

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Fee Schedule.

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1749.

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:

The 45-day public comment period began on April 26, 2019, and ended on June 10, 2019. 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 several comments were received. On June 21, 2019, after having considered the comments in the record, the Board adopted the regulation text as noticed on April 26, 2019.

To the extent that the regulation duplicates the information from statute, such duplication is to ensure that the regulated public can readily and easily find the Board's fees in one place, rather than having to review multiple sources.

Additionally, the board notes that subdivision (r) has been amended to increase the fee for a temporary nonresident sterile compounding pharmacy license is seven hundred fifteen dollars (\$715) for clarity. The board's authority to issue a temporary license to a nonresident sterile compounding pharmacy is specified by B&P section 4127.7 and the fee is set at the maximum of \$715 as specified within B&P section 4400(u).

Local Mandate

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

Small Business Impact

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 determined 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. This proposal will ensure that the board has sufficient resources to maintain current board operations to meet 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

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. The board considered not updating its fee schedule. This alternative was rejected as the board would be insolvent and unable to maintain operations, which would jeopardize the health, safety, and welfare of California residents. Additionally, the board is also required by statute to seek to maintain a year's reserve in its fund. Taking no action would counter the spirit of B&P section 4400(p), which requires that the board maintain a reserve fund equal to approximately one year's expenditures.
2. The board considered updating its fee schedule to the mid-point between the statutory minimum and maximum as specified within B&P sections 4400, 4119.01, 4180.5, and 4202.5. This alternative was rejected as it would not restore the board's reserve fund. While raising the fees to the mid-point would increase the board's revenue to cover existing expenditures, it would not account for growth and it would not restore the board's reserve fund in a timely manner.
3. The board considered updating its fee schedule by 5% or 10% as recommended by public comment; however, increasing all license types by the identified 5% or 10% would not eliminate the structural imbalance and would not begin restoring the board's mandatory 1-year reserve fund.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from April 26, 2019 to June 10, 2019, the board received several comments. The comments were provided in the meeting materials for the June 21, 2019 board meeting, and were reviewed and considered by the board.

Written Comments from Audrey Paules, Pharmacist

Comment: Ms. Paules expressed concern that fees have been increased by 40% for some licensees, while others (wholesalers, non-resident wholesalers, and 3PLs) are only increasing 5%. Ms. Paules questioned how the 5% increase was justified. Additionally, Ms. Paules expressed concern that chain stores are decreasing pharmacist wages.

Response to Comment: The board rejected this comment. The board notes that the statutory minimum and maximum are set in statute (Business and Professions Code (B&P) section 4400). The fee schedule established in statute was based upon a fee analysis conducted by the Department of Consumer Affairs and vetted as part of the board's Sunset Review Process. The fee analysis assessed fees separately, including the cost to deliver the various services. This review resulted in variations in percentages of growth in fees as historically the board's fee structure provided subsidies between the license types.

As indicated in the Initial Statement of Reasons, the board must eliminate the structural imbalance in its budget to ensure the financial viability of the board. The proposed regulation increases the board's fees to the statutory maximum, which will resolve the imbalance and slowly restore the board's depleted fund reserve. Increasing all license types by the same percent increase (5%) would not eliminate the structural imbalance and would not begin restoring the board's mandatory 1-year reserve fund. Additionally, the board notes that the board does not have regulatory jurisdiction over employee wages within California.

Written Comments from Gerald Tung

Comment: Mr. Tung indicated that he is opposed to the fee increase because licensee salaries have not increased with inflation and prescription reimbursements are decreasing. Additionally, Mr. Tung indicates that the board's fees have increased in the last five years and it is unreasonable to increase the fees again. Finally, Mr. Tung indicated that an increase in the licensee population should provide an increase in revenue for the operation of the board.

