

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: ADDRESS CHANGE NOTIFICATION

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) proposes taking 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 18, 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 that 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 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 (BPC) authorizes the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4003, 4013, and 4100 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The board's mandate and its mission is to protect the public (BPC § 4001.1).

Existing pharmacy law requires a licensed facility to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and to update its email address with the board's notification list within 30 days of a change in the facility's email address (BPC § 4013). Additionally, existing pharmacy law requires that each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in California to join the board's email

notification list within 60 days of obtaining a license or at the time of license renewal and to update their mail address with the board's notification list within 30 days of a change in the licensee's email address. This notification list is an automated listserv. The primary purpose of the listserv is to send licensees, and other interested parties who provide an email address, automated mass email alerts regarding general board information such as meetings, notices, important information, and product recalls. As it is a listserv generating automated emails, the board does not have direct access to obtain specific licensee email addresses for the purpose of direct communication to the licensee via email.

This proposal will require that each applicant and person holding a certificate, license, permit, registration or exemption to practice, who has an electronic mail (email) address, provide the board with the email address and maintain a current email address, if any. Additionally, the proposal will require the individual to notify the board of any change in their email address within 30 days of the change. This requirement is consistent with the 30-day address change notification in subdivision (a) as well as BPC 4013. The board determined that communication through email is an efficient way to communicate with applicants and licensees regarding both application status and license status.

Anticipated Benefits of the Proposed Regulations

The proposed regulatory action will continue to provide consumer protection per the board's mandates, which affects the protection of public health and safety. This means the pharmacy's license to practice is not affected, or discontinued because of the lack of communication, or mail getting lost. Ultimately, this benefits the health and welfare of California residents.

By requiring applicants and licensees to provide and maintain their electronic mail address with the board, the board can email application deficiency notices, renewal notices, and renewal deficiency notices to applicants and licensees. This will eliminate postal delays and reduce the possibility of notices being lost in the mail or misdelivered. If an applicant or licensee does not have an electronic mail address, the applicant and licensee would not have to provide one to the board.

Consistency and Compatibility with Existing State Regulations

While developing these regulations and amendments, the board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. As noted above, these amendments make state law more consistent with federal law.

Fiscal Impact and Related Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The Board estimates 120 email

address changes will be processed by an Office Technician per year at cost of \$1.80 per update (five minutes of workload) with total costs of \$220 per year.

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 determined that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months in numerous board and committee meetings. The board determined that electronic mail addresses are often free to obtain from numerous online companies and providing the electronic mail address to the board is as simple as writing it on an application when applying for a license or submitting a renewal application. Additionally, most applicants and licensees already provide an email address to the board as it is an effective method of communication.

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action.

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 and clinics) are a “small business,” as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action will not have a significant adverse economic impact directly affecting small businesses. The board determined that electronic mail addresses are often “free” to obtain from numerous online companies and providing the electronic mail address to the board is as simple as writing it on an application when applying for a license or submitting a renewal application. Additionally, most applicants and licensees already provide an email address to the board as it is an effective method of communication.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

For the reasons listed above, the Board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

Benefits of Regulation:

The regulatory proposal would ensure continued consumer protection per the board's mandate. This means the pharmacy's license to practice is not affected, or discontinued because of the lack of communication, or mail getting lost. Ultimately, this benefits the health and welfare of California residents.

The Board determined that this proposed regulatory action will not impact worker's safety, or the state's environment.

Consideration of Alternatives

The Board must determine that no reasonable alternative that 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 at the address listed for the Contact Person during the written comment period.

Initial Statement of Reasons and Information

The Board has prepared an Initial Statement of Reasons for the proposed action and has 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 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at <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
Fax No.: (916) 574-8618
E-Mail Address: Debbie.Damoth@dca.ca.gov

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.