

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. 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 of Pharmacy at its office not later than 5:00 p.m. on July 29, 2013.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Department of Consumer Affairs, First Floor Hearing Room, 1625 N. Market Blvd, Sacramento, CA 95834, on July 30, 2013 at 1:00 p.m.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals 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 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

Pursuant to the authority vested by section 4005 of the Business and Professions Code and to implement, interpret and make specific reference sections 122, 163.5, 4127.5 and 4400 of the Business and Professions Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as discussed below.

Informative Digest/Policy Statement Overview

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy and the administration of Chapter 9, Division 2 of that code.

Business and Professions Code section 122 allows the board to charge a fee for the processing and issuance of a duplicate copy of any certification of licensure or other form evidencing licensure or renewal of licensure.

Business and Professions Code section 163.5 establishes the criteria to determine the delinquency fee for any licensee within the Department of Consumer Affairs.

Business and Professions Code section 4400 establishes the statutory minimum and maximum fee schedule for application, renewal and other fees for additional board applicants and licensees. This statute was last amended in 2009 and the fees therein went into effect on January 1, 2010.

Title 16 of the California Code of Regulations section 1749 specifies fee schedules for various application, renewal and other fees for board licensees and applicants. That regulation was last updated

January 2008. As noted above, the board's statutory fee schedule found at Section 4400 of the Business and Professions Code (statutory minimums and maximums) was amended in 2009. As a result, since January 1, 2010, the board has been charging applicants and licensees the minimum fees specified in statute. The fee for a centralized hospital packaging pharmacy went into effect on January 1, 2013, as a new license category. Through this rulemaking, the regulation at 16 CCR Section 1749 is being updated to reflect the statutory maximum for each fee category. This proposal is necessary to ensure sufficient resources to maintain current board operations to meet its consumer protection mandate.

Business and Professions Code 4400(p) directs that the board shall seek to maintain a reserve in its fund equal to approximately one year's expenditure. The fund balance for the board provides specific information on the board's current fund as well as projections for future years. A review of the board's fund condition report (provided as underlying data in this rulemaking file) demonstrates that overall revenue for the board has increased by \$4,066,259 (54.9%), yet expenditures have increased by \$5,763,111 (63.78%) since FY 2007/2008. This creates a structural imbalance that is unsustainable without a fee increase. To emphasize this point, it is estimated that absent a fee increase, the board's fund condition will be reduced to a two and one half month reserve by the end of fiscal year 2014/15 and will be in a deficit of four months by the end of fiscal year 2016/17. A fund simply cannot go into a negative balance. That is the equivalent of an individual writing a check when there is no money in their checking account and no money forthcoming. The board can only spend up to the amount of cash that is in its fund which supports the need for this regulation.

The board identified several factors that attributed to the existing structural imbalance, including the costs the board incurs to deliver its services. A comparison of detailed expenditures between FY 2007/08 and FY 2012/13 reveal an overall increase in expenditures of 63.78%. More specifically, the board's personnel expenditures have increased from \$4.8M to a projected \$8.3M; a 72% increase. Additionally, the board has experienced a significant increase in the amount of pro rata assessed for both department services as well as statewide services. Specifically, pro rata charges the board must pay have increased 93% - from paying about \$1.2M in FY 2007/03 to a projected \$2.4M in FY 2012/13. A third area in which the board has seen tremendous growth is in its enforcement-related costs which have increased from about \$1.1M to a projected \$2.3M for FY 2012/2013 – a 102% increase. Eliminating personnel services or enforcement costs is not an option as that would have a significant impact in several areas of the board operations including issuing licenses as well as regulating licensees and taking appropriate enforcement and disciplinary actions against errant licensees. Further, the board can neither control nor negotiate pro rata costs that are determined by its control agency.

Anticipated Benefits of the Proposed Regulations

The board considered specific benefits anticipated by the proposed amendment of the section described, including, to the extent applicable, nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government, among other things. As stated above, this proposal ensures sufficient resources to maintain current board operations to meet its consumer protection mandate.

Consistency and Compatibility With Existing Regulations

The board conducted a search of the California Code of Regulations and determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Cost/Savings in Federal Funding to the State:

It is estimated that the proposed fee increase will result in an increase in board revenues for FY 14/15 by approximately \$3.2 million and an increase to ongoing annual revenue by approximately \$3.2 million.

The board does not anticipate any impact on federal funding.

This proposal does not impact any government owned business as by current law, as 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 Section 17561 Requires Reimbursement:

None.

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The following types of businesses would be affected by this regulation: pharmacies, drug wholesalers, distributors of hypodermic needles and syringes, clinics, veterinary- food animal drug retailers, and compounders of sterile injectable drug products.

