

TITLE 16
California State Board of Pharmacy

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING

Substantial Relationship Criteria, § 1770
Criteria for Rehabilitation, § 1769
California Code of Regulations

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) is proposing to take the action described in the Informative Digest.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Person" in this Notice.

COMMENT PERIOD

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 no later than April 27, 2020**, or must be received by the Board at the hearing. Oral comments should be made at the hearing, if any.

AVAILABILITY OF MODIFICATIONS

The Board, upon its own motion or at the insistence 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 the 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 481, 482, 493, and 4005 of the Business and Professions Code (BPC), and to implement, interpret, or make specific BPC sections 141, 475, 480, 481, 482, 488, 490, 492, and 493, the Board is considering amending sections 1769 and 1770 of Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST

BPC section 4005 authorizes the Board to adopt, amend, or repeal such rules and regulations as may be reasonably necessary to enable it to carry into effect the provisions of Pharmacy Law. Additionally, as required under Assembly Bill (AB) 2138 (Chiu, Chapter 995, Statutes of 2018), the primary purpose of this proposal is to implement, interpret, and make specific the provisions of BPC sections 141, 475, 480, 481, 482, 488, 490, 492, and 493 relative to substantial relationship and rehabilitation criteria.

Changes to substantial relationship criteria: In accordance with the statutory amendments implemented by AB 2138, beginning July 1, 2020, BPC sections 481 and 493 will require the Board, when considering the denial, suspension, or revocation of a license based on a crime, to determine whether the crime is substantially related to the qualifications, functions, or duties of a licensee by using specified criteria, including the nature and gravity of the offense, the number of years elapsed since the date of the offense, and the nature and duties of a licensee.

Changes to rehabilitation criteria: BPC section 482 requires the Board to develop criteria to evaluate the rehabilitation of a person when considering the denial, suspension, or revocation of a license. Beginning July 1, 2020, BPC section 482 will require the Board, when considering the denial, suspension, or revocation of a license based on a crime, professional misconduct, or act, to consider whether the applicant or licensee is rehabilitated based on either (1) having completed their criminal sentence without violating parole or probation, or (2) the Board's standard criteria for evaluating the rehabilitation of applicants and licensees. (BPC § 482, as added by AB 2138, § 9.)

Existing regulations: Currently, 16 CCR section 1770 establishes the criteria for determining when a crime or act is substantially related to the qualifications, functions, and duties of a licensee, and 16 CCR section 1769 establishes the criteria for evaluating the rehabilitation of an applicant or licensee when considering the denial, suspension, or revocation of a license.

Problem statement: The passage of AB 2138 requires 16 CCR sections 1769 and 1770 to be updated to clearly specify the criteria the Board uses when (1) making a substantial relationship determination regarding an applicant's or licensee's criminal conviction, professional misconduct, or act, or (2) evaluating the rehabilitation of an applicant or licensee when considering denial, suspension, or revocation of a license.

The Board is proposing the following changes:

Amend 16 CCR section 1770 (Substantial Relationship Criteria):

The proposed regulation, for purposes of denial, suspension, or revocation of a license, would add professional misconduct and disciplinary actions taken by another state, by any agency of the federal government, or by another country as described in BPC section 141 as grounds requiring the Board to consider the substantial relationship criteria in 16 CCR section 1769, and require the Board, in making the substantial relationship determination for a crime, to consider

the following criteria: (1) the nature and gravity of the offense; (2) the number of years elapsed since the date of the offense; and (3) the nature and duties of a person holding the license. The proposal would also clarify that substantially related crimes, professional misconduct, or acts include those which violate or attempt to violate, directly or indirectly, or aid, abet, or conspire to violate various specified state or federal laws. The list would further include crimes, professional misconduct, or acts that involve various specified elements.

Amend 16 CCR section 1769 (Criteria for Rehabilitation):

The proposed regulation would clarify that the Board, when considering a license denial, suspension, or revocation on the ground that the applicant or licensee was convicted of a crime, would have to determine whether the applicant or licensee made a showing of rehabilitation and is presently eligible for a license, if the applicant or licensee completed the criminal sentence without a violation of parole or probation. In making that determination, the proposal would require the Board to consider the nature and gravity of the crime, the length of the parole or probation period, the extent to which the parole or probation period was shortened or lengthened, and the reasons therefor, the terms or conditions of parole or probation and the extent to which they bear on the applicant's or licensee's rehabilitation, and the extent to which the terms or conditions of parole were modified, and why. The proposal would require a broader set of rehabilitation criteria to be considered for applicants and licensees who had not completed the criminal sentence without a violation of parole or probation, did not sufficiently demonstrate their rehabilitation under the narrower set of criteria, or, in the case of denial proceedings, when the denial proceedings are based on something other than a criminal conviction.

Policy Statement Overview/Anticipated Benefits of Proposal

As specified in the legislative analyses of AB 2138, this proposal seeks to reduce barriers to licensure for applicants and licensees with criminal convictions or disciplinary histories or who have committed other acts that may be grounds for denial, suspension, or revocation of a license, which may reduce recidivism and provide economic opportunity to California's residents. In addition, the proposal seeks to improve clarity, transparency, and consistency for applicants and licensees in the Board's use of their criminal convictions, disciplinary histories, or other past conduct in its denial, suspension, and revocation proceedings.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has conducted a search of 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 or Savings to State Agencies:

The Board anticipates that there may be an increased cost to the state as a result of amending and adopting the sections identified in the regulatory proposal. By further defining the

substantial relationship and rehabilitation criteria for criminal convictions, Board staff may see an increased workload to research convictions and to substantiate that rehabilitation has been achieved.

Costs/Savings in Federal Funding to the State: None

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 have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses, the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

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 an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over a few months. This proposal may impact available qualified potential employees; however, it should not have a significant fiscal impact on small businesses. Furthermore, the regulatory action will not impact small business because the intent of AB 2138 is to reduce barriers to licensure for applicants and licensees with a criminal history or licensure discipline.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses, 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 proposal may benefit individuals, who would have greater access to licensure, reduce criminal recidivism, and provide economic opportunity to California residents with a criminal history. The public may benefit from the proposal with increased access to licensed professionals, which may benefit the health and welfare of Californians. The regulatory proposal does not affect worker safety or the state's environment.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would 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.

To date, the following alternatives were considered:

Option 1: To pursue a regulatory change that requires the Board to find rehabilitation if the applicant or licensee completed their terms of their criminal probation or parole. Courts give little weight to the fact that an applicant or licensee did not commit additional crimes or continue addictive behavior while in prison or while on probation or parole since they are under the direct supervision of correctional authorities and are required to behave in an exemplary fashion. As such, the Board believes that reviewing each individual on the basis of multiple criteria is the better indicator of whether individuals are rehabilitated and not a danger to the public's health, safety, and welfare. For these reasons, the Board rejected this option.

Option 2: To do nothing, meaning the Board would not adopt the regulations. The Board opted not to pursue this option because per AB 2138, the Board is mandated to adopt proposed regulations by July 1, 2020.

Any interested person may submit comments to the Board in writing relevant to the above determinations at 2720 Gateway Oaks, Suite 100, Sacramento, California 95833.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board 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 at 2720 Gateway Oaks, Suite 100, Sacramento, California 95833.

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: Lori Martinez
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Sacramento, CA 95833
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The backup contact person is:

Name: Debbie Damoth
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Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.