

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Partial Filling of Schedule II Controlled Substance Prescriptions; Unprofessional Conduct Defined; Criteria for Rehabilitation

Sections Affected: Amend § 1745 of Article 5 of Division 17 of Title 16 Cal.Code Reg.
Add § 1762 to Article 8 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1769 of Article 8 of Division 17 of Title 16 Cal.Code Reg

Introduction / Consumer Protection Enforcement Initiative:

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 Time 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.

Specific Purpose of the Proposed Changes:

Amend Section 1745:

Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations specifies under what circumstances a prescription for a Schedule II controlled substance may be partially filled, and the conditions that must be met when doing so. Currently, when partially filling a prescription pursuant to Section 1745, the pharmacist is required to record information in a readily retrievable form and on the original prescription document. In a practical application, the pharmacist records the information in an electronic prescription record maintained by the pharmacy, and also on the original prescription document maintained by the pharmacy. The Board’s proposal would allow the pharmacist to record the information required by Section 1745 in a readily retrievable form or on the original prescription document. Since the section became operative in 1992, pharmacies have increasingly utilized technology for the purpose of maintaining pharmacy and prescription records. The Board’s proposal will allow the

pharmacy to record information related to the partial filling of a Schedule II controlled substance in an electronic pharmacy record, without having to also record the partial filling on the original (hard copy) prescription document. This proposal would align California's regulation with federal regulatory requirements (Title 21 Code of Federal Regulations Section 1306.18) which allows for the recording of a partial fill of a Schedule II controlled substance to be on either the written or electronic prescription record.

Factual Basis/Rationale:

Existing regulation at Section 1745 of Title 16 of the California Code of regulations specifies the circumstances under which a prescription for a Schedule II controlled substance may be partially filled. This regulation became operative in 1992. The board has received requests to allow a pharmacy – when partially filling a Schedule II controlled substance – to record the date and amount that was partially filled in the pharmacy's electronic record, and not be required to also record that information on an original prescription document (hard copy). Since the section became operative in 1992, pharmacies have increasingly utilized technology for the purpose of maintaining pharmacy and prescription records. Likewise, current federal regulation at 21 CFR 1306.13(b) allows a pharmacy to document the partial filling of a Schedule II controlled substance either on an original prescription document or in the electronic prescription record. The Board's proposal will align California's regulation to federal regulatory requirements.

Add Section 1762:

Existing law at Business and Professions Code Section 4301 specifies acts that constitute unprofessional conduct and authorizes the Board to take action against any holder of a license that is guilty of unprofessional conduct. The Board's proposal would add a new Section 1762 to specify additional acts that constitute unprofessional conduct to include: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and would authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires such registration. This proposal would allow the Board to pursue regulatory action to assist with investigating and prosecuting complaints in a timely manner, and also would provide the Board with tools to improve the enforcement process and ensure patient safety.

Factual Basis/Rationale:

Since 2010, the Board has discussed topics related to improving the enforcement utilized by the board. In March 2010, Department of Consumer Affairs (DCA) developed a report (Department of Consumer Affairs "*Consumer Protection Enforcement Initiative BCP Independent Verification & Validation Report, March 2010*") regarding enforcement problems faced by healing arts boards and encouraged boards to pursue regulatory actions to ensure patient safety. The Board's proposal would implement provisions of the Department of Consumer Affairs' (DCA) Consumer Protection Enforcement Initiative relative to unprofessional conduct. In addition to the acts that constitute unprofessional conduct found at Business and Professions Code Section 4301, the Board's has determined it would be necessary to protect the public by taking action against the holder of any licensee who is guilty of the acts specified in its proposal. These additional acts include: gag clauses in a civil suit settlement; failure to provide information as requested by

the board; failure to comply with a court order or subpoena for records; and would authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires such registration.

Business and Professions Code Section 480 specifies grounds for which an applicant may be denied a license by the Board. The Board has determined that it is necessary to ensure the safety of the public and to further the DCA's Consumer Protection Enforcement Initiative, to specify additional grounds for which the board may revoke a license or deny an application for a license; specifically, the board has determined that the commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration of a sex offender, constitutes an act that may result in revocation of a license or denial of an application.

Business and Professions Code Section 726 specifies conduct, including sexual abuse and misconduct, that would constitute unprofessional conduct and grounds for disciplinary action for an individual licensed by the Board. The Board has determined that it is necessary to ensure the safety of the public and to further the DCA's Consumer Protection Enforcement Initiative, to also specify that the commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration of a sex offender, would also constitute unprofessional conduct.

