

**BOARD OF PHARMACY
INITIAL STATEMENT OF REASONS**

Subject Matter of Proposed Regulations: Renewal Requirements

(4) Section(s) Affected: Amend section 1702 of Article 1 of Division 17 of Title 16 of the California Code of Regulations. Add sections 1702.1, 1702.2 and 1702.5 to Article 1 of Division 17 of Title 16 of the California Code of Regulations.

Specific Purpose of each adoption, amendment, or repeal:

The Board of Pharmacy (Board) proposes to amend section 1702 of Article 1 of Division 17 of Title 16 of the California Code of Regulations and add and adopt sections 1702.1, 1702.2 and 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations for the purpose of amending Board's regulations to update the renewal requirements for pharmacists, pharmacy technicians, designated representatives, nonresident wholesalers and nonresident pharmacies as specified below.

The purpose of proposed regulations is to require and standardize the fingerprinting requirement and the reporting of convictions and disciplinary action at the time of renewal for pharmacists, pharmacy technicians and designated representatives as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary action by other entities at time of renewal.

Business and Professions Code section 4001.1 states that the "protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." The purpose of the proposed regulatory changes is to ensure that the Board upholds its mandate to protect the public in accordance with this section. In order to protect the public from incompetent, unethical and unprofessional practitioners, it is necessary for the Board to be informed of past and current criminal convictions and disciplinary action that are substantially related to the qualifications, functions, or duties of their professional service for which they are licensed. The unprofessional conduct statutes of Board licensing law as defined in Business and Professions Code sections 4301 and 4311 allow the Board to deny a license or suspend or revoke a license for unprofessional conduct, including the conviction of a crime substantially related to the qualifications, functions or duties of a licensee. In order to fully implement the unprofessional conduct statutes that require the Board to discipline a license that has been convicted of a crime substantially related to the qualifications, functions, or duties

of their profession, the Board must receive notice of and all information related to those criminal convictions and discipline.

Existing regulation at section 1702 specifies the fingerprinting requirement for pharmacist applicants for renewal on or after the implementation date of December 7, 2010 that have not previously submitted fingerprints to the Department of Justice (DOJ) in an electronic format. The regulation requires a pharmacist, as a condition of renewal, to disclose specified conviction information on the renewal form. Failure to comply with these requirements will result in the application for renewal being considered incomplete and an inactive pharmacist license will be issued in lieu of an active pharmacist license. The proposed regulations will identify similar requirements for pharmacy technicians and designated representatives applying for renewal. In addition, the proposal will specify the disclosure of disciplinary action at the time of renewal for pharmacists, pharmacy technicians, designated representatives, nonresident wholesalers and nonresident pharmacies.

Amend Section 1702: This section defines the fingerprinting and criminal conviction requirements that are currently required as a condition of renewal for pharmacists. This regulation took effect in 2010. It specifies the mandatory submission of fingerprints to the Department of Justice (DOJ) for state and federal level criminal offender record information search and the ability of the board to bring disciplinary action against a licensee that fails to comply with the fingerprinting requirement.

The proposed changes will add as condition of renewal the disclosure of disciplinary action taken against any license issued to the individual by a government agency. The proposal defines “disciplinary action” for the purposes of this section. The proposal would also clarify that the disclosure of criminal conviction information pertains to convictions that have occurred since the licensee last renewed to avoid receiving notification of incidents that have already been reviewed. By increasing the fine standard for traffic violations that are required to be disclosed on the renewal form to \$500, it would ensure consistency between fine standards on the applications and renewal forms. This proposal also removes reference to the implementation date for the fingerprinting requirement as multiple renewal cycles have passed since this regulation took effect; therefore, all pharmacists are required to now be in compliance.

Factual Basis/Rationale

Business and Professions Code section 490 authorizes the Board to suspend or revoke a license or discipline a licensee for the conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Business and Professions Code section 4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first.

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

Business and Professions Code Section 4036 provides the definition for “pharmacist” and specifies that the holder of an unexpired and active pharmacist license is entitled to practice pharmacy as defined in pharmacy law.

Business and Profession Code section 4200.5 authorizes the board to issue a retired pharmacist license to a pharmacist who has been licensed by the board.

Business and Professions Code section 4207 requires the board to conduct a thorough investigation of each applicant to determine whether the applicant is qualified for the license being sought. This section generally specifies that the board may request any information it deems necessary to complete its investigation and that the information requested for this purpose shall not be required to be adopted by regulation.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined, including conviction of a crime substantially related to the qualifications of a licensee (subdivision I).

