

Board of Pharmacy

Final Statement of Reasons

Hearing Date: October 29, 2008

Subject Matter of Proposed Regulation: Ethics Course

Title 16 Sections Affected: Amend 1773
Adopt 1773.5

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein is updated as follows:

During the 45-day Comment Period which concluded October 20, 2008, the Board of Pharmacy (board) received a request that a hearing be conducted on the subject matter. The hearing was scheduled for and conducted on October 29, 2008, to coincide with the board's public board meeting in an effort to increase public awareness and seek comment.

Also during the 45-day Comment Period, a text modification was recommended to 1773.5. As a result, and following the board's October 29, 2008, hearing, the board issued on December 2, 2008, a notice of and provided modified text for a 15-day comment period. The specific text modified was changing the word "medicine" to "pharmacy" in 1773.5(a)(5)(B). No comments were received to this modification during the 15-day comment period which concluded on December 17, 2009.

Local Mandate

None.

Small Business Impact

The board has determined that this action will not have a significant adverse economic impact on small businesses. This determination was based on the absence of testimony indicating adverse economic impact regarding this rulemaking proposal during the regulation hearing held by the board and during the 45-day and 15-day comment periods. Likewise, the regulation is applicable only to pharmacists who are disciplined by the board, placed on probation, and ordered to take an ethics course as a condition of probation.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board 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 proposed regulation.

Specific Technologies or Equipment

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

Objections or Recommendations / Responses

The following recommendations, objections or comments were made regarding the proposed action.

Comments Received During 45-Day Comment Period:

The Board received the following comments during the 45-Day Comment Period:

Comments received from John A. Cronin, Pharm.D., J.D. Dr. Cronin testified at the public hearing held October 29, 2009, and provided the following written comments:

1. Dr. Cronin states he has no dispute with including an ethics course as an optional probation term in the board's disciplinary guidelines and can think of many circumstances where such a requirement would be a beneficial component of discipline. Nonetheless, he states the difficult part of this type of requirement is in the execution. He does not believe the specifics of the ethics course requirements in the proposed regulation are appropriate.

Board's Response

The Board appreciates Dr. Cronin's support of an ethics course as an optional probation term within the board's disciplinary guidelines. The board however disagrees with Dr. Cronin's comment that the specified ethics course requirements are not appropriate. In 2007, the board established a subcommittee to review this issue and to provide recommended course requirements. Based on that subcommittee's research and recommendation, the board voted to adopt the course requirements which include direct contact hours to allow for case presentations, group discussion, and experiential exercises; and role-playing to ensure sufficient time to discuss and evaluate situations. The board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decision(s) that led to the violation(s) and ultimate referral to the program as well as longitudinal studies that occur post-classroom

instruction. The 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 that may result from unethical behavior. While Dr. Cronin states the specifics of the ethics course requirements may not be appropriate, he does not make a recommendation as to what would be appropriate. The board believes that the specified ethics course requirements as stated in the regulation and passed by a vote of the board are appropriate as an optional term of discipline.

2. Dr. Cronin refers to the regulation language as a "one size fits all" approach to an ethics course requirement and implies a lack of flexibility in the course criteria. He further states that the board does not provide a good reason why EVERY violation that will trigger this probation term should require a 22-hour ethics course or why all licensees who have this term imposed should be subject to a 6- and 12-month longitudinal follow up. He states the appearance drawn from the proposed language is that the board has essentially copied the language adopted by the Medical Board and that the Board of Pharmacy has not given significant consideration to this new probationary term.

Dr. Cronin states this probation term should not be seen as the same for physicians and pharmacists. He further states the need for an ethics course cannot be identical for the broad spectrum of violations of pharmacy law for which this requirement can be imposed. He states the specifics of the course cannot be the same for violations of controlled substance law as they are for violations of the unfair trade practices laws. He states that by adopting a fixed and inflexible set of criteria for the ethics course, the board is compromising the utility of such a course as a tool in discipline. He asks that the board give more consideration to 'this proposed approach' before adopting any regulation detailing the criteria for ethics courses.

Board's Response

Dr. Cronin's comment appears to assert that the board has not given significant consideration to this new optional probationary term. On the contrary, the board established a subcommittee in April 2007 to examine the development of an ethics course. Since that time, the subcommittee has met with ethicists, has reviewed the ethics course used by the Medical Board, and the board has heard testimony from a course provider. Through these communications, the subcommittee and the board have determined that the development of a course "similar" to that of the Medical Board's course would be able to address ethics-related violations of disciplined pharmacists.

