

California State Board of Pharmacy

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item III. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1709 Related to Ownership, Management & Control of Business Entities, including Consideration of Public Comments Received during the 45-day comment period

Background:

At the October 2016 Board meeting, the Board approved proposed regulation text to amend Section 1709 related to Ownership, Management & Control of Business Entities. This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on July 23, 2021, which ended on September 7, 2021. One comment was received during the comment period. Attached following this memo are the following:

- 1. The proposed text released for 45-day public comment.
- 2. Board staff prepared summarized comment with recommendations
- 3. Comment received during the 45-day comment period

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

- 1. Adopt the regulation text as noticed for 45-day comment on July 23, 2021.
- 2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 45-day comment on July 23, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy Proposed Text

Legend: Insertions are **Underlined**; Deletions are **Stricken**

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. Names of Owners and Pharmacist In Charge Ownership, Management, and Control of Pharmacies and Other Regulated Business Entities.

- (a) Each permit license issued by the board to operate a pharmacy shall reflect show the name and address of the pharmacy, the form of ownership, (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners, and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days of the change.
- (b)(1) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit license was issued, shall require written notification to the board within 30 days of the transfer.
- (2) 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.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a <u>change of ownership transfer of permit</u> and <u>shall</u> require <u>a new application for a change of ownership licensure</u>:
 - (1) 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. The new owner shall apply to the board for licensure in advance of the proposed transaction taking place.
- (d) 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:

- (1) 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;
- (2) 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;
- (3) 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;
- (4) Include in the application and annual renewal the name, address, phone number, and any email address for each grantor, settlor, trustee, and/or trust protector, as applicable;
- (5) Include in the application and annual renewal 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(ies) shall be identified; and
- (6) Notify the board in writing within 30 days of all the following:
 - (A) A change in trustee, protector or any other person with management or control of the business entity:
 - (B) 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(ies) shall be identified;
 - (C) The revocation of the trust:
 - (D) The dissolution of the trust;
 - (E) Any amendment to the trust since the original application; and
 - (F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.
- (e) 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, or 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4037, 4058, 4101, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4131, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4205, 4207, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.



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Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

<u>Summarized 45-day Comments Regarding Pharmacy Ownership, Management, and Control,</u> Including Through Trusts with Board Staff Recommendations:

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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes 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. Board staff disagrees 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, Board staff disagrees with the statement that positions of management and control of the business are not relevant to the licensing of pharmacies. Board staff notes 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: Board staff have reviewed this comment and do 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. Board staff further notes 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff do 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. A trustee holds legal title to property for the benefit of the beneficiaries. The trustee is required to manage trust assets and distribute the trust assets

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

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, Board staff notes 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.

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).

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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)



September 7, 2021

Ms. Lori Martinez California Board of Pharmacy 2720 Gateway Oaks Dr, Ste 100 Sacramento, CA 95833

Dear Ms. Martinez,

Thank you for the opportunity to provide comments regarding proposed regulations on Pharmacy Ownership, Management, and Control, Including Through Trusts.

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The California Pharmacists Association (CPhA) is fully supportive of providing relevant information to the Board in relation to ownership interests. CPhA supports requirements that provide the name, address, and contact information of each grantor, settlor, trustee, and trust protector, as applicable to the Board. CPhA also supports providing the name, address, and contact information of each beneficiary aged 18 or older and notification to the Board of specific changes made to the trust that includes change in trustees or anyone with management or control of the trust, changes in beneficiaries, revocation, dissolution and amendments to the original trust. CPhA feels this information is within the scope of the Board's duties as regulators to ensure the protection of the public.

However, CPhA is concerned that some of these proposed regulations require information to be sent to the Board that is not relevant to the duties of the Board. For example, 1709(d)(1) requires, in part, that "...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 is not only unclear, but it's problematic because 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. As such, we respectfully request that the Board to strike this proposed regulation.

Additionally, while we appreciate that the regulation language in 1709(d)(2) would "be considered confidential financial documents by the board," CPhA feels that asking for the entire Trust document, along with any amendments to that Trust, would enhance the Board's mission of patient protection. Outside of the relevant information for grantors, settlors, trustees, trust protectors, or beneficiaries, CPhA does not believe the "any other information in the Trust" is relevant to the licensing responsibilities of the Board. As such, we are respectfully requesting the board to modify the regulations so that disclosure of information in the Trust is limited to the necessary information needed for disclosure of ownership matters, along with any amendments to ownership or management, while keeping irrelevant information confidential.

Finally, these proposed regulations do not recognize the distinction between an irrevocable trust and a revocable trust. There is a distinction with a significant difference. In a revocable trust, the beneficiary <u>has no interest (beneficial, legal or otherwise) in the trust assets until the death of the Grantor(s)/Settlor(s)</u>. The named beneficiary or beneficiaries can be changed at any time. The Grantor(s)/Settlor(s) maintain control and management of the trust assets and can direct the trustee, who is generally responsible for managing the trust

property as the Grantor(s)/Settlor(s) direct for the Grantor(s)/Settlor(s) benefit. This is important because the trustee does <u>not</u> act for the beneficiaries' benefit because they have no interest in the trust assets until the death of all Grantor(s)/Settlor(s). CPhA believes that requiring documentation from beneficiaries or notice each time the Grantor(s)/Settlor(s) change the beneficiary on a Revocable Trust places undue burden and expense on such Grantor(s)/Settlor(s). For irrevocable trusts, this doesn't apply because in irrevocable trusts, beneficiaries cannot be changed by the Grantor(s)/Settlor(s) and the beneficiaries typically receive periodic financial payments derived from the trust assets and paid to them by the Trustee of the trust. As such, CPhA would like to request that the regulation should be modified to apply to irrevocable trusts.

Should you have any questions about these suggested changes, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com.

Thank you for your consideration of our comments.

Sincerely,

Danny Martinez

Director of Regulatory Affairs and Policy Development

California Pharmacists Association.