

**Board of Pharmacy  
Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Fee Schedule

Section Affected: Amend Section 1749 of Article 6 of Division 17 of Title 16, California Code Regulations

**Problems Addressed**

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Professions Code (B&P) section 4000, *et seq.*). The board's mandate and its mission is to protect the public (B&P section 4001.1).

In November 2015, the Department of Consumer Affairs (DCA) completed an analysis of the board's fund condition and fee structure. This analysis, initiated at the request of the board and done in partnership with the board, was to determine the sustainability of the board's fund and to ensure that the board was collecting sufficient revenue to fully reimburse the board for the cost of regulating those individuals and businesses within its jurisdiction. As indicated in the report, the goal of the analysis was to identify the board's actual budgetary need to process each initial and renewal application the board is required to process.

The analysis found that the current level of fees was not sufficient to keep the board's fund solvent and that fees needed to be adjusted to reflect the actual cost to the board to provide service and process each license type. The analysis recommended that new fee ceilings be set at a rate that would allow the board the flexibility to adjust fees through the regulatory process and maintain the fund's solvency through the next ten years.

B&P section 4400 establishes the statutory minimum and maximum fee schedule for applications for most of the initial license types, applications for renewal and other fees for board applicants and licensees. After review and consideration of the findings of the fee analysis, the board pursued a statutory change in 2016 as part of its sunset review process to recast its fees. This recasting resulted in new statutory minimum and maximum fees within B&P 4400. The fees went into effect on July 1, 2017.

While the board's new fee structure took effect on July 1, 2017, not all fees were increased at that time. Of the board's 118 fees, seven application fees and 14 renewal fees were increased. Three application fees were reduced. Furthermore, since the new fee structure took effect, new statutory fee categories were created.

Since the completion of the fee analysis there have been major budget adjustments impacting the board. According to the DCA, the board's expenditures have increased, on average, 11% each year. The increases in expenditures are primarily due to programmatic and legislative changes, new staff positions to implement legislation, the

associated increases in departmental and State distributed costs (pro rata), and legislatively approved bargaining unit salary and benefit increases.

The Legislature has set specific guidance for the board for setting fees: B&P section 4400(p) requires that the board seek to maintain a reserve in its fund equal to approximately one year's expenditures. A review of the board's fund condition report demonstrates that the overall revenue for the board has increased to approximately \$24,000,000; however, the board's expenditures have increased to approximately \$27,000,000 since Fiscal Year (FY) 2016-17. This creates a structural imbalance that is unsustainable without a fee increase. While revenue has increased significantly since FY 2016-17, it is not increasing at the same rate as the 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.

Increasing the fees to the statutory maximum will eliminate the structural imbalance and begin restoring the board's reserve fund. The board considered raising the fees to the mid-way point between the statutory minimum and maximum; however, the mid-way point would only allow for a reserve of 3.4 months, far short of the statutory one-year requirement. The board determined that the statutory maximum was warranted as it would increase the board's revenue by an additional 8 million dollars a year, which would restore the board's reserve fund and allow the board to meet the objective established by B&P section 4400(p) in a timelier manner.

Existing law at 16 CCR section 1749 establishes the current fees for applications for initial license and renewal, and other fees for various board licensees and applicants based upon the statutory minimum and maximum established primarily by B&P section 4400. Currently, most of the board's fees are set to the statutory minimum. The board is proposing to increase application, renewal, penalties, and other fees, not currently at their maximum, to their statutory maximum, to address the structural imbalance and ensure that the board is able to continue fulfilling its consumer protection mandate. Raising fees to the statutory maximum will ensure that those fees cover the expenses associated with protecting the public through licensing, regulating, compliance, and disciplining the licensees of the pharmacy industry.

## **Benefits**

This regulatory proposal benefits the health and welfare of California residents. 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 meet its consumer protection mandate by implementing new legislation, continuing to review applicant qualifications and ensure only qualified individuals are licensed, investigating complaints, and inspecting licensed facilities to ensure the licensees are operating within pharmacy law. Additionally, the proposal will slowly restore the Pharmacy Board Contingent Fund to meet the statutory mandate of a reserve of one year's operating expenses. This proposal will also ensure that future board operations are not jeopardized by ensuring that the reserve fund is not entirely depleted by current board functions. As the pharmacy industry continues to grow and evolve, the board must put

itself in a financial position to continue to evolve as well and put consumer protection first. This change allows the board to continue operations and plan for future board functions which will ensure the health, safety, and welfare of California residents.