Business and Professions Code sections 4300, 4301 and 4311 allows the board to deny a license or a registration, or suspend or revoke a license of registration for unprofessional conduct, including the conviction of a crime substantially related to the qualifications, functions or duties of a licensee.

Business and Professions Code section 4400 specifies the fee schedule that is fixed by the board. Subdivision (e) specifies the application fee and the renewal fee ranges for a pharmacist.

As a requirement for initial licensure, applicants are required to disclose any disciplinary action taken against a license held by the applicant. The Board utilizes multiple means of identifying disciplinary action prior to the issuance of a pharmacist license including requiring applicants for the pharmacist examination and licensure to submit a sealed original Self-Query Report from the National Practitioner Data Bank (NPDB) and official

license verification for any professional healthcare license currently or previously held by the applicant. This information is valuable when making a licensing decision; however, it only provides information at the time of licensure. There are no regulations currently that require disclosure of new disciplinary action taken since a license has been issued or since a license was last renewed. The proposed regulations would allow the Board a mechanism to identify such discipline.

Add Sections 1702.1 and 1702.2: The proposed regulation at section 1702.1 would define the requirements for a pharmacy technician applicant for renewal and the proposed regulation at section 1702.2 would define the requirements for a designated representative applicant for renewal. It would specify the mandatory submission of fingerprints to the Department of Justice (DOJ) for state and federal level criminal offender record information search and the ability of the board to bring disciplinary action against a licensee that fails to comply with the fingerprinting requirement.

Business and Professions Code section 144 requires an applicant to furnish to specified agencies, including the California State Board of Pharmacy (Board), a full set of fingerprints for the purpose of conducting criminal history record checks. Additionally, this section allows the Board to obtain and receive criminal history information from the Department of Justice (DOJ) and the United States Federal Bureau of Investigation (FBI).

The fingerprinting of applicants allows the Board a mechanism to enhance public protection by conducting a more thorough screening of applicants for possible licensure. Pharmacy technicians and designated representatives licensed prior to January 1, 2001 were not routinely required to submit fingerprints to the Board for purposes of securing a background check by the United States Federal Bureau of Investigation (FBI). This proposed regulation would require all Board licensees for whom an electronic record of his or her fingerprints does not exist in the DOJ's criminal offender record identification database to successfully complete a state and federal level criminal offender record information search conducted through the DOJ. Requiring all pharmacy technicians and designated representatives licensed prior to January 1, 2001, to submit fingerprints for processing during their next renewal will ensure that the Board receives timely notification of any arrest(s) or conviction(s) from the DOJ in the future.

Specifically these proposed regulations would:

- Require all pharmacy technician and designated representative applicants for renewal on or after the effective date of this regulation who have not previously submitted fingerprints to the FBI or for whom an electronic record of the submission of the fingerprints does not exist with DOJ, to complete a state and federal level criminal offender record information search conducted through the DOJ before his or her license renewal date. The purpose of this provision is to

ensure the Board receives criminal background and subsequent conviction information on pharmacy technicians and designated representatives in order to protect the public from unprofessional practitioners and fully implement the Board's mandate to enforce the unprofessional conduct statutes of Board licensing law.

- Requires licensees to retain for at least three years either a receipt showing that he or she has electronically transmitted his or her fingerprint images to DOJ, or for those licensees who did not use an electronic fingerprinting system, a receipt evidencing that the licensee's or registrants fingerprint's were taken. The purpose of this provision is to permit the licensee to demonstrate compliance with the fingerprinting requirement in the event that fingerprint submissions are not processed correctly by DOJ.
- Provides that a revoked license may not be reinstated until the applicant has submitted fingerprints for a criminal records search conducted through DOJ. This provision is in addition to any other conditions of reinstatement as determined by the Board. The purpose of this provision is to make certain that all licensees, irrespective of licensure status, meets the fingerprinting requirements set forth in this regulation before resuming practice with the public.
- Require pharmacy technician and designated representative applicants for renewal to pay the actual cost of compliance with the fingerprinting requirement.
- Exempts from the requirements of this proposed regulation pharmacy technicians and designated representatives actively serving in the United States military. The purpose of this provision is to allow those licensees not in active practice to only meet the requirement before returning to active practice with the public.
- Require pharmacy technicians and designated representatives, as a condition of renewal, to disclose on the renewal form any arrest or conviction information, as specified, since the licensee's last renewal.
- Require pharmacy technicians and designated representatives, as a condition of renewal, to disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. The proposal defines "disciplinary action" for the purposes of this section. As a requirement for initial licensure, applicants are required to disclose any disciplinary action taken against a license held by the applicant. This information is valuable when making a licensing decision; however, it only provides information at the time of licensure. There are no regulations currently that require disclosure of new disciplinary action taken since a license has been issued or since a license was

last renewed. The proposed regulations would allow the board a mechanism to identify such discipline.

