, the Board received written comments from one commenter. The comments were provided in the meeting materials for the September 23, 2021 board meeting, and the Board reviewed and considered them.

Summarized 45-day Comments:

Written Comments from Daniel Martinez, CPhA

Comment 1:

The commenter expressed concern regarding the requirement of CCR 1709(d)(1) to disclose “. . . 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”. Commenter states that “pharmacies may use staffing services, billing services, and other services that qualify as ‘person in any position with management of the business entity’ that aren’t relevant in the licensing of pharmacies.”

Response to Comment 1:

The Board reviewed this comment and did not recommend any changes to the text based thereon. The Board noted that Business and Professions Code (BPC) 4201(a) requires disclosure of each person beneficially interested or any person with management and control over the license. This is an existing statutory requirement and not being established by the regulation. The Board disagreed with the commenter regarding the “use of staffing services, billing services, and other service” as having management and control of the business as these are “services” utilized to conduct business by those with management and control. Additionally, the Board disagreed with the statement that positions of management and control of the business are not relevant to the licensing of pharmacies. The Board noted that the proposed language was developed in coordination with an attorney from the Business and Tax Section of the Office of the Attorney General (see underlying data, June, and September 2016 Licensing Committee meeting minutes. The meeting minutes are also available on the Board’s website: https://www.pharmacy.ca.gov/about/meetings_licensing.shtml).

Further, as previously discussed by the Board (October 2016 Board Meeting (see underlying data, October meeting minutes. The meeting minutes are also available on the Board’s website:

https://www.pharmacy.ca.gov/meetings/minutes/2016/16_oct_bd.pdf)), disclosure of any individual with management and control of the pharmacy is, not only required by statute, but necessary to ensure that the board has the most current information, on file, for the licensee, ensures prohibited ownership (i.e. previous discipline or prescriber ownership) is not occurring, and to identify if changes in management or control have occurred without notification, to the board, to ensure compliance with pharmacy law.

Comment 2:

The commenter expressed concern regarding the requirement to provide the entire trust document in subsection (d)(2) as not all information in the trust “is relevant to the licensing responsibilities of the Board.” Commenter requests that the language be amended to limit the disclosure to ownership and keep “irrelevant information confidential.”

Response to Comment 2:

The Board reviewed this comment and did not recommend any changes to the text based thereon. The legislated mandate of the Board is to protect the public and only issue licenses to conduct a pharmacy to appropriate and qualified individuals. It is vital to that mandate that the Board be able to obtain the entire trust document in the event that a trust has an ownership interest in a pharmacy. Specifically, Bus. & Prof. Code sections 4111, 4302, and 4307, provide limitations as to who may own a pharmacy (prohibited persons). As previously discussed by the Board (July and October 2016 Board Meetings (see underlying data, July, and October 2016 meeting minutes. The meeting minutes are also available on the Board’s website: https://www.pharmacy.ca.gov/about/meetings_full.shtml)), it is, unfortunately, not uncommon for an individual who is prohibited from having management and control of a pharmacy to attempt to conceal ownership and continue to profit from and run the pharmacy, while on paper it looks as though someone else owns it. Trusts are a perfect vehicle for such hidden ownership interest because the property could legally be titled in someone else’s name but held for the sole benefit of the beneficiary. As such, Board staff must review the entire trust document to ascertain whether any prohibited person receives a benefit under the trust. The Board further noted that the trust documents received with the application or renewal are maintained as confidential financial documents in the Board’s possession, and the documents, themselves, may be withheld from release to the public under the Public Records Act pursuant to Government Code sections 6254, subdivisions (k) and (n), and 6254.15; Evidence Code sections 1040 and 1060. A detailed explanation is contained in the Initial Statement of Reasons (pages 4 and 5).

Comment 3:

The commenter expressed concern regarding the lack of distinction between irrevocable and revocable trusts. Commenter states that trustees of a revocable trust do not act on behalf of beneficiaries and as such, commenter does not believe the disclosure of beneficiaries is necessary. Additionally, commenter states that requiring documentation of beneficiaries or when a change of beneficiary is made places an undue burden and expense on the licensee. Commenter recommends that the language be amended to apply only to irrevocable trusts.

Response to Comment 3:

The Board reviewed this comment and did not recommend any changes to the text based thereon. The Board did not agree with the commenters statement that trustees do not act on behalf of beneficiaries. By definition, beneficiaries of a trust have an equitable property interest in trust assets.¹ A trustee holds legal title to property for the benefit of the beneficiaries.² The trustee is required to manage trust assets and distribute the trust assets and income from the assets to the beneficiaries according to the terms of trust.³ The beneficiaries of a trust are considered its equitable owners.⁴

Further, the Board noted that a trust can also be established giving the beneficiaries (or a single beneficiary) a 100% right to all of the profits of the trust. The Board must be able to review the full trust document in order to ascertain the rights of the beneficiaries. As previously discussed by the Board (July and October 2016 Board Meetings (see underlying data, July, and October 2016 meeting minutes. The meeting minutes are also available on the Board's website:

https://www.pharmacy.ca.gov/about/meetings_full.shtml)), it is, unfortunately, not uncommon for an individual who is prohibited from having management and control of a pharmacy to attempt to conceal ownership and continue to profit from and run the pharmacy, while on paper it looks as though someone else owns it. Trusts are a perfect vehicle for such hidden ownership interest because the property could legally be titled in someone else's name but held for the sole benefit of the beneficiary.

Also, where an individual owner of a pharmacy dies, thereby leaving his or her interest in the pharmacy to their beneficiaries under a will, the license is automatically cancelled due to the change in ownership and the new owner, including any beneficiary under that will, must apply for a new license to be issued in their name. This is true even if the pharmacy retains the same name and all other indicia of ownership. If the settlor dies in a trust situation, the trust still owns the pharmacy, and again, depending on the terms of the trust that ownership may automatically pass to the beneficiary. The Board must know the identity of the beneficiaries of a trust are in order to ascertain whether any of them fall into the class of a prohibited person. The Board has a Legislative mandate to ensure prohibited ownership does not happen.

¹ 90 C.J.S. *Trusts* section 266; *Empire Properties v. County of Los Angeles* (1996) 44 Cal.App.4th 781, 787 [52 Cal.Rptr.2d 69, 73]

² Rest.3d, *Trusts* section 2, comment d

³ Witkin, *Summary 11th Trusts* section 74 (2020)

⁴ Scott & Ascher (5th ed.) *Trusts*, §§ 13.1, 13.2; Bogert *Trusts and Trustees* (rev. 2d and 3d) § 183; 76 Am.Jur.2d (2016 ed.), *Trusts* § 259 et seq.; 13 Witkin, *Summary 11th Trusts* § 161 (2020)

Finally, Board staff does not agree that “requiring documentation from beneficiaries or notice each time the Grantor(s)/Settlor(s) change the beneficiary on a Revocable Trust” places an undue burden and expense on the licensee. Board staff notes that notification in writing is required and must include the name, address, phone number, and any email address for each named beneficiary of the trust who is age 18 or older or the guardian of any beneficiary who is under the age of 18. If the beneficiary change results in a change in the management and control of the entity, the cost to the business entity to report the changes and update the licensee ownership, management, and control, 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, this is not an additional expense for the licensee as licensees must already pay this fee if there is a change in the ownership structure of the license. A detailed explanation is contained in the Initial Statement of Reasons (pages 4 - 6).

At its September 23, 2021 meeting, the Board voted to adopt the regulation text as it was noticed on July 23, 2021.