

## **TITLE 16. BOARD OF PHARMACY**

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) 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 at its office not later than 5:00 p.m. on September 26, 2016.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

The Board, 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 sections 4001.1 and 4005 of the Business and Professions Code, and to implement, interpret or make specific sections 490, 4022.5, 4036, 4038, 4053, 4112, 4115, 4161, 4200.5, 4202, 4207, 4300, 4301, 4301.5, 4311, 4400 of the Business and Professions Code and sections 11105(b)(10) and 11105(e) of the Penal Code, the Board of Pharmacy is proposing 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, 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations as follows:

### **INFORMATIVE DIGEST**

#### **A. Informative Digest**

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, 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 pertaining to the fingerprinting requirement and reporting of convictions and disciplinary action as specified below.

## B. Policy Statement Overview

Existing regulation at section 1702 defines the fingerprinting and conviction disclosure requirements for a pharmacist applicant for renewal. 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 regulations would make changes to the existing pharmacist renewal requirements as well as place similar renewal requirements for pharmacy technicians and designative representatives. In addition, this proposal would specify the disclosure of disciplinary action as a condition of renewal for nonresident wholesalers and nonresident pharmacies.

### Amend Section 1702 Pharmacist Renewal Requirements

The proposed regulatory change at section 1702 would require a pharmacist applicant for renewal, as condition of renewal, to disclose on the renewal form any disciplinary action taken against any license issued to the applicant. This proposal would remove reference to the implementation date of the fingerprinting requirement found in this section. The proposed regulation would also clarify the requirements for the disclosure of criminal conviction information. Specifically, that it pertains to convictions that have occurred since the licensee last renewed. The proposal would also increase the threshold for traffic infractions the require disclosure on the renewal form.

### Add Sections 1702.1 and 1702.2 Pharmacy Technician and Designated Representative Renewal Requirements

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.

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.

#### Add Section 1702.5 Nonresident Wholesaler and Nonresident Pharmacy Renewal Requirements

The proposed regulation would require a nonresident wholesaler or 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 proposed regulation gives the Board the ability to enforce the disclosure requirements by declaring any incomplete application ineligible for renewal.

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.

#### Anticipated Benefits of Proposal

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.

#### C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board of Pharmacy has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

#### **FISCAL IMPACT ESTIMATES**

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The Board estimates a cost of about \$10,000 annually beginning in FY 2016/17.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulatory action

would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

AND

The following studies/relevant data were relied upon in making the above determination:

There would be no costs to businesses to comply with this regulation. Any costs associated with this proposed regulation would only affect pharmacy technicians and designated representatives 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.

Cost Impact on Representative Private Person or Business:

The current processing fees associated with Live Scan fingerprinting are \$32.00 for DOJ and \$17.00 for FBI, with some Live Scan agencies charging additional fees for “rolling” fingerprints and/or administrative processing. Applicants are responsible to pay all fees associated with the fingerprint process. The board estimates that there are approximately 12,792 licensees that have not submitted electronic fingerprinted through the DOJ and will require Live Scan to be completed consisting of 12,519 pharmacy technicians and 273 designated representatives. These licensees will be required to complete a state and federal level criminal offender record information search through DOJ in order to have an electronic record in the DOJ database.

Effect on Housing Costs: None

**EFFECT ON SMALL BUSINESS:**

The Board has determined that the proposed regulations would not affect small businesses. This proposed regulation would 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.

There are approximately 1380 vendors statewide who provide fingerprinting services. There should be no initial or ongoing cost impact upon the vendors because they are already equipped to provide the service and the fingerprinting requirement will be staggered and extended over the licensees' renewal periods.

**RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:**

### Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have any 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.

### Benefits of Regulation:

The Board has determined that this regulatory proposal will have the following benefits to health and welfare of California residents, worker safety, and state's environment:

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.

## **CONSIDERATION OF ALTERNATIVES**

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, 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 statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.



## **INITIAL STATEMENT OF REASONS AND INFORMATION**

The Board of Pharmacy has prepared an initial statement of the 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 any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <http://www.pharmacy.ca.gov>.

## **AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE**

All the information upon which the proposed regulations are 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**

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

Name:	Katrina Trinchera
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7946
Fax No.:	(916) 574-8617
E-Mail Address:	Katrina.Trinchera@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
Fax No.:	(916) 574-8617
E-Mail Address:	Anne.Sodergren@dca.ca.gov

**Website Access:** Materials regarding this proposal can be found at the Board of Pharmacy's website: [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).