Response to Comment: The board rejected this comment. While the board's fees did increase effective July 2017, not all the fees were increased at that time. Of the board's 118 fees, seven application fees and 14 renewal fees were increased, while three application fees were reduced. While revenue has increased significantly since FY 2016-17, it is not increasing at the same rate as the board's expenditures, which has created a structural imbalance and the board's reserve fund is quickly depleting. Increasing the fees to the statutory maximum will eliminate the structural imbalance and begin restoring the board's reserve fund.

Written Comments from Jared Sewall, Pharmacist

Comment: Mr. Sewall expressed concern about the fee increase, specifically, the renewal fee for pharmacists. Mr. Sewall indicates that the board review its budget and spending if a budget deficit is taking place. Additionally, Mr. Sewall states that it is “unreasonable and absolutely absurd to raise fees on entities and persons to fund an organization that provides no benefit to these parties.” Mr. Sewall states that the State and taxpayers need to provide the additional resources that the board needs.

Response to Comment: The board rejected this comment. Board staff notes that the board does not take fee increases lightly and reviews its budget and expenditures frequently. Additionally, the board does not agree that licensees receive no benefit from the board as the board provides numerous free outreach programs for licensees and several free continuing education opportunities. Finally, the board is a self-funded agency, which means that the board’s revenue is obtained from its application and renewal fees. The board does not obtain revenue from the State’s general fund (i.e. tax revenue).

Written Comments from Linda Goetz, Pharmacy Technician

Comment: Ms. Goetz opposed the fee increase for pharmacy technicians. She indicated that due to tax law changes, technicians can no longer write off their renewal fees and the 39% fee increase would cause a financial strain.

Response to Comment: The board rejected this comment. The board notes that the fees for pharmacy technicians are increasing from a biennial fee of \$140 to a biennial fee of \$195. The increase, split over two years, amounts to a yearly increase of \$27.50, which board staff believes to be a manageable increase.

Written Comments from Omeed Askari

Comment: Mr. Askair indicated that the board recently raised all its renewal fees and added a new license requirement (automated delivery systems), which has resulted in an added cost and business resources to remain compliant. Mr. Askair indicated that he does not believe that the board thoroughly considers the repercussions of its actions. He indicated that the board should address the fraudulent practice of insurance-owned pharmacies and that the government’s job is to level the playing field. He indicated that the fee increase will “disenfranchise” independent pharmacies in favor of corporate health care companies.

Response to Comment: The board rejected this comment. While the board’s fees did increase effective July 2017, not all the fees were increased at that time. Of the board’s 118 fees, seven application fees and 14 renewal fees were increased, while three

application fees were reduced. Additionally, the board notes that the new license requirement for automated delivery systems was established by legislation and not as a result of board regulations. Finally, the board notes that Mr. Askair's comments, with respect to the business practices of health insurers within California, go beyond the scope of this regulation. The board also notes that as part of any rulemaking package, the fiscal and economic impacts are required to be identified and published under the provisions of the Administrative Procedures Act.

Written Comments from Pravin Patel, Pharmacist

Comment: Mr. Patel indicated he does not see justification for the fee increase for pharmacists and requested that retired senior pharmacists be exempt from the fee increase.

Response to Comment: The board rejected this comment. The board notes that the fee increase is necessary to ensure that the board has sufficient resources to maintain current operations to meet its consumer protection mandate and begin to restore its reserve fund in a timely manner. Additionally, the board notes that a pharmacist, who is retired and does not plan on returning to work, can "retire" their license and would no longer be required to pay the license renewal fee (B&P 4200.5). The onetime fee for a retired license is \$45.00.

Written Comments from Kiritkumar Patel, Pharmacist

Comment: Mr. Patel indicated he opposes the fee increase due to cost of living and inflation for pharmacists and requested the retired senior pharmacists be exempt from the fee increase.

Response to Comment: The board rejected this comment. The board notes that the fee increase is necessary to ensure that the board has sufficient resources to maintain current operations to meet its consumer protection mandate and to slowly restore its reserve fund. Additionally, the board notes that a pharmacist, who is retired and does not plan on returning to work, can "retire" their license and would no longer be required to pay the license renewal fee (B&P 4200.5). The onetime fee for a retired license is \$45.00.

