

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy 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 of Pharmacy at its office not later than 5:00 p.m. on December 3, 2012.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 15 days before the close of the written comment period.

The Board of Pharmacy, 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 4005 of the Business and Professions Code; and to implement, interpret or make specific Sections 480, 726, 820, 4005, 4030, 4200, 4300, 4301, and 4400 of the Business and Professions Code, and interpret or make specific Sections 11055, 11153, 11154, 11166, 11200 of the Health and Safety Code, the Board of Pharmacy is proposing to amend Sections 1745 and 1769 of, and add Section 1762 to Division 17 of Title 16 of the California Code of Regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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.

For this purpose the Board of Pharmacy (“Board”) proposes to amend Section 1769 of, and add Section 1762 to Division 17 of Title 16 of the California Code of Regulations (“CCR”) to effect additional consumer protections through exercising its licensing, regulatory and disciplinary functions.

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. Thus, the Board proposes to add Section 1762 to Title 16 CCR. The additional acts that would constitute unprofessional conduct 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. In addition, the Board’s proposal 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.

Existing regulations at 16 CCR § 1769 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.

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. 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.

Consistency and Compatibility with Existing State and Federal Regulations

The Board has evaluated this regulatory proposal and has determined it is not inconsistent nor incompatible with existing state regulations.

The Board conducted a search of Title 21 Code of Federal Regulations (Food and Drugs), and has identified Title 21 CFR Section 1306.13 as a comparable regulation to the Board's proposal at Section 1745.

With regard to the Board's proposals at Section 1762 and 1769, related to the DCA's Consumer Protection Enforcement Initiative, the board searched Title 16 of the California Code of Regulations and found the following regulations that may be similar to the Board's Proposals:

"Unprofessional Conduct"

- 16 CCR § 317 – Board of Chiropractic Examiners
- 16 CCR § 3541, 3542, 1399.521, 1399.525 - Physician Assistant Committee
- 16 CCR § 1018.05 – Dental Board of California
- 16 CCR § 1376 – Medical Board of California
- 16 CCR § 1397.2 – Board of Psychology
- 16 CCR § 1399.24 – Physical Therapy Board of California
- 16 CCR § 1399.156 – Speech-Language Pathology Board
- 16 CCR § 1845, 1859, 1881 – Board of Behavioral Sciences
- 16 CCR § 2518.8 – Board of Vocational Nurse and Psychiatric Technician Examiners
- 16 CCR § 2857 – Bureau of Personnel Services
- 16 CCR § 4149 – Board of Occupational Therapy
- 16 CCR § 4260 – Naturopathic Medicine Committee

"Application Review and Criteria for Evaluating Rehabilitation"

- 16 CCR § 315 – State Board of Chiropractic Examiners
- 16 CCR § 1020 – Dental Board of California
- 16 CCR § 1399.507.5 – Physician Assistant Examining Committee of the Medical Board of California
- 16 CCR § 2509 – Board of Vocational Nurse and Psychiatric Technician Examiners
- 16 CCR § 4148 – Board of Occupational Therapy

Required Actions Against Sex Offenders

- 16 CCR § 1399.23 – Physical Therapy Board of California
- 16 CCR § 4148 – Board of Occupational Therapy
- 16 CCR § 1399.523.5 – Physician Assistant Examining Committee of the Medical Board of California
- 16 CCR § 2524.1, 2579.11 – Board of Vocational Nurse and Psychiatric Technician Examiners
- 16 CCR § 4256 – Naturopathic Medicine Committee

Anticipated Benefits of the Proposed Regulations: Please see “Benefits” below under “Results of the Economic Impact Analysis.” In coming to this conclusion, the board considered specific benefits anticipated by the proposed amendment of the sections described, including, to the extent applicable, nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government, among other things.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: For each individual 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, the Board may incur costs of approximately \$2,500.

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’s proposal at § 1745 would allow a pharmacy to record information in either an electronic record or a prescription record; they are currently required to record the information in both, so the Board’s proposal would reduce an entity’s workload associated with the recording of a partial filling of a Schedule II controlled substance.

The Board’s proposal at § 1762 does not place any requirements on or require a business to incur any costs does not place requirements on entities. Thus, the Board’s proposal would not result in any economic impact that would directly affect businesses, including the ability of California businesses to compete with businesses in other states.

The Board’s proposal at § 1769 does not place any requirements on or require a business to incur any costs associated with the examination that the Board would be authorized to require of an applicant and would result in no economic impact that directly affects businesses, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action. This determination is based on the fact that for an individual who is required to undergo an evaluation to determine if the applicant may be unable to safely practice due to mental illness or physical illness affecting competency, the cost of such an evaluation is paid by the Board.

Effect on Housing Costs: None

Small Businesses: The board's proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are "small businesses" as defined in Government Code Section 11342.610.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

The Board of Pharmacy conducted an Economic Impact Analysis (EIA) and has made an initial determination that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs, businesses or the expansion of businesses in the State of California.

The Board's proposed rulemaking will impact individuals and entities licensed by the board and may impact applicants for individual licenses 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...." As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that 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 proposed herein will serve to protect the public health by ensuring that applicants may be required to submit to an evaluation if it appears that the licensee is unable to safely practice due to mental illness or physical illness affecting competency; will authorize the board to revoke the license or deny the application of an individual who is required to register as a sex offender, as specified; and by establishing additional acts that constitute unprofessional conduct, for which the board may take disciplinary action.

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 or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

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 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 Web site <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 Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

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

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	Carolyn.Klein@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
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E-Mail Address:	Anne.Sodergren@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.