The board believes that the proposed regulation provides an adequate framework in which an ethics course can be developed and administered utilizing information that is relevant and related to violations that result in the administrative action against a pharmacist license. One goal of an ethics course is to teach ethical decision making. It is unreasonable and unnecessary to individualize an ethics course for every participant. The

goal of the program is to achieve behavior change to ensure that the individual makes better choices and decisions in the future, not just to prevent the same violation from occurring.

Further, the regulation does not limit the board to the approval of only one ethics course. The proposed regulation provides the board with the authority to approve any course developed by a provider that satisfies that course criteria detailed in the proposed regulation.

The board believes the components of an ethics course, as proposed, are sufficient to ensure that a participant's unique circumstances are addressed.

3. Dr. Cronin reflects on a presentation made at the Board of Pharmacy's January 2007 board meeting by Lorie Rice, former Medical Board member, and expressed concern about how to apply various criteria. He reiterated that Ms. Rice stated the Board of Pharmacy needed to consider for its ethics course what types of cases would be referred, what criteria would be needed to assess rehabilitation, redemption and contrition, and how to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee's action on society and how it impacted patients.

Board Response

This comment by Dr. Cronin appears to be rhetorical and it is uncertain what Dr. Cronin is asserting in this comment. However, the types of cases that may result in referral to an approved ethics course will be only those in which a pharmacist is serving a period of probation as a result of a formal disciplinary action or order of the board. The board does address various categories of violations as well as recommended discipline for those violations in its disciplinary guidelines.

The board believes that the content specified in 16 CCR 1773.5 provides an acceptable scope by which the board will consider and approve a provider of an ethics course which will assess a participant's rehabilitation, redemption and contrition, as well as how a participant may build skills involving empathy, focus on the impact of the participant's actions, as well as the impact to patients.

4. Dr. Cronin states there is a clear difference in how those factors [*see comment #3*] would be applied to physicians versus pharmacists. He states the language in the referenced Disciplinary Guidelines gives little indication of what violations or cases would trigger the requirement for the optional term of having to complete an ethics course. He states that he expects the requirement of an ethics course would be imposed more frequently by the board than initially expected, and that the requirement to complete an ethics course as part of discipline could easily expand until it becomes a "standard optional" term for probation in disciplinary actions or for abatement in cite and fine cases.

Dr. Cronin states that the broad application of this requirement calls for additional guidance from the board members as to how and when an ethics course should be required.

Board Response

The board's disciplinary guidelines generally describe violations to determine a potential for harm to patients and public safety. These guidelines state that in addition to the various categories of offenses, the board may impose those "... *optional terms and conditions as appropriate.*" The ethics course is identified as an optional term and condition for those serving a probationary period. To require the ethics course as a standard term and condition would require a regulation change, at which time Dr. Cronin as well as all other interested parties would be afforded the opportunity to provide comments on the proposed change. Additionally, each administrative action is different and the terms and conditions of probation likely vary for each. Through the administrative disciplinary procedure, the board will consider a case's specific violations and/or crimes and circumstances to determine if an ethics course is required as part of an order or a settlement agreement.

The board has made no representation as to how frequently it will impose an ethics course as an optional term of probation. However, in fiscal year 2007/08, only seventeen out of the more than 35,000 licensed pharmacists were placed on a period of probation resulting from an administrative action or order of the board. It is these administrative cases in which an ethics course would be an optional term and condition of probation. The use of the ethics program does not expand outside of the disciplinary guidelines.

5. Dr. Cronin states that ethics violations vary, as do the reasons for the violations. He states that while an ethics course may be an appropriate requirement for rehabilitation, the specifics of that course will be equally varied and he is concerned about the duration and content of the course criteria proposed. He states that the framework of the ethics course as proposed will be appropriate and needed for some violations, but that it will not be for other violations. He states that while the proposed language is vague, it is sufficiently detailed to limit the number of eligible courses that the board could approve and the number of providers who could develop approvable courses. He states he is of the understanding that the board currently has only one contractor with only a single ethics course under development. He asserts this can hardly provide the variety needed for effective implementation of the ethics course requirement.

Dr. Cronin states that a more open approach to approval of ethics courses is needed. He states there is no reason why a properly structured and focused course, regardless of its length, could not satisfy the need for ethical consideration and training to which the requirement is directed. He states that courses can be developed to address some or all of the violations for which an ethics course is required.