Amend Section 1769:

Section 1769 of Article 5 of Division 17 of Title 16 of the California Code of Regulations specifies information that the Board will consider when evaluating the rehabilitation of an applicant and when considering the denial of a license under Section 480 of the Business and Professions Code. The Board's proposal would allow the Board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. This proposal is one measure in response to the DCA CPEI and would allow the Board to pursue regulatory action to assist with the investigation of an applicant for the purpose of ensuring patient safety. Specifically, the Board's proposal would provide the board with the authority to require an applicant for licensure to be examined by a physician and surgeon, or psychologist if the applicant appears to be unable to safely practice due to a mental illness or physical illness that affects competency. If the applicant does not comply with evaluation, the application will be deemed incomplete. The report of the evaluation would be provided to the applicant and the board is responsible for the cost of the examination. The Board's proposal would authorize the Board to deny the application if the evaluation demonstrates that the applicant is unable to safely practice.

Factual Basis/Rationale:

Since 2010, the Board has discussed topics related to improving the enforcement utilized by the board. In March 2010, Department of Consumer Affairs (DCA) developed a report (Department of Consumer Affairs "Consumer Protection Enforcement Initiative BCP Independent Verification & Validation Report, March 2010") regarding enforcement problems faced by healing arts boards

and encouraged boards to pursue regulatory actions to ensure patient safety. Existing law, Section 820 of the Business and Professions Code, authorizes the board to examine licensees for mental illness or physical illness affecting competency. In the past the board has experienced applicants demonstrating behavior that could potentially affect competency and could lead to unprofessional conduct endangering patient safety. The Board has experience with examination applicants who have displayed unreasonable anger and have endangered patient safety during the examination process. Currently, the Board is not authorized to further evaluate applicants who pass a licensure examination, even though they may demonstrate a physical or mental illness affecting the competency necessary to safely practice. This section would authorize the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice.

Business and Professions Code Section 820 permits the Board to order a licentiate to be examined whenever it appears that the licentiate may be unable to practice safely because he or she is impaired due to mental or physical illness affecting competency. The Board has determined that it is necessary to ensure the public safety and to further the DCA's Consumer Protection Enforcement Initiative to authorize the board to request that an applicant for licensure undergo an examination to determine if the applicant is safe to practice, if it appears the applicant may be unable to safely practice due to mental or physical illness affecting competency.

Additional Factual Basis:

Business and Professions Code section 4001.1 declares that the protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4300 specifies that every license issued may be suspended or revoked by the Board.

Business and Professions Code section 4301 authorizes the board to take action against any holder of a license that is guilty of unprofessional conduct, as specified.

Underlying Data

1. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Enforcement Committee Meeting held September 14, 2010
2. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held October 20, 2010
3. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Enforcement Committee Meeting held December 6, 2010

4. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held February 1, 2011
5. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held July 26-27, 2011
6. Title 21 Code of Federal Regulations Section 1306.13
7. Department of Consumer Affairs *“Consumer Protection Enforcement Initiative BCP Independent Verification & Validation Report, March 2010”*
8. Economic Impact Analysis

Business Impact

The Board does not believe that this regulation will have a significant adverse economic impact on businesses. With regard to the Board’s proposal to amend Section 1745, the Board’s proposal would align California regulation with federal regulatory requirements, thereby providing clarity and consistency as to how records of partially filled Schedule II controlled substances are made and maintained in a pharmacy licensed by the Board. The Board does not believe this will result in an adverse economic impact on pharmacies.

With regard to the Board’s proposal to add Section 1762, the Board does not believe its proposal would have an adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This determination is made because the proposed regulation would apply only to those individuals or entities licensed by the board that have engaged in acts specified in the proposal.

With regard to the Board’s proposal to amend Section 1769, the Board does not believe its proposal would have an adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This determination is made because the proposal would apply to individuals (not businesses) who apply to the Board for a license. Existing law allows the Board to require that a *licensee* be examined by one or more physicians and surgeons or psychologists if it appears that the licensee is unable to safely practice due to mental illness or physical illness affecting competency. The Board’s proposal would extend this authority to individuals (not business) / applicants who are seeking a license to be issued by the Board.

Benefits

Business and Professions Code section 4005 states that “the board may adopt rules and regulations....pertaining to the practice of pharmacy....” Further, Business and Professions Code 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 board believes the regulatory changes as described in the Notice will serve to protect the public health by clarifying the information that is made and maintained in a pharmacy with regard to partially filling a Schedule II Controlled Substance. The board also believes that the changes described in the Notice will serve to protect the public from harm by

improving the Board's ability to investigate and discipline errant licensees and applicants. The enforcement enhancements will also serve to protect the public from harm by furthering provisions in the DCA's Consumer Protection Enforcement Initiative.

Specific Technologies or Equipment

The Board's proposal does not specify or mandate the use of specified technology. Where the Board's proposal would allow for the electronic recording of a partially filled Schedule II Controlled Substance, the Board does not prescribe the technology or software that a pharmacy must utilize for recording information.

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that 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.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Not adopt the regulations. This alternative was rejected because the Board identified areas of concern regarding enhanced protection of consumers.
2. Adopt the regulations. This alternative was determined to be the most feasible because it will assist the Board in its consumer protection mandate.