

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Ethics Course

Sections Affected: Amend 1773
Adopt 1773.5

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1773 of Division 17 of Title 16 of the California Code of Regulations to include completion of an ethics course that meets requirements as specified in 16 CCR section 1773.5 as a possible term of probation imposed on a pharmacist.

The board proposes to adopt Section 1773.5 of Division 17 of Title 16 of the California Code of Regulations to specify the ethic course requirements.

Existing regulation 16 CCR 1760 specifies that the board, in reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/2001), which are incorporated by reference in this section. These "Disciplinary Guidelines" provide for an ethics course, but does not address minimum requirements for the provider or course content.

The proposed regulation would specify all the criteria for an ethics course to include: duration; faculty; educational objective; method of instruction; content (background assessment, baseline assessment, participant's expectations, didactic presentation, experiential exercises, and a longitudinal follow-up); class size, evaluation; records; program completion; and change in course content or instructor.

Factual Basis/Rationale

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

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

California Code of Regulations section 1760 incorporates by reference the Disciplinary Guidelines.

The Board disciplines licensees for ethical violations and this proposal is necessary so that those licensees who are placed on probation will participate in an ethics course that is designed to rehabilitate them so that they do not repeat the violation.

This proposed regulation change would amend Title 16, CCR section 1773 to include completion of an ethics course as a possible term and condition imposed. Completion of an ethics course is not a new provision; it is currently incorporated in the board's Disciplinary Guidelines however currently there are no course parameters established to provide guidance to a probationer to assist them in identifying an acceptable course.

In addition, this proposal would create Title 16, CCR section 1773.5 that establishes the criteria for the ethics program. This section specifies the program duration as a minimum of 22 hours, requires that faculty be appropriately licensed, requires that the educational objectives be clearly stated and describes the methods of instructions. This section also details the content of the course, class size, evaluation method, records retention and notification of course completion.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board, that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements will better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary based on testimony received during the October 2007 Board Meeting. During this meeting the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethic course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

The board anticipates that an acceptable program will be structured similar to the detail below:

- Pre-program requirements
 - Background Assessment Application
 - Baseline Assessment of Knowledge Test
 - Reading Assignment
 - Participant Expectation of Program Statement
- Two-day Ethics Course
 - Case presentations
 - Break out groups
 - Experiential exercises
 - Role-playing
- Longitudinal Study
 - 6 month
 - 12 month

Underlying Data

1. October 24-25 Board Meeting Minutes
2. Institute for Medical Quality program brochure
3. California Code of Regulations section 1358.1
4. Disciplinary Guidelines

Business Impact

The board does not believe that this regulation will have a significant adverse economic impact on businesses as it only affects pharmacists that are disciplined for serious violations of pharmacy law.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The only alternative to this proposal is to continue to require completion of an ethics course that is unspecified. This alternative is not reasonable given that the board is unable to require program components that will provide the desired outcome; rehabilitation of behavior to prevent future violations of pharmacy law that result from unethical behavior. It would be contrary to the board's public protection mandate to not pursue the proposed change designed to allow the board better ensure the rehabilitation of pharmacists on probation with the board.

No reasonable alternative to amending the regulation would be either 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 than the repeal of the regulation.