### **Specific Purpose of Proposed Changes and Rationale**

The board's proposal is to make the following changes:

#### **Amend Section 1749 of Article 6 of Division 17 of Title 16 of the CCR**

For consistency within the regulation text, the term "shall be" was changed in certain sections of the regulation text to "is" so that all sections would be consistent throughout the regulation. Additionally, the license types were also added to each subsection in regard to the fee for failure to renew so that each subsection is specific, and it is easily determined which penalty applies to which license types. Where the statute identified the fee as a fee for application, the regulation was changed to "application fee" to be consistent with statute and to specify that the fee was for processing the application. Other non-substantive changes in word placement or grammar were made as necessary to be consistent throughout the document.

The board issues several different types of temporary licenses, including pharmacy, wholesaler, and sterile compounding. Where applicable within each subdivision, the license category has been added to provide additional clarity to the regulated public that the fee within that subdivision is specific to that licensing category.

The board is proposing to amend the beginning paragraph of this section for simplicity and clarity. The section is amended to read "The application, renewal, penalties, and other fees, unless otherwise specified, are hereby fixed as follows:", removing references to certificates and permits, since the board refers to them as licenses. This sentence is also amended to succinctly define the fees identified within the regulation and to make a more general characterization of the categories of fees so that this section will not need to be amended if other fees are established. Additionally, "unless otherwise specified" was added to ensure that the regulated public is aware that other fees may exist, particularly when new fees are established in statute that have not been incorporated through the regulatory process.

As defined below, the board is increasing the fees for the application for initial license, application for renewal, and other fees to the statutory maximum. This increase will eliminate the structural imbalance and begin restoring the board's reserve fund, as stated in B&P 4400(p). The board determined that the statutory maximum was warranted as it would increase the board's revenue by an additional 8 million dollars a year, which would cover existing expenditures, account for growth, and restore the board's reserve fund in a timelier manner.

License type	Proposed Application Fee (Statutory Maximum)	Existing Application Fee	Proposed Renewal Fee (Statutory Maximum)	Existing Renewal Fee	Temporary License Fee (if applicable)
Pharmacy	\$570	\$520	\$930	\$665	No Change
Pharmacy Technician	\$195	\$140	\$195	\$140	N/A
Pharmacist Examination	\$285	\$260	N/A	N/A	N/A
Pharmacist License	\$215	\$195	\$505	\$360	N/A
Wholesaler	\$820	\$780	\$820	\$780	No Change
Third-Party Logistics Provider	\$820	\$780	\$820	\$780	No Change
Hypodermic Needle	\$240	\$170	\$280	\$200	N/A
Designated Representatives- (B&P 4053, 4053.1, or 4053.2)	\$210	\$150	\$300	\$215	N/A
Nonresident Wholesaler	\$820	\$780	\$820	\$780	No Change
Nonresident Third-Party Logistics Provider	\$820	\$780	\$820	\$780	No Change
Intern Pharmacist	\$230	\$165	N/A	N/A	N/A
Clinic	\$570	\$520	\$360	\$325	N/A
Sterile Compounding	\$2,305	\$1,645	\$1,855	\$1,325	To \$715 From \$550
Nonresident Sterile Compounding	\$3,335	\$2,380	\$3,180	\$2,270	To \$715 From \$550
Veterinary Food-Animal Drug Retailer	\$610	\$435	\$460	\$330	No Change
Centralized Hospital Packaging Pharmacy	\$1,150	\$820	\$1,125	\$805	N/A
Outsourcing Facility	\$3,180	\$2,270	\$1,855	\$1,325	No Change
Nonresident Outsourcing Facility	\$3,335	\$2,380	\$3,180	\$2,270	No Change

In addition to the fee amendments identified in the table, the following changes have been made:

Subdivision (a) is amended to add “including a remote dispensing site pharmacy” to two locations within this subdivision. The remote dispensing site pharmacy (RDSP) is a new pharmacy license type, specified by B&P section 4130. An RDSP is regulated in a manner consistent with pharmacies, and as such, their treatment like other pharmacies and inclusion in this subdivision is appropriate. As pharmacy law has evolved, various types of pharmacies have emerged within the law. The fees for each pharmacy, however, are the same for any of the pharmacy licenses. Therefore, to make this clear to the regulated public, within the second sentence, and in subdivision (b), the term “any” is added before pharmacy. This change is made for consistency with the first sentence of subsection (a) that states “any pharmacy.”

