



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Consideration and Possible Adoption of Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists

Attachment 2

Background:

In July 2015, staff initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law (OAL) for final review on June 3, 2016.

At the July 2016 board meeting, DCA Staff Counsel Laura Freedman explained OAL found problems and disapproved the regulation due to a lack of clarity and ambiguity in the language. OAL's main issue was with the language that prohibits experiential hours earned under a collaborative practice agreement to also be used to fulfill the criteria for the residency program.

OAL also raised two minor concerns regarding the rulemaking file. The first issue was the board's requirement that the application be submitted under penalty of perjury. The second issue OAL raised was the board defining one-year as 1,500 hours. Each of the requirements will be easily explained to OAL, and would be remedied by supplementing the Initial Statement of Reasons (ISR) to explain the board's rationale behind each of the two requirements.

Ms. Freedman drafted modified language to address the clarity issue raised and reviewed the text with the board. The board approved the "Draft Third Modified Text" as provided at the July 2016 board meeting. The board approved board staff to initiate a 15-day comment period. The board initiated a 15-day comment period for the addition of documents to the rulemaking file and third modified text. The 15-day comment period began August 12, 2016, and will end August 27, 2016. Board staff will bring to the board meeting comments with staff recommendations.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment(s) received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2016 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

The Attachment 2 contains the Draft Third Modified Text that was noticed on August 12, 2016.

Attachment 2

Title 16. BOARD OF PHARMACY
Third Modified Text

Changes made to the originally proposed language in the **first modified text** are shown by ~~double strikethrough~~ for deleted language and **bold and dashed underline** for added language. (Additionally, the modified text is listed in **red** for color printers.)

Changes made to the proposed language in the **second modified text** are shown by ~~double strikethrough and bold underline~~ for deleted language and **bold and double underline** for added language. (Additionally, the modified text is listed in **blue** for color printers.)

Changes made to the proposed language in this **third modified text** are shown by ~~double strikethrough and bold wavy underline~~ for deleted language and **bold wavy underline** for added language. (Additionally, the modified text is listed in **purple** for color printers.)

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, **subdivision** (a)(2)(A).

Note: Authority cited: Sections **4005 and 4210 and 4400**, Business and Professions Code.
Reference: Section ~~4052.6~~ 4210 ~~and 4400~~, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of **Business and Professions Code section** 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following ~~sub~~**section**~~divisions~~.

~~(a)~~ **(1)** Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, **subdivision** (a)(2)(A), ~~an applicant shall by~~ **providing** either:

~~(1)~~ **(A)** A copy of the certification award that includes the name of the

applicant pharmacist, the area of specialty and date of completion, or

~~(2)(B)~~ A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

~~(b) (2)~~ Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, **subdivision (a)(2)(B)**—~~an applicant shall by~~ **providing** either:

~~(4) (A)~~ A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

~~(2)(B)~~ A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, **the area of specialty and** the dates of participation and completion, ~~and area(s) of specialty.~~ **For an applicant who that cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

~~(e) (3)~~ Demonstrate that experience earned under a collaborative practice agreement or protocol, **as required by Business and Professions Code section 4210, subdivision (a)(2)(C)**, has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must ~~be composed of~~ **include** no fewer than 1,500 hours of experience providing clinical services to patients, ~~and must be earned within four consecutive years.~~ The experience earned under a collaborative practice agreement or protocol ~~must include initiating, adjusting, **modifying or and**~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

~~(4) (A)~~ A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A) (i)~~ Earned the clinical experience within the required time frame; **and**

~~(B) (ii)~~ Completed the required number of hours of **experience providing** clinical services to patients, as specified in **this subdivision subsection (a)(3), and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and**

~~(i) (I)~~ The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(ii) (II)~~ If a copy of the collaborative practice agreement or protocol

is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(2) (B)~~ A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~one year~~ **1,500 hours** of experience providing clinical services to patients. **For an applicant who that cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection~~(2)~~.**

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections ~~4005, and 4210 and 4400~~, Business and Professions Code.
Reference: Sections ~~4052.1, 4052.2, and 4052.6, 4210 and 4400~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars (\$195)** ~~two hundred seven dollars (\$207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.