

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Substantial Relationship and Rehabilitation Criteria

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1769 and 1770

Effective Date

The Board requests that this regulatory proposal become effective upon filing to align as closely as possible with the statutory implementation date of July 1, 2020, in Assembly Bill (AB) 2138 (Chiu, Chapter 995, Statutes of 2018). AB 2138 changed a policy of automatic denials of licensure for individuals with criminal convictions. These regulations make clear the Board's statutory commitment to providing an opportunity for a "second chance" and explain how the Board will individually examine each licensure, renewal, or reinstatement decision for individuals with a criminal conviction. Further, they clarify to the public how the Board will decide which convictions are substantially related to licensure. As noted by the public comments received and discussed herein, these regulations would benefit all Californians, both those given a "second chance" for licensure and those that could employ or receive services from them. Further, allowing for licensure and employment could potentially reduce recidivism as well as provide Californians with greater choices in licensees. Therefore, it would be of public benefit to hasten the effective date of these regulations.

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above sections. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on March 13, 2020, and ended on April 27, 2020. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the comment period.

During the comment period, one comment was received. On May 7, 2020, the Board considered the one comment as well as nonsubstantive changes recommended by the Department of Consumer Affairs Legal Counsel. After having considered the comment in the record and the recommended nonsubstantive changes, the Board adopted the amended regulation, as presented to the Board on May 7, 2020.

Section 1769 (“Criteria for Rehabilitation”):

1. In subdivision (a), added the new heading “Examination of applicant by medical professionals to assess competency” to clarify the subject matter of this subdivision.
2. In subdivision (b), added the new heading “Denial of a license” to clarify that this subdivision sets forth rehabilitation criteria applicable to license applicants.
3. Consolidated subdivisions (b) and (c) into paragraphs (1)(A)-(E) and (2)(A)-(F) of subdivision (b), redesignated subdivision (d) as subdivision (c), and revised the cross-references to those provisions accordingly, so that all provisions setting forth rehabilitation criteria for applicants are contained within one subdivision.
4. In subdivision (b)(1), replaced “was” with “has been.” “Has been” refers to an activity that began in the past and continues in the present, while “was” refers to an activity that began and ended in the past. This change was to clarify that this subdivision applies to a licensee who continues to have a criminal conviction on their record. Subsection (b)(1) was further amended to remove “and is presently fit for a license.” The meaning of the term “presently” was unclear to the regulated public and the phrase was determined to be unnecessary given the other clarifying modifications to the proposal. This is a non-substantive change as it does not change the regulatory effect of the language.
5. In subdivisions (b)(1) and (c), revised “licensing or registration” and “the licensee or the registrant,” respectively, to delete the superfluous references to registrations and registrants, because B&P section 4032 already defines “license” to include “registration.”
6. In subdivision (b)(2), spelled out the circumstances in which the rehabilitation criteria in paragraph (1) would be “inapplicable” in a denial proceeding under B&P section 480 and the Board would be required to apply the rehabilitation criteria in paragraph (2). Whereas paragraph (1) would apply if an applicant with a criminal conviction has completed their criminal sentence without violating parole or probation, paragraph (2) would apply if the applicant did violate parole or probation; the applicant did not violate parole or probation, but was not determined by the Board to have made a showing of rehabilitation based on the criteria in paragraph (1); or the denial proceeding under B&P section 480 is based on professional misconduct (and not a crime). The modification enables applicants to better understand which set of criteria will be used to evaluate their rehabilitation. This is a non-substantive change as it aligns the regulation text with B&P section 480.

7. In subdivision (c), added the heading “Suspension or revocation of a license” to clarify that this subdivision sets forth rehabilitation criteria applicable to licensees. Further, this section was reworded to make the language clearer with respect to a licensee’s rights and responsibilities. This is a non-substantive change as it does not change the regulatory effect of the language. These are non-substantive changes as they have no regulatory impact.
8. In the Authority and References, added B&P section 481 and 482 to the authorities cited. This is a non-substantive change as it has no regulatory impact.