- Specifies that failure to comply will result in the application for renewal being considered incomplete and the license shall not be renewed until the licensee demonstrates compliance with all requirements. The purpose of this provision is to give the Board the ability to enforce the fingerprinting and disclosure requirements by declaring any incomplete application ineligible for renewal.

Factual Basis/Rationale

Business and Professions Code section 490 authorizes the Board to suspend or revoke a license or discipline a licensee for the conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Business and Professions Code section 4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first.

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

Business and Professions Code section 4115 generally defines activities permitted by a pharmacy technician.

Business and Professions Code Section 4022.5 provides the definition of “designated representative”.

Business and Professions Code Section 4038 provides the definition of a “pharmacy technician”.

Business and Professions Code section 4202 sets forth requirements for the issuance of a designated representative license.

Business and Professions Code section 4202 sets forth requirements for the issuance of a pharmacy technician license.

Business and Professions Code section 4207 requires the board to conduct a thorough investigation of each applicant to determine whether the applicant is qualified for the

license being sought. This section generally specifies that the board may request any information it deems necessary to complete its investigation and that the information requested for this purpose shall not be required to be adopted by regulation.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined, including conviction of a crime substantially related to the qualifications of a licensee (subdivision l).

Business and Professions Code sections 4300, 4301 and 4311 allows the board to deny a license or a registration, or suspend or revoke a license of registration for unprofessional conduct, including the conviction of a crime substantially related to the qualifications, functions or duties of a licensee.

Business and Professions Code section 4400 specifies the fee schedule that is fixed by the board. Subdivision (h) specifies the application fee and the renewal fee ranges for a designated representative.

California Code of Regulations Section 1702 details the fingerprint and criminal conviction requirements that are currently required as a condition of renewal for a pharmacist.

In July 2009, the Los Angeles Times published an article indicating that the Board of Registered Nursing often takes years to take disciplinary action on complaints of egregious misconduct, while the licensees were still practicing. These articles exposed the need for healing arts boards within the Department of Consumer Affairs (DCA) to improve the enforcement process to ensure patient safety.

As a result of the LA Times article, the DCA held an informational hearing and investigated the problems that were addressed in the article. The DCA developed a report (Department of Consumer Affairs “*Consumer Protection Enforcement Initiative BCP Independent Verification & Validation Report*, [CPEI] March 2010”) regarding the existing enforcement problems and made recommendations for improving the enforcement programs of healing arts boards. The DCA also sponsored legislation, Senate Bill 1111 (Negrete McLeod), during the 2009-2010 Legislative Session to codify many of the recommendations within the report; however, the bill failed to be enacted. When the bill failed to be enacted into law, the DCA encouraged healing arts boards to pursue regulatory action to assist the boards with investigating and prosecuting complaints in a timely manner, and to provide the boards with tools to improve the enforcement process and ensure patient safety.

As part of the Consumer Protection Enforcement Initiative in 2008/2009, the board undertook review and evaluation of several areas of its enforcement and licensing functions to identify areas where the board could improve its ability to ensure it received or had access to information necessary to make appropriate licensing decisions as well as ensure it received relevant information to initiate investigations and take appropriate action to better protect consumers.

As part of this effort the board sought new regulatory authority to require fingerprinting of pharmacists that had not previously submitted fingerprints to the Department of Justice (DOJ) in an electronic format. To augment this effort, the board also sought to require as a condition of renewal, that a pharmacist also self-report any convictions. These changes took effect in December 2010. At the time the board adopted the changes, they requested that similar provisions be implemented for pharmacy technicians and designated representatives.

At Licensing Committee meeting held on April 12, 2013, the committee discussed a staff recommendation that would make changes to the existing pharmacist renewal as well as place similar renewal requirements for the pharmacy technician and designative representative licenses.

At the May 20, 2013 Licensing Committee meeting, the committee further discussed the definition of disciplinary action and made revisions to the proposed language. At the board meeting held on July 30-31, 2013, the board approved the proposed language and directed staff to take all steps necessary to initiate the formal rulemaking process. The board authorized the Executive Officer to make any non-substantive changes in the rulemaking package and provide for a public comment period.