Cost Impact on Representative Private Person or Business:

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

Pharmacist

Examination: \$200 (current) to \$260 (proposed)
Examination Regrade: \$90 (current) to \$115 (proposed)
Initial License: \$150 (current) to \$195 (proposed)
Renewal: \$150 (current) to \$195 (proposed)/biennial
Delinquent Fee: \$75 (current) to \$97.50 (proposed)

Designated Representative

Application: \$255 (current) to \$330 (proposed)
Renewal: \$150 (current) to \$195 (proposed)/annually
Delinquent Fee: \$75 (current) to \$97.50 (proposed)

Designated Representative (Food Animal-Drug Retailer)

Application: \$255 (current) to \$330 (proposed)
Renewal: \$150 (current) to \$195 (proposed)/annually
Delinquent Fee: \$75 (current) to \$97.50 (proposed)

Pharmacy Technician

Application: \$80 (current) to \$105 (proposed)
Renewal: \$100 (current) to \$130 (proposed)
Delinquent Fee: \$50 (current) to \$65 (proposed)

Pharmacy Intern

Application: \$75 (current) to \$115 (proposed)
Transfer of Hours: \$35 (current) to \$45 (proposed)

Reissuance of a License that has been lost, destroyed or a name changed
\$35 (current) to \$45 (proposed)

Resident, Nonresident and Hospital Pharmacy

Application: \$400 (current) to \$520 (proposed)
Renewal: \$250 (current) to \$325 (proposed)/annually
Temporary License: \$250 (current) to \$325 (proposed)
Delinquent Fee: \$125 (current) to \$150 (proposed)

Centralized Hospital Packaging Pharmacy

Application: \$600 (current) to \$800 (proposed)
Renewal: \$600 (current) to \$800 (proposed)/annually
Temporary License: \$250 (current) to \$325 (proposed)
Delinquent Fee: \$0 (current) to \$150 (proposed)

Resident and Nonresident Wholesalers

Application: \$600 (current) to \$780 (proposed)
Renewal: \$600 (current) to \$780 (proposed)/annually
Temporary License: \$550 (current) to \$715 (proposed)
Application for over 20 facilities: \$225 (current) to \$300 (proposed)

Hypodermic Needle and Syringe

Application: \$125 (current) to \$165 (proposed)
Renewal: \$125 (current) to \$165 (proposed)/annually
Delinquent Fee: \$62.50 (current) to \$82.50 (proposed)

Clinic

Application: \$400 (current) to \$520 (proposed)
Renewal: \$250 (current) to \$325 (proposed)/annually
Delinquent Fee: \$125.00 (current) to \$150 (proposed)

Veterinary Food-Animal Drug Retailer

Application: \$405 (current) to \$425 (proposed)
Renewal: \$250 (current) to \$325 (proposed)
Delinquent Fee: \$125 (proposed)

Compound Sterile Injectable Drug Products

Application: \$600 (current) to \$780 (proposed)
Renewal: \$600 (current) to \$780 (proposed)/annually
Temporary License: \$550 (current) to \$715 (proposed)
Delinquent Fee: \$150 (proposed)

Reissuance of a Business License resulting from a change in information
\$100 (current) to \$130 (proposed)

Reissuance of a Business License that has been lost, destroyed or the business name has
changed
\$35 (current) to \$45 (proposed)

Effect on Housing Costs:

None.

Results of the Economic Impact Analysis

The Board of Pharmacy conducted an Economic Impact Analysis (EIA) and has made an initial determination that the proposed regulatory action would not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

Business and Professions Code section 4005 states that “the board may adopt rules and regulations....pertaining to the practice of pharmacy....” As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. To ensure the solvency of and adequate reserve funds, the board regularly monitors its fund condition. As described in this Notice, overall revenue for the board has increased by \$4,066,259 (54.9%), yet expenditures have increased by \$5,763,111 (63.78%) since FY 2007/2008, creating a structural imbalance that no longer sustains board operations. Absent a fee increase, the board’s fund condition will be reduced to a two and one half month reserve by the end of fiscal year 2014/15 and will be in a deficit of four months by the end of FY 2016/17.

Impact on Jobs/Business

The Board of Pharmacy has determine that this regulatory proposal will not have a significant impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California. This determination has been made based upon the absence of public testimony during public meetings where this proposal has been discussed, most recently during the April 2013 Public Board Meeting.

Effect on Small Business

The board’s proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are “small businesses” as defined in Government Code Section 11342.610. This determination has been made based upon the absence of public testimony to this effect during public meetings where this proposal has been discussed, most recently during the April 2013 Public Board Meeting.

Consideration of Alternatives

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the

purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action 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 written statements relevant to the above determinations to the Board of Pharmacy at the address indicated under contact person.

Initial Statement of Reasons and information

The Board of Pharmacy 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 of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N-219, Sacramento, California 95834, or from the Board of Pharmacy web site (www.pharmacy.ca.gov).

Availability and Location of the Final Statement of Reasons and Rulemaking File

All the information upon which the proposed regulation is 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

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

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1625 N. Market Blvd N-219
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The backup contact person is:

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Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov