

BOARD OF PHARMACY

Final Statement of Reasons

Subject Matter of Proposed Regulations: Quality Assurance Programs

Sections Affected: Title 16, Section 1711

Hearing Date: April 26, 2001

Updated Information

The proposed regulation was changed by the board during the April 26, 2001 regulation hearing. Those changes were subject to a 15-day notice and the revised text is summarized below.

Section 1711 would be added.

Subdivision (a) requires pharmacies to establish quality assurance programs consistent with this section.

Subdivision (b) defines medication error.

Subdivision (c) requires pharmacies to have written policies and procedures describing the quality assurance program. This subdivision also requires that information regarding the error and corrective actions are communicated to the subject of the error and the healthcare team.

Subdivision (d) requires quality assurance programs to have a process to detect medication errors. It further requires that an investigation of the error commence as soon as possible. Lastly, if the investigation indicates that the error is attributable in whole or in part to the pharmacy or its personnel a quality assurance review must be performed.

Subdivision (e) specifies the minimum elements required in a quality assurance review to include an investigation and documentation of the error.

Subdivision (f) requires that records relating to the quality assurance review must be retained in the pharmacy for one year.

Subdivision (g) prohibits the discovery of the proceedings or records in a quality assurance review.

Subdivision (h) requires the board to consider compliance with the quality assurance program as a mitigating factor in an investigation.

Subdivision (i) permits pharmacies to contract with third parties to perform quality assurance reviews.

Subdivision (j) specifies that this section becomes operative on January 1, 2002.

Summary of Comments Received During the 45-Day Comment Period (May 12, 2000 to June 26, 2000)

1. In a letter dated April 5, 2001, Ms. Astrid G. Meghrihan, Legal Counsel for the California Medical Association (CMA), made several comments.

Ms. Meghrihan stated that the CMA opposes the definition of “medication error” in the proposed regulation. The CMA believes the proposed definition is overbroad and would result in the wasteful investigation of errors unrelated to patient safety. The CMA advocates adopting a definition similar to the definition of a “sentinel event” which is:

“... an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof....the phrase of “the risk thereof” includes any process variation for which a reoccurrence would carry a significant chance of a serious adverse outcome.”

The definition of “medication error” in the proposed regulation reads as follows:

“...any act or omission in the dispensing process that may cause or lead to patient harm. Medication error, as defined in this section, does not include any act or omission that is corrected prior to furnishing the drug to the patient or patient’s agent.”

The board responds that the sentinel event definition is inadequate because it fails to require review of “near miss” events where a potentially harmful error occurs but patient harm is avoided by luck. Evaluating every medication error, regardless of its consequences for the patient, is essential to a quality based approach to error reduction. Errors that may not cause harm to an otherwise healthy adult patient can be fatal to children, seniors, or individuals with other complicating health conditions. By this standard, the definition of “medication error” in the proposed regulation is inadequate, and the board altered the definition to encompass any deviation from the prescription in the drugs dispensed to the patient that is not authorized by law.

Ms. Meghrihan stated that the CMA opposes provisions requiring pharmacists to communicate details of any medication error to the patient. Instead, the CMA argues that the patient need only be notified if it is necessary to protect the patient’s well being. In addition, the communication with the patient should be limited to the occurrence of the medication error and any steps needed to remedy it. The CMA also opposes the requirement that the pharmacist communicate the medication error to the prescriber and other members of the health care team as appropriate.

The board responds that patient and prescriber notification are essential. Medication errors can have serious health consequences for patients (both through the direct effect of the drug and through the consequences of not being treated with the correct drug). Patients have a right to this information and pharmacists have a professional, moral and ethical obligation to take whatever steps are required to prevent harm to their patients. Furthermore, prescribers need to be informed so that the prescriber can assess the impact of the error on the patient's condition and the consequences for the patient's course of treatment.

Ms. Meghriyan stated that the CMA wants the regulation amended to prohibit any participant from voluntarily testifying in a court of law. The proposed regulation should prohibit any person participating in a quality assurance review from being compelled to provide testimony in a court of law.

The board responds that such an amendment exceeds the board's rulemaking authority. The statute requiring adoption of these regulations provides for a limited exception from discovery that does not extend to prohibiting voluntary speech.

2. In a facsimile dated April 9, 2001, Steven W. Gray of Kaiser Permanente (Kaiser) made several comments.

Mr. Gray stated that Kaiser opposes the requirement that records of quality assurance reviews be retained for three years. Kaiser believes that the three year requirement is unduly burdensome and exposes the pharmacy to excessive risk. Kaiser proposes that records be retained for six months.

The board responds that the record retention period has been reduced to one year. This is the shortest reasonable time period that is consistent with the board's need to enforce the quality assurance program mandate.

Mr. Gray stated that Kaiser requests that the proposed regulation be clarified to establish that the board may not remove quality assurance review documents from a pharmacy.

The board responds that existing law (Business and Professions Code Section 4332) permits board inspectors to remove documents related to the acquisition and disposition of dangerous drugs or dangerous devices. Prohibiting the board from obtaining quality assurance documents (directly related to the disposition of dangerous drugs and dangerous devices) would conflict with that statute.

Mr. Gray stated that Kaiser requests that the proposed regulation be amended to restrict access to the quality assurance records to the board.

The board responds that this request is inconsistent with the underlying statute. Senate Bill 1339 (Chapter 677, Statutes of 2000) specifies that both the board and other

government agencies with jurisdiction over the pharmacy can review the records to protect the public health and safety or if fraud is alleged.

3. In a letter dated April 9, 2001, John A. Cronin, General Counsel for the California Pharmacists Association (CPhA), made several comments.

Mr. Cronin states that the CPhA opposes the existing regulation and requests changing the definition of “medication error” to that used in the Institute of Medicine study *To Err Is Human*. That study defines error as “a failure of planned action to be completed as intended.” The CPhA believes the definition in the proposed regulation is overbroad.

The board responds that the definition of “medication error” proposed by Mr. Cronin is substantially broader than that used in the proposed regulation. The board agrees that the proposed definition is inadequate and has changed the definition. The board altered the definition to encompass any deviation from the prescription in the drugs dispensed to the patient that is not authorized by law.

Mr. Cronin states that the CPhA opposes the requirement that pharmacists communicate with the patient and prescriber regarding a medication error. CPhA believes that communication needs to be tailored to the individual situation and should not be specified in regulation.

The board responds that patient and prescriber notification are essential. Medication errors can have serious health consequences for patients (both through the direct effect of the drug and through the consequences of not being treated with the correct drug). Patients have a right to this information and pharmacists have a professional, moral, and ethical obligation to take whatever steps are required to prevent harm to their patients. Furthermore, prescribers need to be informed so that the prescriber can assess the impact of the error on the patient’s condition and the consequences for the patient’s course of treatment. The board has altered the notification requirement so that regulation simply requires that the pharmacist make the notification. It does not specify the content or manner of notification other than to require disclosure of the error and actions that are needed to mitigate the error.

Mr. Cronin states that the CPhA opposes the inclusion of essential cause examination. The CPhA believes that the requirement is excessively burdensome.

The board responds that evaluating systems and processes in the pharmacy is the key element of any error reduction strategy. In deference to the concern raised here, the “essential cause examination” was removed and pharmacies are permitted to develop their own tools in making those system and process evaluations.

Mr. Cronin states that the CPhA opposes the retention of quality assurance review documents for three years and cannot see any need to retain these records for that length of time. The CPhA requests a one year record retention requirement.

The board responds that the comment is appropriate and the regulation has been changed to require a one-year retention period.

Summary of Comments Received During the Public Hearing April 26, 2001.

1. Mr. Bruce Young, representing the California Retailers Association, made a number of comments on the proposed regulation.

Mr. Young stated that those who report errors must feel safe to report them in a confidential non-punitive environment with legal protection, and that the focus should be on lessons learned from quality assurance programs rather than seeking a mandate to punish pharmacies and pharmacists.

The board responds that the regulation does not seek a mandate to punish pharmacies and pharmacists. The regulation does not require reporting errors to the board. It requires that the fact that a pharmacy or pharmacist fulfilled the quality assurance mandate mitigate any enforcement action taken against the licensee by the board. Furthermore, the board provided numerous assurances during the hearings on this regulation that the quality assurance program will not be used to ferret out additional medication errors for enforcement action. The purpose of this regulation is to require pharmacies and pharmacists to engage in thoughtful, systematic study of medication errors in their pharmacy and use that study to improve the pharmacy's systems and processes.

Mr. Young noted that it should be conveyed to pharmacies that this regulation would not be used in a punitive fashion or as punishment, but more to avoid repetition of errors.

The board responds that the proposed regulation has been modified to state the intent of the board. In addition, the board will communicate that intent in both its newsletter distributed to all licensees of the board and in the Health Notes monograph that the board is commissioning on quality assurance.

Mr. Young asked the board to consider inviting Mr. Michael Cohen of the Institute of Safe Medication Practices to the July board meeting to advocate his position of a blameless environment. He asked the board to examine the regulation more carefully and postpone action until the July hearing. He asked the board to consider developing a position whereby pharmacists and pharmacies are not punished for mistakes.

The board responds that it concurs with the need for a "blameless" environment for medication error reduction. The board further responds that Mr. Cohen or any other member of the public is always welcome to present testimony to the board.

However, because the board is adopting a regulation that does not impose “blame” on pharmacies and pharmacists that engage in thoughtful, systematic quality assurance programs, there is no need to delay the regulation any further.

Mr. Young expressed concern that inspectors might review quality assurance programs and initiate investigations from this data that would lead to discipline by the board.

The board responds that such activity is inconsistent with board policy. The documentation required as part of the quality assurance program exists merely to document the pharmacy’s full compliance with the quality assurance regulation. The board intends to take strong enforcement action against licensees that fail to fulfill the quality assurance mandate established by SB 1339. Furthermore, the board provided numerous assurances during the hearings on this regulation that the quality assurance program will not be used to ferret out additional medication errors for enforcement action.

Mr. Young asked the board to insert this intent language in the regulation. Mr. Young stated that there is concern and fear that pharmacies will be written up for medication errors. Mr. Young further indicated that this concern is based on the perceptions of pharmacists not the text of the regulation. He further added that the mitigation language proposed in the amendments presented at the hearing does help address this concern.

The board responds that it will take every reasonable step to communicate its intent with this regulation to its licensees. This will include articles in the board’s newsletter, “The Script,” as well as publishing a special monograph with details about the regulation and quality assurance in health care settings for pharmacies and pharmacists. Furthermore, the board holds two public meetings each year to discuss enforcement issues with the public and the quality assurance regulation will certainly be a major item of discussion at those meetings which are open to full participation by any member of the public. The board further responds that it recognizes the fear created by the cultural change required by this regulation and it will remain active in supporting that cultural change.

2. Ms. Teri Miller, representing the California Society of Health System Pharmacists, made several comments regarding the proposed regulation.

Ms. Miller referred to item (b) and the new definition of medication errors. She referred to the California Medical Association’s recommendation to adopt a definition similar to “sentinel event” used in the hospital environment because of the potential to cause major harm or death to a patient.

The board responds that the definition of sentinel event requires connection to patient harm. The board believes that it is essential to examine all errors. The same

error can result in disparate outcomes because of its context. This is particularly true when considering children and seniors to whom standard adult dosages can be fatal. Furthermore, comments received from Albertson's preferring the examination of all errors regardless of patient harm reinforces the board's position.

Ms. Miller referred to section (e) and the removal of the "essential cause examination" definition. She added that the focus should be on systems and process improvements rather than individuals

The board responds that it agrees with Ms. Miller's comment in this regard and the "essential cause examination" language has been removed in favor a general requirement of evaluating systems and processes.

3. Mr. Phil Burgess, representing Walgreens, made several comments on the proposed regulation.

Mr. Burgess stated that pharmacy errors and other medical errors are not intentional acts and should be treated accordingly.

Mr. Burgess stated that efforts to improve medical errors require a non-punitive, blame-free approach that does not use sanctions or punishment against health care providers or professionals.

Mr. Burgess stated that each pharmacy operation is unique and, therefore, must be allowed to develop and implement quality assurance programs that are distinct to each pharmacy's practice setting so that quality improvement efforts can be successful.

The board responds that it agrees with this comment and has intentionally drafted this regulation to permit each pharmacy to develop its own quality assurance process. This approach permits the tailoring of a quality assurance system to the circumstances of the particular pharmacy and also provides each pharmacy with the freedom to find innovative solutions.

Mr. Burgess stated that promoting the lessons learned from quality assurance programs is a better approach to patient safety than mandating error-reporting programs.

The board responds that it agrees with this comment and has chosen not to pursue mandatory reporting of errors to the board or any other entity. The board has moved forward with this proposal that requires pharmacies to undergo the self examination and study required to learn from the errors that do occur.