Section 1770:

1. In subdivision (a), revised the reference to the “qualifications, functions, or duties of a licensee or registrant” to instead refer to the “qualifications, functions, or duties of the practice, profession, or occupation that may be performed under the license type sought or held” to clarify that the Board will evaluate a criminal conviction based on its relationship to a licensed practice, profession, or occupation, and not an individual applicant or licensee who may have qualifications, functions, or duties that are unrelated to the licensed practice, profession, or occupation. Additionally, licensee or registrant was deleted are duplicative and the Board no longer uses the term “registrant” for licensees. This is a non-substantive change as it aligns the regulation text with B&P section 480.
2. In subdivision (a), revised “present or potential unfitness of a licensee” to read “present or potential unfitness of an applicant or licensee.” This modification is a technical correction because section 1770 establishes substantial relationship criteria for license denial proceedings, which concern applicants, and not only disciplinary proceedings, which concern licensees.
3. In subdivision (a), revised each instance of “licensee or registrant” and “license or registration” to delete the superfluous references to registrations and registrants, because B&P section 4032 already defines “license” to include “registration.”
4. In the Authority and References, remove the strikeout of B&P section 481 to maintain the reference, remove section 493 from the authorities cited and add section 475 to the references. These are non-substantive changes as they have no regulatory impact.

Throughout sections 1769 and 1770: Added “professional misconduct” for consistent use with the term and to differentiate “professional misconduct” as a ground for denial provided under new BPC section 480, subsection (a)(2), from other “acts” that are grounds for denial provided under BPC sections 490, 493, and 494.5.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Economic Impact

To the extent that applicants and licensees were convicted of a crime or were previously disciplined, the proposed regulations could impact individual licensees and premises licensees by authorizing individuals with criminal convictions to obtain licensure by the Board, if they have met the rehabilitative criteria, and the criminal convictions are substantially related, as established in the regulatory proposal.

The Board historically denies approximately 50 initial license applications per year for criminal convictions and estimates approximately 23 of these applicants (18 – Pharmacy Technicians, 2 – Pharmacist Intern, 2 – Designated Representatives, and 1 – Pharmacist) would be granted licensure under the proposed regulations.

The Board notes, Pharmacist Technicians, Pharmacist Interns, and Designated Representatives would not incur additional costs related to initial licensure because these applicants are required to pay a non-refundable initial application fee. Denied applicants do not receive a refund from the Board, so approved applicants would have no additional costs.

The Board estimates annual initial costs to Pharmacist applicants as follows:

Registration and License Type	Applicants Per Year	Initial Fee Costs	Total Initial Costs
Pharmacy Technician	18	\$0	\$0
Pharmacist Intern*	2	\$0	\$0
Designated Representative*	2	\$0	\$0
Pharmacist	1	\$195	\$195
Totals:	23		\$195

*Applicants pay a non-refundable application fee

Pharmacy Technicians, Designated Representatives, and Pharmacists will also be required to pay ongoing biennial renewal fees. Pharmacist Interns pay no renewal fees. The following chart displays bi-ennial renewal fees as follows:

Registration and License Type	Applicants Per Year	Initial Fee Costs	Total Initial Costs
Pharmacy Technician	18	\$140	\$2,520
Pharmacist Intern*	2	\$0	\$0
Designated Representative	2	\$215	\$430
Pharmacist	1	\$360	\$360
Totals:	23		\$3,310

*No Renewal Fee Required

The total economic impact is estimated to range from \$195 to \$13,435 per year and up to \$68,150 over a ten-year period as follows:

AB 2138 Impact - Estimates Number of Additional Registrants and Licensees Per Year														
Registration and License Type	Applicants Per Year	Fee Costs Per Year	Years Ongoing											
			1	2	3	4	5	6	7	8	9	10	Total	
Pharmacy Technician														
Pharmacy Technician Initial License	18	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$0
Pharmacy Technician Renewal License	Various	\$140	\$ -	\$ -	\$2,520	\$2,520	\$5,040	\$5,040	\$7,560	\$7,560	\$10,080	\$10,080	\$50,400	
Total Costs:			\$ -	\$0	\$2,520	\$2,520	\$5,040	\$5,040	\$7,560	\$7,560	\$10,080	\$10,080	\$50,400	
Pharmacist Intern*														
Pharmacist Intern Initial License	2	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Pharmacist Intern Renewal License	Various	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Costs:			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Designated Representative														
Designated Representative Initial License	2	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Designated Representative Renewal License	Various	\$215	\$ -	\$ -	\$430	\$430	\$860	\$860	\$1,290	\$1,290	\$1,720	\$1,720	\$8,600	
Total Costs:			\$ -	\$0	\$430	\$430	\$860	\$860	\$1,290	\$1,290	\$1,720	\$1,720	\$8,600	
Pharmacist														
Pharmacist Initial License	1	\$195	\$195	\$195	\$195	\$195	\$195	\$195	\$195	\$195	\$195	\$195	\$1,950	
Pharmacist Renewal License	Various	\$360	\$ -	\$ -	\$360	\$360	\$720	\$720	\$1,080	\$1,080	\$1,440	\$1,440	\$7,200	
Total Costs:			\$195	\$195	\$555	\$555	\$915	\$915	\$1,275	\$1,275	\$1,635	\$1,635	\$9,150	
Total Registrant and License Costs:			\$195	\$195	\$3,505	\$3,505	\$6,815	\$6,815	\$10,125	\$10,125	\$13,435	\$13,435	\$68,150	

*No Initial or Renewal License Fees Required

Small Business Impact

While the Board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code section 11342.610, the Board determined that any adverse economic impact will not be significant. This proposal may impact available qualified potential employees; however, it should not have a significant fiscal impact on small businesses. Furthermore, the regulatory action does 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.

Fiscal Impact

The Board anticipates approximately 23 additional applicants will be provided initial licensure per year, of which 21 will be required to renew biennially, as a result of the proposed regulations. Any workload and costs to process the initial and renewal applications is estimated as follows:

AB 2138 Impact - Estimates Number of Additional Registrants and Licensees Per Year											
Registration and License Type	Years Ongoing										
	1	2	3	4	5	6	7	8	9	10	Total
Initial License and Applications Submitted Per Year	23	23	23	23	23	23	23	23	23	23	230
*Program Technician III (10 minutes - \$16 per License)	\$352	\$352	\$352	\$352	\$352	\$352	\$352	\$352	\$352	\$352	\$3,520
**Staff Services Analyst (10 minutes - \$16 per License)	\$16	\$16	\$16	\$16	\$16	\$16	\$16	\$16	\$16	\$16	\$160
Postage and materials (\$10 per)	\$230	\$230	\$230	\$230	\$230	\$230	\$230	\$230	\$230	\$230	\$2,300
Total Initial Costs:	\$598	\$598	\$598	\$598	\$598	\$598	\$598	\$598	\$598	\$598	\$5,980
Biennial License Renewal (Does not include Pharmacist Interns)	-	-	21	21	42	42	63	63	84	84	420
***Office Technician (10 minutes - \$14 per License)	-	-	\$294	\$294	\$588	\$588	\$882	\$882	\$1,176	\$1,176	\$5,880
****Enforcement-related costs - \$159 per licensee	-	-	\$3,339	\$3,339	\$6,678	\$6,678	\$10,017	\$10,017	\$13,356	\$13,356	\$66,780
Postage and materials (\$10 per)	-	-	\$210	\$210	\$420	\$420	\$630	\$630	\$840	\$840	\$4,200
Total Renewal Costs:	-	-	\$3,843	\$3,843	\$7,686	\$7,686	\$11,529	\$11,529	\$15,372	\$15,372	\$76,860
Total Initial and Renewal Costs:	\$598	\$598	\$4,441	\$4,441	\$8,284	\$8,284	\$12,127	\$12,127	\$15,970	\$15,970	\$82,840

*Program Technician III (approximately \$95 per hour - includes DCA distributed costs)
 **Staff Services Analyst (approximately \$95 per hour - includes DCA distributed costs)
 ***Office Technician (approximately \$81 per hour - includes DCA distributed costs)
 ****Enforcement Costs (\$22,219,453)/Licensee Population (139,473) = Average - \$159 per licensee

The Board estimates annual initial and renewal license fee revenues ranging from approximately \$195 to \$13,435 per year and up to \$68,150 over a ten-year period.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Board considered the following alternatives:

- Option 1: To pursue a regulatory change that requires the Board to find rehabilitation if the applicant or licensee completed the terms of their criminal probation or parole. Courts give little weight to the fact that an applicant 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.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from March 13, 2020 to April 27, 2020 the Board received one comment. The comment was provided in the meeting materials for the May 7, 2020 Board meeting, and was reviewed and considered by the Board.

Written Comments from Vinuta Naik, Community Legal Services in East Palo Alto, Faride Perez, Root and Rebound, and Other Organizations

Initial Comment: General Statement/Purpose of the Letter

Commenters stated that the proposed regulations leave some gaps in the regulatory scheme pursuant to the changes to Business and Professions Code (BPC) section 480, 481, 482, and 493 as modified by AB 2138. The comment stated that the proposed regulations fail to fully implement these statutes. Additionally, the comment stated that the proposed regulations fall short of the intent of the bill, which includes combating discrimination against people with records who have demonstrated rehabilitation and seek to establish themselves professionally.