Written Comments from Rosalie Weber, Pharm.D.

Comment: Dr. Weber expressed concern about the fee increase for sterile compounding pharmacies. She requested that the board consider the possible financial strain to independent pharmacies.

Response to Comment: The board rejected this comment. The proposed regulation increases all the board's fees to the statutory maximum. Additionally, the fee increase is

necessary to ensure that the board has sufficient resources to maintain current operations to meet its consumer protection mandate and to slowly restore its reserve fund. The fees for all sterile compounding licensees within California are the same and not based on ownership structure. The board's current fee structure is working to eliminate fee subsidies between licensing programs and be more directly tied to the costs to deliver the associated services.

Written Comments from Shannon Quijano, Pharm.D.

Comment: Dr. Quijano indicated that she has loans to pay and has to commute to her job so she cannot afford another fee. She indicated that the board should get money from the increase in the licensee population and not by raising fees. Additionally, she indicated that if a fee increase is needed, the board should only raise the fees by 10%.

Response to Comment: The board rejected this comment. While revenue has increased significantly since FY 2016-17, it is not increasing at the same rate as the board's expenditures, which has created a structural imbalance and the board's reserve fund is quickly depleting. Increasing the fees to the statutory maximum will eliminate the structural imbalance and begin restoring the board's reserve fund, which per B&P section 4400(p), the board is required to maintain a reserve fund equal to approximately one year's expenditures. Raising fees by 10% as proposed by this commenter would not sufficiently address the board's structural imbalance and would result in the board's fund going insolvent. Additionally, the board notes that as the licensee population has increased, the board's workload has also increased, which results in the need for additional resources.

Written Comments from Teresa Nguyen, Pharmacist

Comment: Ms. Nguyen indicated that she is opposed to the fee increase because of the cost of malpractice insurance, CE courses, and other daily expenses. She requested that the proposal be reconsidered.

Response to Comment: The board rejected this comment. The costs of malpractice insurance and other daily expenses are outside of the board's control. Rather, the board's mandate is consumer protection. The board notes that as part of its mandate, the board provides several free continuing education opportunities and numerous free outreach programs for licensees. Additionally, this proposal is necessary to ensure the solvency of the board to maintain operations. Without a fee increase, the board will become insolvent and be unable to protect the residents of California.

Written Comments from Vadim Poznyak, Pharm.D.

Comment: Dr. Poznyak requested that the board consider other options to help mitigate the cost of the license renewals due to the increasing cost of living in California. While he understands the need for the fee increase, he recommended that the board look at utilizing technology to reduce costs, i.e. digital meetings or allow for volunteer work.

Response to Comment: The board rejected this comment. This proposal is necessary to ensure the solvency of the board to maintain operations. Currently, the board does webcast its board meetings; however, the board does not have the technology to hold digital meetings and still comply with the Bagley-Keene Open Meeting Act. The board is in the initial phases of the business modernization process. As part of this process, the board assess for opportunities to streamline processes and leverage technology. In addition, outside assessments are done as well. This process is expected to ultimately result in improved business functionality and better customer engagement. Regrettably, this process takes several years. However, once completed and implemented, should significant cost savings be realized, the board can reassess its fee structure and determine if fees should be reduced either via the regulation process or statutorily.

Written Comments from Kamal Parekh, Pharmacist

Comment: Mr. Parekh opposes the 40% increase in all the fees. Mr. Parekh indicated that he is opposed to the fee increase because licensee salaries and prescription reimbursements are decreasing. Mr. Parekh requests that the board only raise the fees by 10%.

Response to Comment: The board rejected this comment. This proposal is necessary to ensure the solvency of the board to maintain operations. Without a fee increase, the board will become insolvent and be unable to protect the residents of California. Increasing the fees to the statutory maximum will eliminate the structural imbalance and begin restoring the board's reserve fund, which per B&P section 4400(p), the board is required to maintain a reserve fund equal to approximately one year's expenditures. Raising fees by 10% as proposed by this commenter would not sufficiently address the board's structural imbalance and would result in the board's fund going insolvent.

