

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Abandonment of Applications.

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1706.2.

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 August 30, 2019 and ended on October 14, 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 no comments were received. At its November 5-6, 2019 board meeting, the board adopted the regulation text as noticed on August 30, 2019.

A technical, non-substantive change was made to subsection (b) of the adopted text to remove the extra comma after (e) within the added language as a grammatical change. Additionally, Business and Professions Code section 4042 was removed from the reference section as the reference does not apply.

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 (pharmacies) are a "small business" as defined in Government Code section 11342.610, the board has made the determination that this proposal will not have a significant adverse impact directly affecting small businesses. If a small business decided to again pursue licensure after the application was deemed abandoned, the estimated costs to the small business would be a new application fee as set by Business and Professions Code section 4400 and/or California Code of Regulations section 1749. There would not be any ongoing annual costs to small business as a result of this regulatory change.

Economic Impact

The board historically deems approximately 27 applications (various types) for initial licensure as abandoned per year. To the extent these applicants choose to re-apply and are granted licensure, these applicants will be required to pay initial license fees to the board as follows:

Registration and License Type	Fee Amount	Applicants Per Year	Total Costs
Initial App - Designated Representative - 3PL	\$150	9	\$1,350
Centralized Hospital Packaging - Org License	\$820	3	\$2,460
Hospital Application	\$520	4	\$2,080
Drug Room Application	\$520	2	\$1,040
Third-Party Logistics Providers	\$780	7	\$5,460
Outsourcing Pharmacy	\$2,270	2	\$4,540
Total Initial Costs:			\$16,930

These licensees will also be required to pay annual renewal fees to the board as follows:

Registration and License Type	Fee Amount	Applicants Per Year	Total Costs
Designated Representative - 3PL Annual Renewal	\$150	9	\$1,935
Centralized Hospital Packaging – Annual Renewal	\$820	3	\$2,415
Hospital Annual Renewal	\$520	4	\$2,620
Drug Room Annual Renewal	\$520	2	\$1,310
Third-Party Logistics Providers Annual Renewal	\$780	7	\$5,460
Outsourcing Pharmacy Annual Renewal	\$1,325	2	\$2,650
Total Initial Costs:			\$16,390

The total economic impact is estimated to be up to approximately \$164,980 per year and \$909,550 over a ten-year period as follows:

Registration and License Type	Fee Amount	Applicants Per Year	Years Ongoing										Total	
			1	2	3	4	5	6	7	8	9	10		
Initial App - Designated Representative - 3PL	\$150	9	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$1,350	\$13,500
Design Rep 3PL Renewal Fee	\$215	Various	\$0	\$1,935	\$3,870	\$5,805	\$7,740	\$9,675	\$11,610	\$13,545	\$15,480	\$17,415	\$17,415	\$87,075
Centralized Hospital Packaging - Org License	\$820	3	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$2,460	\$24,600
Centralized Hospital Packaging - Renewal	\$805	Various	\$0	\$2,415	\$4,830	\$7,245	\$9,660	\$12,075	\$14,490	\$16,905	\$19,320	\$21,735	\$21,735	\$108,675
Hospital Application	\$520	4	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$2,080	\$20,800
Hospital Annual Renewal	\$665	Various	\$0	\$2,660	\$5,320	\$7,980	\$10,640	\$13,300	\$15,960	\$18,620	\$21,280	\$23,940	\$23,940	\$119,700
Drug Room Application	\$520	2	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$1,040	\$10,400
Drug Room Annual Renewal	\$665	Various	\$0	\$1,330	\$2,660	\$3,990	\$5,320	\$6,650	\$7,980	\$9,310	\$10,640	\$11,970	\$11,970	\$59,850
3PL Providers	\$780	7	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$54,600
3PL Renewal Fee	\$780	Various	\$0	\$5,460	\$10,920	\$16,380	\$21,840	\$27,300	\$32,760	\$38,220	\$43,680	\$49,140	\$49,140	\$245,700
Outsourcing Pharmacy Annual Renewal	\$2,270	2	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$4,540	\$45,400
Outsourcing Pharmacy Initial	\$1,325	Various	\$0	\$2,650	\$5,300	\$7,950	\$10,600	\$13,250	\$15,900	\$18,550	\$21,200	\$23,850	\$23,850	\$119,250
Total Costs:			\$16,930	\$33,380	\$49,830	\$66,280	\$82,730	\$99,180	\$115,630	\$132,080	\$148,530	\$164,980	\$164,980	\$909,550

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 amending the regulation. The board determined that this alternative was unacceptable because it is necessary to provide clarity to the regulated public so that they may be aware of the criteria used by the board to deem an application abandoned and, subsequently, withdrawn by the board. This alternative would also preserve the current inefficient process of the board developing and submitting regular rulemaking actions each time a new license type is established in statute.
2. The board considered amending the list of license types within the regulation text. This alternative was unacceptable because the regulation would require frequent amendments as the board's regulatory authority increases and a large list within the body of the text would reduce clarity within the regulation. This alternative is less efficient for the board than the proposed action.

Fiscal Impact

The board historically averages a limited number (27) of abandoned initial license applications per year. The proposed regulations will allow the board to standardize the process to remove any deficient applications from the license application process. Because the board historically has only 27 abandoned applications per year, any efficiencies and/or additional workload and costs resulting from the proposed regulations are anticipated to be minimal and would be absorbed within existing resources.

In the event an applicant chooses to re-apply and is granted licensure, and then continues to renew annually, the board will receive initial and renewal license fees revenues.

Objections or Recommendations/Responses to Comments

During the 45-day public comment period from August 30, 2019 to October 14, 2019, the board received zero comments.

At its November 5-6, 2019 meeting, the board voted to adopt the regulation text as it was noticed on August 30, 2019.