Response: The Board rejected this comment. The purpose of the proposed regulations is to clarify substantial relationship criteria and criteria for rehabilitation, as required by AB 2138. (BPC, § 481.) Consistent with the requirements enacted by AB 2138, these regulations would adopt all of the following criteria, which would assist the Board in implementing a balanced approach to evaluating an applicant's eligibility for licensure:

1. The nature and gravity of the offense.
2. The number of years elapsed since the date of the offense.
3. The nature and duties of the profession in which the applicant seeks licensure or in which the licensee is licensed.

Clarifying how to determine whether a crime is substantially related and clarifying the factors that will be considered when evaluating rehabilitation should assist applicants and licensees with demonstrating their rehabilitation.

Comment 1: Commenters expressed concern that section 1769 relies heavily on law enforcement reports and determination of the applicant's progress. The commenters indicated that rehabilitation can take many forms and they believe the proposed text does not "embrace" this.

The commenters further reference another comment (number 5) within their own document. See response to comment number 7 for a response to this specific comment.

Response to Comment 1: The Board rejected this comment. The proposed text for section 1769, subdivisions (b)(2)(F) and (c)(6) already provide that the Board will consider any evidence of rehabilitation submitted by the applicant or licensee, including as provided in the Board’s disciplinary guidelines, which is not limited to reports or determinations by law enforcement. The disciplinary guidelines already list various other forms of evidence an applicant or licensee may choose to provide to show rehabilitation.

Comment 2: Commenters expressed concern that section 1770 lists certain crimes, professional misconduct, or act(s) and defines them as substantially related regardless of the time that has passed or the nature and gravity of the offense in contravention of AB 2138, Business and Professions Code (B&P) section 481. Commenters note that AB 2138 allows the Board discretion in determining which crimes are substantially related on an individual basis. The commenters expressed concern that section 1770 does not include language stating that a licensee may not be denied a license based on criminal history (a conviction) or acts underlying the conviction if the applicant obtains a Certificate of Rehabilitation, is granted clemency or a pardon by a state or federal executive, dismissal per Penal Code section 1203.4 et seq., or an arrest that resulted in a disposition other than a conviction (including an infraction, citation, or juvenile adjudication) shall not be denied a license, as provided in B&P section 480, subdivisions (b) through (d).

Response to Comment 2: The Board rejected this comment. In response to the comment that section 1770 deems certain listed crimes to be substantially related without requiring the Board to consider those crimes on an individual basis, section 1770 lists those crimes in order to save the Board duplicative determinations in the case of crimes that would necessarily disqualify an applicant from licensure, for the reasons stated in the Initial Statement of Reasons, and to save applicants who have been convicted of those crimes the time and resources necessary to apply for a license.

In response to the comment that, in listing those crimes, Section 1770 does not state the exceptions set forth in B&P section 480 to the Board’s authority to deny a license based on a criminal conviction, the Board determined that the proposed text does not need to include the time periods already set out in statute [B&P section 480(a)(1)], or the above-described extenuating circumstances already set out in statute [B&P section 480(b)-(d)], as this information would be duplicative with statute. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).)

Additionally, the Board determined that within the disciplinary guidelines, the time passed since the act(s) or offense(s) and evidence of the case being set aside or dismissed are factors to be considered in denial and disciplinary proceedings.

Comment 3: Commenters again expressed concern that the proposed regulations do not include the 7-year washout period for consideration of convictions or discipline which are not statutorily considered serious felonies under Penal Code 1192.7.

Response to Comment 3: The Board rejected this comment. The Board determined that the proposed text does not need to include the time periods already set out in statute [B&P section 480(a)(1)] as this information would be duplicative. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).) Additionally, the Board noted that within the disciplinary guidelines, the time passed since the act(s) or offense(s) is a factor to be considered when determining penalties.

Comment 4: Commenters again expressed concern that the proposed regulations do not specify that a person with a criminal history shall not be denied a license on the basis of a conviction for which the applicant has obtained a Certificate of Rehabilitation, a conviction that has been dismissed per Penal Code section 1203.4, 1203.4a, 1203.41, or 1203.42, or on the basis of an arrest that led to a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or juvenile adjudication.

Response to Comment 4: The Board rejected this comment. The Board determined that the proposed text does not need to include whether the conviction has been dismissed, pardoned, etc., as this information would be duplicative with statute [B&P section 480(c)]. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).) Additionally, the Board notes that within the disciplinary guidelines, the time passed since the act(s) or offense(s) and evidence of the case being set aside or dismissed are factors to be considered in denial and disciplinary proceedings.

Comment 5: Commenters expressed concern that the proposed regulations do not to include that the Board shall not require an applicant to disclose any information or documentation regarding the applicant's criminal history.

Response to Comment 5: The Board rejected this comment. The Board determined that the amendments made to B&P section 480, subdivision (f)(2) already prohibit the Board from requiring an applicant to disclose any information or documentation regarding the applicant's criminal history. Including this requirement in regulation is not appropriate as it would be duplicative with statute. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).) In addition, inclusion of this requirement would not fall within the scope of the regulation, which establishes substantial relationship and rehabilitation criteria for the Board to consider after the Board already has knowledge of a conviction.

Comment 6: Commenters expressed concern that the proposed regulations do not include the requirement for the Board to notify the applicant in writing if the applicant is denied or disqualified from licensure. The commenters note that the Board must provide procedures describing the process for the applicant to challenge the decision or to request reconsideration, that the applicant has a right to appeal the Board’s decision, and the process of requesting a complete conviction history.

Response to Comment 6: The Board rejected this comment. The Board determined that notification requirements and the appeal process are already set forth in B&P sections 480, subdivision (f)(3), 485 through 487, and the Administrative Procedure Act, at Government Code section 11500, *et seq.*, including requirements for providing the legal and factual basis for the denial, service of the denial on the applicant, and notice to the applicant regarding the opportunity to request a hearing to challenge the decision. Including the process in regulation is not appropriate as it would be duplicative. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).)

Comment 7: The commenters indicated that the intent of AB 2138 was not to incorporate mere probation or parole reports into the occupational licensing determinations. Commenters indicated that looking to law enforcement will not adequately show how an applicant would do on the job. Rather, commenters state that rehabilitation can and does take many forms that extend beyond mere law enforcement supervision. To better define rehabilitation, commenters recommend that the Board provide examples of evidence of mitigating circumstances and rehabilitation efforts to assist both the Board and licensing applicants. The letter recommends that the Board consider adding the following rehabilitation criteria:

- Volunteer service;
- Successful employment in a related field;
- A history of work experience in an employment social enterprise.
- Unpaid work in the community;
- Furthered education;
- Abstinence from controlled substances and/or alcohol;
- Stability of family life, fulfillment of parental and familial responsibilities;
- New and different social and business relationships from those which existed at the time of the underlying charges at issue;
- Change in attitude of the applicant as evidenced by:
 - Personal testimony,
 - Evidence of rehabilitation submitted by the applicant,

- Evidence from family, friends, and/or other persons familiar with the applicant's previous behavior patterns and subsequent attitude and behavioral changes; and
- Other markers of rehabilitation.

Response to Comment 7: The Board rejected this comment. The Board determined that section 1769, subdivisions (b)(2)(F) and (c)(6) already require the Board to consider any evidence of rehabilitation submitted by the applicant or licensee, including as provided in the Board's disciplinary guidelines. The disciplinary guidelines already list various forms of evidence an applicant or licensee may choose to provide to show rehabilitation, and the Board believes that including a lengthy list of more examples, in section 1769, of evidence an applicant or licensee may provide to show rehabilitation—including the examples suggested by commenters—may result in misinterpretation by applicants, licensees, or others that the list is exhaustive. In addition, the Board believes it is misleading to say any one specific criteria in and of itself demonstrates rehabilitation.

Comment 8: Commenters expressed concern that the proposed regulations fail to include any mention of requirements to obtain statistical information on the number of applicants with a criminal record who apply and receive notice of denial/disqualification of licensure, provided evidence of mitigation or rehabilitation, the final disposition of the application, and demographic information, as provided in B&P section 480, subdivision (g).

Response to Comment 8: The Board rejected this comment. The Board determined that it is a requirement for the Board to maintain and post records on its website and as such, does not fall within the scope of the regulation, which would establish substantial relationship and rehabilitation criteria. Additionally, the Board notes that including this requirement in regulation is also not appropriate as it would be duplicative with statute [B&P 480(g)]. Regulations should not indiscriminately incorporate statutory language. (Gov. Code section 11349(f).)

At its May 7, 2020 meeting, after having considered the comment in the record and the recommended nonsubstantive changes, the Board adopted the amended regulation, as it was presented to the Board.