Written Comments from Allyson Vander Broek, Pharmacist

Comment: Ms. Vander Broek opposes the increase in the renewal fee for pharmacists. Ms. Vander Broek indicated that the renewal fee for pharmacists was increased in 2017 and opposed the percent increase compared to other licensees. Ms. Vander Broek requested a full public disclosure of where the board's money is being spent.

Response to Comment: The board rejected this comment. While the board's fees did increase effective July 2017, not all the fees were increased at that time. Of the board's 118 fees, seven application fees and 14 renewal fees were increased, while three

application fees were reduced. The board notes that as part of the rulemaking package, the board provided three different board fund condition analyses. The board also notes that the board does not take fee increases lightly and reviews its budget and expenditures at each quarterly public board meeting. This proposal is necessary to ensure the solvency of the board to maintain operations. Without a fee increase, the board will become insolvent and be unable to protect the residents of California. Additionally, B&P section 4400(p) requires that the board maintain a reserve fund equal to approximately one year's expenditures. This fee increase will begin restoring the board's reserve fund in a timely manner.

Written Comments from Kirit Merchant, Pharmacist

Comment: Mr. Merchant indicated he opposes the fee increase due to cost of living and inflation for pharmacists. Mr. Merchant indicated that retired senior pharmacists have limited income and the fee increase will make it difficult to supplement his income. He has requested that the board consider other alternatives.

Response to Comment: The board rejected this comment. The board notes that the board considered not raising fees and also considered updating its fee schedule to the mid-point between the statutory minimum and maximum as specified within B&P sections 4400, 4119.01, 4180.5, and 4202.5. However, these alternatives were rejected as the board would be insolvent and unable to maintain operations and would not restore the board's reserve fund in a timely manner, which would jeopardize the health, safety, and welfare of California residents. This fee increase is necessary to ensure that the board has sufficient resources to maintain current operations to meet its consumer protection mandate and to slowly restore its reserve fund.

Written Comments from Dilipkumar Amin, Pharmacist

Comment: Mr. Amin indicated he does not see justification for the fee increase for pharmacists and requested the retired senior pharmacists be exempt from the fee increase.

Response to Comment: The board rejected this comment. As referenced in the ISR, this proposal is necessary to ensure the solvency of the board to maintain operations. Without a fee increase, the board will become insolvent and be unable to protect the residents of California. Increasing the fees to the statutory maximum will eliminate the structural imbalance and begin restoring the board's reserve fund, which per B&P section 4400(p), the board is required to maintain a reserve fund equal to approximately one year's expenditures. Additionally, the board notes that a pharmacist, who is retired and does not plan on returning to work, can "retire" their license and would no longer be required to pay the license renewal fee (B&P 4200.5). The onetime fee for a retired license is \$45.00.

Written Comments from Elizabeth Johnson, Pharmacist

Comment: Ms. Johnson indicated that she opposes the fee increase for pharmacists to the statutory maximum as the renewal fee was just raised two years ago. Ms. Johnson has requested a more transparent accounting of the board's expenditures.

Response to Comment: The board rejected this comment. While the board's fees did increase effective July 2017, not all the fees were increased at that time. Of the board's 118 fees, seven application fees and 14 renewal fees were increased, while three application fees were reduced. The board notes that as part of the rulemaking package, the board provided three different board fund condition analyses. The board also notes that the board does not take fee increases lightly and reviews its budget and expenditures at each quarterly public board meeting. This proposal is necessary to ensure the solvency of the board to maintain operations. Without a fee increase, the board will become insolvent and be unable to protect the residents of California.

At its June 21, 2019 meeting, the board considered the comments received and voted to adopt the regulation text as it was noticed on April 26, 2019.