Subsection (b) adds the term “pharmacy” to be consistent with subdivision (a), and adds clarity as to what type of temporary license is being referred to. B&P section 4400(a) authorizes a temporary pharmacy license fee, and this amendment simply conforms to the statute.

Subdivision (c) is amended to increase the delinquency fee for a pharmacy technician to \$97.50, which is 50% of the renewal fee, not to exceed \$150, as set by B&P section 163.5.

Subdivision (h) is amended and reworded for consistency throughout the regulation text. The issuance and renewal fees have been separated to be consistent with the way the other subsections are structured. “The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars (\$715)” has been added. This fee is set in B&P section 4400(f) and has been added for consistency and 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.

Subdivision (i) is amended to increase the delinquency fee for a hypodermic license to \$140, which is 50% of the proposed \$280 renewal fee as formulated by B&P section 163.5.

Subdivision (j) is amended to add “of the Business and Professions Code” for consistency and clarity. This subdivision also adds, “or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code” and “designated representative-reverse distributor” to two locations within this subdivision. By statute, this new license type has the same fee structure as the other designated representative classifications. Accordingly, the fee for this license type is added to this subdivision and established at the statutory maximum for reasons already discussed. Finally, the delinquency fee has been increased to \$150 in accordance with B&P section 163.5. The proposed renewal fee is \$300. Therefore, \$150, which is 50% of the renewal fee, and does not exceed \$150, should be the new amount.

Subdivision (k) is reworded for consistency throughout the regulation text. Application and renewal fees are separated to be consistent with the way other subdivisions are structured.

Subdivision (m) removes the words “permit” and “or certificate” since those are not used by the board to reference any license types. The fee in this subdivision has been increased to the statutory maximum of \$130, from \$100 to be consistent with the board’s intention of raising fees to the statutory maximum in furtherance of eliminating the structural imbalance and begin restoring the board’s reserve fund, as discussed.

Subdivision (q) is amended to add “or a hospital satellite compounding pharmacy” to four locations within this subdivision. The hospital satellite compounding pharmacy is a new license type specified by B&P section 4127.15. A hospital satellite compounding pharmacy is regulated in a manner consistent with sterile compounding facilities and has the same fees assessed pursuant to B&P section 4400(u). As such, their inclusion in this subdivision is appropriate and established at the maximum amount for reasons

already discussed. Additionally, the term “products” was amended to “preparations” for consistency with the terminology used within 16 CCR section 1751 et seq.

Subdivision (s) is amended to increase the delinquency fee of a designated representative for a veterinary food-animal drug retailer to \$150. The proposed renewal fee is \$300. Therefore, \$150 is 50% of the renewal fee, and since it does not exceed \$150, this fee is appropriate as set by B&P section 163.5.

Subdivisions (s) and (t) were also amended to add reference to “veterinary food-animal drug retailer” as applicable for consistency within the regulation and clarity with respect to which license type these sections apply to.

Subdivision (x) is amended to add, “The fee for a temporary nonresident outsourcing facility license is seven hundred fifteen dollars (\$715)” for clarity to include the temporary fee for nonresident outsourcing facility within the appropriate subsection. The board’s authority to issue a temporary license to an outsourcing facility is specified by B&P section 4129.8 and the fee is set at \$715 as specified within B&P section 4400(w).

Subsection (y) was added to include correctional clinics, which is a new licensing category added by Assembly Bill 1812 (Chapter 36, Statutes of 2018). The fees are established within B&P section 4400(z) and became effective June 27, 2018. The fees are set at the statutory maximum which is consistent with the board’s intention to raise fees in all categories to the statutory maximum, as discussed. The delinquent renewal fee is set in accordance with B&P section 163.5.

In addition to the amendments described above, this proposal adds the following fees, that are set by statute, to the regulation:

License type	Proposed Application Fee	Proposed Renewal Fee	Delinquency Fee (if applicable)
EMSADDS (B&P 4119.01)	\$100	\$100	\$35
Co-Location Clinic (B&P 4180.5)	\$750 (one-time fee)	N/A	N/A
Designated Paramedic (B&P 4202.5)	\$140	\$140	\$65

The above fees have been added to the regulation for consistency and to ensure that the regulated public can readily and easily find the board’s fees in one place.

The Note’s reference statutes were amended to add appropriate sections to ensure that the statutes are up to date and accurate in compliance with the section 11346.2(a)(2) of the Government Code. Sections 4044.3, 4119.01, 4127.15, 4129.8, 4130, 4180.5, 4187, and 4202.5 of Business and Professions Code were added.

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.

### **Underlying Data**

1. Letter from the Department of Consumer Affairs (Re: Project Fund Insolvency), dated December 10, 2018
2. Pharmacy Board Fund Condition Analysis dated December 10, 2018
3. Pharmacy Board Fund Condition Analysis with current fees dated August 23, 2018.
4. DCA's Analysis of Fund Condition and Fee Structure.
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 23-24, 2018 (Meeting Materials Agenda Item XV, Minutes Pages 1, 18-21).
6. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held December 14, 2018 (Meeting Materials Agenda Item IV, Minutes Pages 1-7).
7. Assembly Bill (AB) 1812 (Chapter 36, Statutes of 2018)

### **Business Impact**

The board determined that the proposed regulatory action will affect several of the board's licensees by increasing application, renewal and delinquency fees for various license categories within the board. The affected licensee business types include the following:

- Resident/Nonresident Pharmacy (includes community, hospitals, drug rooms and remote dispensing site pharmacies)
- Hypodermic Needle and Syringe Retailers
- Resident/Nonresident Wholesalers and Third-Party Logistics Providers
- Veterinary Food-Animal Drug Retailers
- Resident/Nonresident Sterile Compounding
- Hospital Satellite Compounding Pharmacy
- Centralized Hospital Packaging Pharmacy
- Resident/Nonresident Outsourcing Facilities
- Clinic

The board estimates that approximately 11,000 business licensees will be required to comply with the proposed fee schedule. Government owned pharmacies, correctional clinics, and/or organizations are "fee exempt" and would not be affected by this fee increase.

While these business licensees will be impacted, the board has made an initial determination that the fee increase will not have a significant statewide adverse economic impact directly affecting businesses and/or employees including the ability of California businesses to compete with businesses in other states. This determination is based on the fact that the pharmaceutical industry is a multi-billion-dollar industry, with chain drug store revenue exceeding 40 billion dollars a year. Additionally, according to

the National Community Pharmacists Association, the average annual revenue for an independent pharmacy was 3.6 million dollars a year. Furthermore, according to the National Conference of State Legislatures, the annual revenue for compounding pharmacies exceeded 5.6 billion dollars in 2015, while outsourcing facilities had an average annual revenue of 88 billion dollars. Finally, drug wholesalers and third-party logistics providers had an average annual revenue of 39 billion dollars. Therefore, the board determined that the increased fees should be absorbable and will not substantially affect licensee revenue.

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.

### **Economic Impact Assessment**

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.

The board determined that this proposal is unlikely to impact jobs or businesses as the pharmaceutical industry is a multi-billion-dollar industry. The annual revenue for the impacted licensing categories ranges from 3.6 million to 88 billion dollars, depending on the license type.

This regulatory proposal benefits the health and welfare of California residents. This proposal will ensure that the board has sufficient resources to maintain current board operations to meet its consumer protection mandate by allowing the board to continue licensing, regulations, and enforcement activities of the pharmacy industry, which will ensure the health, safety, and welfare of California residents.

This regulatory proposal benefits worker safety and the state's environment because it will ensure that the board has sufficient resources to maintain current board operations to continue operations and enforcement activities. This will allow the board to continue to inspect new and licensed facilities and ensure that they are operating in accordance with law, which will benefit worker safety and the environment.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the

purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. 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).
- (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.