Board Response

The board agrees with Dr. Cronin's comment that the framework of the ethics course as proposed will be appropriate. However, the board does not agree that the regulation limits the number of courses that the board could approve. Proposed regulation § 1773.5 states the minimum requirements of an ethics course that the board must consider for approval – it does not state any limit as to how many courses the board may approve.

The board will not be contracting out for this course and will work with any course provider that is approved by the board. The work group established by the board did communicate with the provider of the Medical Board's ethics course and the board did hear testimony from Lorie Rice who was associated with the Medical Board's ethics course, as part of its research into the development of this regulation.

6. Dr. Cronin states the Board needs to address the cost for the courses. He stated a pharmacist would incur not only the cost of the two-day course identified (he referenced the Institute for Medical Quality program used by the California Medical Board), but a pharmacist may also incur additional costs to take time off work to attend the course, as well as the 6- and 12-month follow up sessions that may be required. He states that while imposing this level of costs may be acceptable in many circumstances, the Board needs to carefully consider whether the value received by the public from an ethics course (as proposed) is worth the imposition of the cost. He states an alternative would be to make sure that the costs paid by licensees as part of the disciplinary process truly provides equivalent benefit to the public.

Board Response

The board recognizes that the cost of an ethics course will be borne by the participant. In a formal administrative disciplinary action, the board utilizes various categories of violations and recommended penalties (described in the board's disciplinary guidelines). Those guidelines iterate the board's belief that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole. Section 4001.1 states that protection of the public shall be the highest priority of the board in exercising its licensing, regulatory and disciplinary functions.

7. Dr. Cronin asks that the Board look into the ethics course requirement further with the goal of identifying 'classes' of violations which would trigger a requirement for an ethics course. For each class of violation, identify the type of remediation sought from taking an ethics course and identify the criteria needed to achieve the remediation sought. Also, Dr. Cronin requests that the board identify the sources that are available for providing appropriate ethics courses and craft regulation language that accommodates the variety of options that result.

Board Response

The Disciplinary Guidelines establish the possible violations and appropriate penalties for such violations. Dr. Cronin's comments about identifying "classes" of violations are outside the scope of this regulation. Also, as stated previously, the board will work with any source (course provided) that establishes a course meeting the criteria established in this regulation that is approved by the board.

The Board received the following comments at the regulation hearing held October 29, 2008.

Verbal comments received from Lynn Rolston, California Pharmacy Association (CPhA).

1. Ms. Rolston stated that CPhA is in support of the comment submitted by Dr. John Cronin.

Board Response

The board acknowledges Ms. Rolston's comments as they relate to those of Dr. John Cronin. Dr. Cronin's comments are included above along with board responses.

2. Ms. Rolston stated that at an earlier board meeting, CPhA had requested that a task force meet at the next regularly scheduled Enforcement Committee meeting to discuss citations and fines, adding that the purpose of the task force would be to discuss which violations essentially triggered which fines, for example. She stated this type of information would allow for clarity as CPhA puts out communication to their licensees advising them of the change in board policy with regard to additional citations and larger fines because of changes in the law.

Board Response

This comment is outside the scope of this regulation. This regulation is establishing the requirements for an ethics program as an optional term and condition or probation.

3. Ms. Rolston stated that CPhA neither supports nor opposes the regulation as it is proposed.

Board Response

The board acknowledges Ms. Rolston's statement that CPhA neither supports nor opposes the regulations as proposed.

4. Ms. Rolston stated that CPhA believes that utilizing an ethics course in the case of certain violations, under certain circumstances, is a fine idea and could provide a lot of merit and

that – from that standpoint – CPhA supports the regulation. She stated, however, that there is a lack of clarity in regards to when it would be applied.

Board Response

The board agrees with Ms. Rolston's comment that an ethics course, under certain circumstances, could provide merit. The scope of this regulation is to establish the criteria for an ethics course - - the board's Disciplinary Guidelines establish the possible violations and appropriate penalties for such violations. Ms. Rolston's comments about identifying "classes" of violations are outside the scope of this regulation.

Verbal comments received by Lorie Rice, UCSF School of Pharmacy

1. Ms. Rice stated that the UCSF School of Pharmacy strongly encourages the adoption of the regulations as proposed. She commented on her tenure as the Board of Pharmacy's Executive Officer (when such a course was not available) and stated she felt such a course would have been helpful. Ms. Rice stated her background as a member of the Medical Board and that she chaired that board's ad hoc committee on ethics, which resulted in the passing of a 2006 regulation which created an ethics program for physicians.

