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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IV. Discussion and Consideration of Board Approved Text to Initiate Rulemaking, Proposed Regulations to Amend Title 16 CCR section 1793.5, Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65, Related to the Pharmacy Technician Certification Programs

Background:

At the July and October 2016 Board meetings, the Board approved proposed text to amend Section 1793.5, related to the Pharmacy Technician Application, Section 1793.6 related to the Pharmacy Technician Training Requirements, and Section 1793.65, related to the Pharmacy Technician Certification Programs. This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians. This regulation was initially submitted to the DCA for pre-review in January 2017.

Subsequent to the initial submission the rulemaking language has been updated to address previously identified issues as well as to incorporate subsequently enacted legislation, most notably the provisions of Assembly Bill 2138 (Low, Chapter 955, Statutes of 2018). As an example, as part of the March 2018 Board meeting, the Board further amended Section 1793.65 to extend the approval date of the certification programs offered by The Pharmacy Technician Certification Board, and The National Healthcareer Association to December 31, 2021.

Recently, during discussions, DCA Legal identified specific areas of concern with respect to the language of the approved regulation text within section 1793.6(c), most notably concerns with the requirement for a drug testing to be required as well as the age requirement established.

Further, given the delay in promulgation, Board staff recommend that the approval date identified in section 1793.65 be again extended to allow additional time for the completion of the rulemaking process, implementation review and completion of an audit of the two examinations.

The attachment includes the recommended changes to the approved, but not yet noticed regulation text. Provided below is a summary of each of the recommended changes.

Section 1793.5 would update the revision date of the application form which is incorporated by reference. Mandatory updates to the application form were required to implement several subsequently enacted legislation including AB 2138 (Low, Chapter 955, Statutes of 2018) and AB 2113 (Low, Chapter 186, Statutes of 2020).

Section 1793.6(c)(2)(A) to recast the criminal background check requirement to more closely align with licensure requirements, while continuing to balance informed consent to the student.

Section 1793.6(c)(2)(B) to recast the drug screening requirement to including a mandatory advisement to an applicant that they may be required to undergo drug screening for illicit drug use and subsequent potential negative impacts of a positive drug screen, including eligibility to continue in the course of training and eligibility for licensure as a pharmacy technician.

Section 1793.6(c)(2)(C) to align the age requirement for enrollment in practical experience course work or externships to more closely align with similar age requirements for pharmacist licensure.

Section 1793.65(b) to extend the validity period of the accepted certification programs to December 2024.

At this Meeting:

The Board will have the opportunity to discuss the regulation text and determine what course of action it wishes to pursue. Among its options:

1. Amend the regulation text based on the recommended language offered and continue with the rulemaking process.
2. Amend the regulation text based on Board discussions during the meeting and continue with the rulemaking process.

Should the Board determine it appropriate to amend the current proposed regulation text, the following motion could be used to facilitate such a change.

Approve the recommended amended language and continue with the rulemaking process. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Attachment

Title 16. Board of Pharmacy

Proposed Regulation Text

Recommended changes to the proposed regulation text are as follows: double underline for added text and double strikethrough for deleted text.

Amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The “Pharmacy Technician Application” (Form 17A-5 (Rev. ~~10/15/2020~~7/2020/2021)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

- (1) Information sufficient to identify the applicant.
- (2) A description of the applicant's qualifications and supporting documentation for those qualifications.
- (3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
- (4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5~~, 114.5, 115.4, 115.5, 4005, ~~4007~~, ~~4038~~, 4115, and 4202, ~~4207~~ and ~~4400~~, Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and ~~4402~~ and ~~4400~~, Business and Professions Code; and Section 11105, Penal Code.

Amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202(a)(2) is:

- (a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,
- (b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
- (c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
 - (~~1A~~) Knowledge and understanding of different pharmacy practice settings.
 - (~~2B~~) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
 - (~~3C~~) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
 - (~~4D~~) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
 - (~~5E~~) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
 - (~~6F~~) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
 - (~~7G~~) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) ~~Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check of and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.~~ Prior to enrolling in any classes or admission into the course of training, an administrator or instructor shall conduct a criminal background check on the applicant that is consistent with the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). If the criminal background check reveals the applicant has committed acts that would constitute grounds for denial of licensure, the administrator or instructor shall counsel applicants about the negative impact to securing licensure.

(B) ~~Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.~~ Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall inform applicants that the course of training includes practical training at a pharmacy which may require the applicant to undergo drug screening for illicit drug use. As administrator or instructor shall counsel applicants about the negative impact of a positive drug screen, including eligibility to continue the course of training and eligibility for licensure.

(C) ~~Require students to be at least 18 years of age prior to the beginning of instruction.~~ Require students to be at least 18 years of age prior to enrolling in any course work involving practical training, such as an externship or any other training equivalent to pharmacy technician trainee placement as defined by Business and Professions Code section 4038, 4115, 4115, and 4115.5

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subdivision (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Add §1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, ~~2024~~ 2024.

Note: Authority cited: Sections 4005 and 4202, Business and Professions Code.

Reference: Sections 4038 and 4202, Business and Professions Code.