Add Section 1702.5: The proposed regulation would require nonresident wholesaler and nonresident pharmacy applicants for renewal, as condition of renewal, to disclose on the renewal form any disciplinary action taken by any government agency since the last renewal of the license. The proposal defines “disciplinary action” for the purposes of this section. The proposed regulation gives the Board the ability to enforce the disclosure requirements by declaring any incomplete application ineligible for renewal.

Factual Basis/Rational

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

Business and Professions Code Section 4112 provides for the regulation of a pharmacy located outside of California that ships, mails, or delivers, in any matter, controlled substances, dangerous drugs, or dangerous devices into this state.

Business and Professions Code Section 4161 provides for the regulation of a wholesaler located outside of California that ships, sells, mails, or delivers dangerous drugs or devices into this state or that sells, brokers or distributes such products.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined, including conviction of a crime substantially related to the qualifications of a licensee (subdivision I).

As part of the requirements for initial licensure as a nonresident pharmacy or nonresident wholesaler, an applicant must hold a current license in the resident state. Prior to issuance of a California license, such applicants provide the Board with license verification from the resident state that provides our board with confirmation of the current standing with the other state board as well as notification if the license has been disciplined. This information is very valuable when making a licensing decision; however, it only provides information at the time of licensure. There are no regulations currently that require disclosure of new disciplinary action taken since a license has been issued or since a license was last renewed. The proposed regulations would allow the board a mechanism to identify such discipline.

At Licensing Committee meeting held on April 12, 2013, the committee discussed a staff recommendation that would require a nonresident pharmacy or nonresident wholesaler applicant for renewal, as a condition of renewal, disclosure of any disciplinary action taken against the entity in its home state.

At the May 20, 2013 Licensing Committee meeting, the committee further discussed the definition of disciplinary action and made revisions to the proposed language. At the board meeting held on July 30-31, 2013, the board approved the proposed language and directed staff to take all steps necessary to initiate the formal rulemaking process. The board authorized the Executive Officer to make any non-substantive changes in the rulemaking package and provide for a public comment period.

Underlying Data

1. Relevant Meeting Materials and Minutes from the Board of Pharmacy Licensing Committee Meeting held April 12, 2013

2. Relevant Meeting Materials and Minutes from the Board of Pharmacy Licensing Committee Meeting held May 20, 2013
3. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held July 30-31, 2013
4. Department of Consumer Affairs *“Consumer Protection Enforcement Initiative BCP Independent Verification & Validation Report, March 2010”*

Business Impact

The Board does not believe that this regulation will have a significant adverse economic impact on businesses as it only affects pharmacy technicians and designated representatives for whom an electronic record does not exist in the DOJ’s criminal offender record identification database and those licensees that do not comply with the proposed regulation.

Economic Impact Assessment

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because this proposal will not be of sufficient amount to have the effect of creating or eliminating jobs. This initial determination is based on the fact that the proposed regulatory changes only affect individuals for whom an electronic record of his or her fingerprints does not exist in the DOJ criminal offender record identification database and those licensees that do not comply with the proposed regulation.
- It will not create new business or eliminate businesses within the State of California. This initial determination is based on the fact that the proposed regulatory changes pertain to licensees applying for renewal with the Board. The proposed regulatory changes could have an impact on businesses that provide Live Scan services; however, any impact would be minor as these businesses are already equipped to provide the service and the fingerprinting requirement will be staggered over the licensee’s renewal periods.
- It will not affect the expansion of businesses currently doing business within the State of California. This initial determination is based on the fact that the proposed regulatory changes pertain to licensees applying for renewal with the Board. The proposed regulatory changes could have an impact on

businesses that provide Live Scan services; however, any impact would be minor as these businesses are already equipped to provide the service and the fingerprinting requirement will be staggered over the licensee's renewal periods.

- This regulatory proposal benefits the health and welfare of California residents because the proposed regulation would enable the Board to receive timely notification of convictions and disciplinary action. In order to protect the public from incompetent, unethical and unprofessional practitioners, it is necessary for the Board to be informed of past and current criminal convictions and discipline that are substantially related to the qualifications, functions, or duties of their profession for which they are licensed.
- This regulatory proposal does not affect worker safety because this proposal is not relative to worker safety. This initial determination is based on the fact that the proposed regulatory changes only affect individuals for whom an electronic record of his or her fingerprints does not exist in the DOJ criminal offender record identification database and those licensees that do not comply with the proposed regulation.
- This regulatory proposal does not affect the state's environment because this proposal is not relevant to the state's environment. This initial determination is based on the fact that the proposed regulatory changes only affect individuals for whom an electronic record of his or her fingerprints does not exist in the DOJ criminal offender record identification database and those licensees that do not comply with the proposed regulation.

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.