Board Response

The board appreciates Ms. Rice's support of the proposed regulations.

2. Ms. Rice stated she discussed at a 2006 National Association of Boards of Pharmacy (NABP) District 7 and 9 Annual Meeting the creation of an ethics program for pharmacists, and that in January 2007 she made a similar presentation to the California Board of Pharmacy. Ms. Rice stated she would provide the board with a copy of her speech to the NABP. Ms. Rice stated that she believes there is an important point of differentiation between a pharmacist error and that of a willful ethics violation. She stated that in her opinion the board's disciplinary guidelines adequately address pharmacist errors but do not respond to ethical violations, which can range from dishonesty, inappropriate exhibition of rage, fraud, cheating on exams, etc.

Board Response

The board agrees with Ms. Rice's statement.

3. Ms. Rice stated that the creation of an ethics program will give the board the tools needed to understand a pharmacist's insight into his/her conduct and assist in the assessment as to whether an incident was aberrant or a "character defect." She stated that evaluation of an ethics program will give the board more information in determining whether education and greater sensitivity will turn the pharmacist around or whether to expect a repeat of the same violation.

Board Response

The board agrees with Ms. Rice's statement.

4. Ms. Rice provided background on the number of physicians that were referred to the Medical Board's ethics program since its creation (2006) and that the program had not yet been in existence for a sufficient period of time for a comprehensive evaluation. She stated that she was requested to provide testimony following Ms. Lynn Rolston because she was aware of some of the comments Ms. Rolston would be making. She added that the idea of narrowing the board's flexibility down to determine which violations can result in referral to an ethics program is an insurmountable task. She stated that the task force of the Medical Board's program began to approach the concept of determining which specific violations would require an ethics program, and they found it was impossible. She stressed that flexibility is needed and that if you narrow down the categories of what would be considered ethics violations, then it would take away the board's ability for appropriate discipline.

Board Response

The board thanks Ms. Rice for the background information related to the Medical Board's ethics program.

5. Ms. Rice commented on the number of ethics programs currently in existence, likening them to "traffic schools" with no evaluation of the appropriateness of the licensee's attendance, success of the program, etc. She stated that the board's proposed regulations are perfect. She concluded by urging the board to pass the regulation as written.

Board Response

The board appreciates Ms. Rice's comment regarding the quality of the proposed regulations.

Verbal Comments from Steven W. Gray, Pharm.D., JD, Kaiser Permanente

1. Dr. Gray stated that, on behalf of Kaiser, it is important to have the availability of ethics training. He stated that in many professions ethics training has shown its worth over time.

Board Response

The board appreciates Dr. Gray's comments in support of having ethics training for pharmacists.

2. Dr. Gray stated that proposed regulation § 1773.5 appears to apply to a pharmacist and intern pharmacist, where proposed regulation § 1773 appears to apply to pharmacists only. He stated that the board may want to determine if both sections should apply to pharmacists, intern pharmacists, and technicians as well. He stated that the board may wish to consider an ethics course for owner-operators, in that pharmacists-in-charge take direction from owner-operators and that the latter can interfere with the pharmacist-in-charge and the appropriate performance of their duties.

Board Response

The board chose to address an ethics course as it relates to a pharmacist or intern pharmacist, as stated in proposed regulation § 1773.5. The board will consider an amendment at a later date to amend § 1773 to specifically include other license type references if appropriate. However, Business and Professions Code § 4300 (a) currently provides for the disciplinary proceedings of every license issued by the board and that such discipline may include placing him or her upon probation.

3. Dr. Gray stated that testimony he has heard thus far appears to apply to those who have been found to be unethical in the context of fraud, for example, and that there is a bigger issue where the pharmacists need training as far as professional clinical ethics when they have two options – one being regulatory and the other being their professional duty to care for the patient.

Board Response

Dr. Gray's comments focus of when the ethic course will be used. This regulation establishes the criteria for an ethics program. The board's Disciplinary Guidelines establish the possible violations and appropriate penalties for such violations, including the requirement for an ethics course. As stated in previous responses, through the administrative disciplinary process, the board will consider each case's specific violations and/or crimes and circumstances to determine if an ethics course will be required as an optional term or condition of probation as part of an order or a settlement agreement.

Comments Received During the 15-day Comment Period

No comments were received during the 15-day comment period: December 2 to December 17, 2008.