

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take 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 on June 10, 2019.

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 his or her 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: Sections 4005 and 4400 of the Business and Professions Code (B&P) authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, 4180.5, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401, and 4403 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy (board) proposes to amend Section 1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations (CCR) to increase application, renewal, and other fees to the statutory maximum to address a structural imbalance within the board's budget and to pursue a reserve in the board's fund equal to approximately one year's expenditure, consistent with the Legislature's intent.

Business and Professions Code (B&P) section 4400 establishes the statutory minimum and maximum application, renewal and other fees for board applicants and licensees.

Existing law at 16 CCR section 1749 establishes the current fee for various applications for initial license and renewal, and other fees for board licensees and applicants, based upon the statutory minimum and maximum established by B&P section 4400, and other sections of the B&P code.

Additionally, existing law at B&P section 4400(p) requires that the board seek to maintain a reserve in its fund equal to approximately one year's expenditures. This action provides specific information on the board's current fund condition as well as projections for future years.

The Department of Consumer Affairs (DCA) provides budgetary and fiscal administrative support to the board. According to the DCA, the board's expenditures have increased, on average, 11% each year. While revenue has increased significantly since FY 2016-17, it is not increasing at the same rate as board's expenditures. As a result, the board's reserve fund is quickly depleting and the board is unable to maintain a reserve fund equal to one year. It is estimated that by the end of FY 2019-20, the board's reserve fund will be negative. This structural imbalance is unsustainable without a fee increase. This proposal will increase the board's application, renewal, and other fees to address this issue and ensure that the board will be able to continue to meet its consumer protection mandate by allowing the board to continue its licensing and enforcement responsibilities.

Anticipated Benefits of the Proposed Regulations

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. This proposal will ensure that the board has sufficient resources to maintain current operations to meet its consumer protection mandate and to slowly restore the Pharmacy Board Contingent Fund to meet the statutory mandate of seeking a reserve of one year's operating expenses. This allows the board to continue licensing, regulations and enforcement activities, which will ensure the health, safety, and welfare of California residents.

Consistency and Compatibility with Existing State Regulations

During the process of 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.

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:

It is estimated that the proposed fee increase will result in an increase in ongoing annual revenue by approximately \$8.1 million beginning in FY 2020/21.

The board does not anticipate any impact on federal funding.

This proposal does not impact any government owned business as by current law, government owned pharmacies, hospitals and clinics are exempt from paying licensure and renewal fees to the board.

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:

Although the proposed action will directly affect businesses statewide, including small businesses, the board has made an initial determination that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant. This determination is based on the fact that the pharmaceutical industry is a multi-billion-dollar industry with annual revenue for the impacted licensing categories ranging from 3.6 million to 88 billion dollars.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy has made an initial determination that proposed regulatory action would change fees for individuals and businesses as detailed below:

Resident Pharmacy/Hospital or Remote Site Dispensing Pharmacy

Application: \$520 (current) to \$570

Renewal: \$665 (current)/annually to \$930 annually

Nonresident Pharmacy

Application: \$520 (current) to \$570

Renewal: \$665 (current)/annually to \$930 annually

Pharmacy Technician

Application: \$140 (current) to \$195

Renewal: \$140 (current)/biennial to \$195 biennial

Delinquent Fee: \$70 (current) to \$97.50

Pharmacist

Exam Application: \$260 (current) to \$285

Initial License Fee: \$195 (current) to \$215

Renewal: \$360 (current)/biennial to \$505 biennial

Resident Wholesaler or Resident Third-Party Logistics Provider

Application: \$780 (current) to \$820

Renewal: \$780 (current)/annually to \$820 annually

Temporary: \$715 (No Change)

Hypodermic Needle and Syringe

Application: \$170 (current) to \$240

Renewal: \$200 (current)/annually to \$280 annually

Delinquent Fee: \$100 (current) to \$140

Designated Representative/Designated Representative-3PL/Designated Representative-Reverse Distributor/Designated Representative-VET

Application: \$150 (current) to \$210

Renewal: \$215 (current)/annually to \$300 annually

Delinquent Fee: \$107.50 (current) to \$150

Nonresident Wholesaler or Nonresident Third-Party Logistics Provider

Application: \$780 (current) to \$820

Renewal: \$780 (current)/annually to \$820 annually

Pharmacy Intern

Application: \$165 (current) to \$230

Reissuance of a License due to a change in information (other than name change)

\$100 (current) to \$130

Clinic

Application: \$520 (current) to \$570

Renewal: \$325 (current)/annually to \$360 annually

Resident Compound Sterile Injectable Drug Products or Hospital Satellite Compounding Pharmacy

Application: \$1,645 (current) to \$2,305

Renewal: \$1,325 (current)/annually to \$1,855 annually

Temporary License: \$550 (current) to \$715

Nonresident Sterile Compounding Pharmacy

Application: \$2,380 (current) to \$3,335

Renewal: \$2,270 (current)/annually to \$3,180 annually

Temporary License: \$550 (current) to \$715

Veterinary Food-Animal Drug Retailer

Application: \$435 (current) to \$610

Renewal: \$330 (current)/annually to \$460 annually

Centralized Hospital Packaging Pharmacy

Application: \$820 (current) to \$1,150

Renewal: \$805 (current)/annually to \$1,125

Resident Outsourcing Facility

Application: \$2,270 (current) to \$3,180

Renewal: \$1,325 (current)/annually to \$1,855

Nonresident Outsourcing Facility

Application: \$2,380 (current) to \$3,335

Renewal: \$2,270 (current)/annually to \$3,180 annually

Temporary: \$715 (No Change)

Correctional Clinic

Application: \$520 (current) to \$570

Renewal: \$325 (current)/annually to \$360 annually

Delinquent Fee: \$150 (No Change)

EMSADDS

Application: \$100 (No Change)

Renewal: \$100 annually (No Change)

Delinquent Fee: \$35 (No Change)

Co-location Clinic

Application: \$750 (No Change)

Designated Paramedic

Application: \$140 (No Change)

Renewal: \$140 biennial (No Change)

Delinquent Fee: \$65 (No Change)

Effect on Housing Costs: None

Effect on Small Business:

While the board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code section 11342.610, the board has made an initial determination that any adverse economic impact will not be significant. This determination is based on the annual revenue for the impacted licensing categories ranging from 3.6 million to 88 billion dollars, depending on the license type.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that it is:

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

Benefits of Regulation:

The board has determined that this regulatory proposal benefits the health and welfare of California residents, worker safety, and the state’s environment. Protection of the public is the board’s highest priority in exercising its licensing, regulatory and disciplinary functions. This proposal will ensure that the board has sufficient resources to maintain current board operations to meets its consumer protection mandate and to slowly restore the Pharmacy Board Contingent Fund to meet the statutory mandate of a reserve of one year’s operating expenses.

Consideration of Alternatives

The board must determine that no reasonable alternative 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 of Pharmacy has prepared an initial statement of the 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 1625 N. Market Blvd., N219, Sacramento, California 95834, 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: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Phone No.: (916) 574-7935
Fax No.: (916) 574-8617
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Debbie Damoth
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Phone No.: (916) 574-7917
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Website Access

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