Mr. Burgess stated that if the board intends to use this program as mitigating circumstances, it should change "may" to "will" in subsection (i). He added that

this would encourage pharmacists' cooperation.

The board responds that it agrees with Mr. Burgess' comment and the language has been changed to reflect that comment.

4. Mr. John Cronin, California Pharmacists Association, provided several comments on the proposed regulation.

Mr. Cronin stated that the definition of medication error should incorporate the concept of an error.

The board responds that the definition does incorporate the concept of error.

Mr. Cronin stated that the record retention requirement is not necessary.

The board responds that the record requirement is necessary to document compliance with the quality assurance requirement. Without documentation, the board has no method to verify that the pharmacy has fulfilled its obligations under the law.

Mr. Cronin stated that the regulation is too complicated for the problems the board is describing. He requested that the board simplify the regulation.

The board responds that the regulation is designed to provide pharmacies considerable freedom to design a system that is appropriate for their particular circumstances. Mr. Cronin's general concern regarding the "complexity" of the regulation is difficult to respond to without reference to specific items that are too "complex."

5. Mr. Steve Gray, representing Kaiser Permanente, provided several comments on the proposed regulation.

Mr. Gray stated that a change to the definition as described in the proposed regulation would be problematic for any other variations that might be authorized by law. Mr. Gray referred to SB 340 (Chapter 631, Statutes of 2001) which allows pharmacists to change the form of medication independently. Mr. Gray suggested that the board use "any other variation or change allowed by law," rather than referencing section 4073.

The board responds that Mr. Gray's comment is appropriate and the regulation has been changed to reflect it.

Mr. Gray added that his second concern is the length of time a pharmacy must retain records. Mr. Gray further stated that the issue of protection is serious because the board wants to encourage pharmacists to participate. Mr. Gray further stated that

the records need to be retained only until the board determines there is a viable program.

The board responds that Mr. Gray's comment is appropriate and the record retention period has been reduced from three years to one year.

Mr. Gray stated that there is no protection for pharmacy error records in federal law.

The board responds that Mr. Gray's comment is accurate, but it is beyond the board's authority to address that issue in this regulation.

Mr. Gray stated that a licensing board could only review confidential patient information on site, unless the board has the patient's permission. He added that the proposed language misleads pharmacists into thinking an inspector can take records from the pharmacy when this would violate the Medical Confidentiality Act.

The board responds that existing law (Business and Professions Code Section 4332) gives the board authority to obtain documents related to the acquisition and disposition of dangerous drugs or dangerous devices. Furthermore, Section 56.10 (b) (2) specifically requires health care providers to disclose medical information to a "board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority."

6. Ms. Orriette Quandt, representing Longs Drugs, made several comments on the proposed regulation.

Ms. Quandt stated that Longs supports Mr. Young's comments that this regulation should not be used in a punitive fashion, but to avoid repetition of errors.

The board responds that the regulation is not a "punitive" regulation. Instead it is a major consumer protection regulation. It requires pharmacies to engage in the systematic study of errors that occur in that pharmacy and apply any lessons learned to improve its systems and process to prevent recurrence. The regulation states plainly that it is intended to reduce the frequency of medication errors.

Ms. Quandt stated that Longs also supports the comments regarding the need for simplicity in the regulations. There are many different types of pharmacies in California with each being unique in its practice. She added that because of the uniqueness, pharmacies need the ability to develop their own quality assurance programs.

The board responds that it agrees with this statement. The regulation is drafted to permit each pharmacy to develop its own quality assurance system or to participate in a larger quality assurance system by its parent organization (i.e., hospital, corporate owner, cooperative system). The regulation also permits pharmacies to

contract with other third parties to conduct its quality assurance program.

She added that although the new proposed language is an improvement over the previous language, it could be simplified even more to allow the uniqueness of each type of practice.

The board responds that it is difficult to respond to this comment without reference to specific aspects of the regulation that could be altered to increase its adaptability to “unique” circumstances.

Ms. Quandt referred to (e) (1) that states “the date of, location, and participants in the quality assurance review conducted,” and she noted that an independent pharmacist would review his or her own program.

The board responds that pharmacists may well participate in the quality assurance process in their own pharmacy. The regulation simply requires that a process exist and be followed when a medication error is discovered. In a small independent pharmacy with only one pharmacist this is almost a certainty rather than a possibility. The board does not see the participation of the involved pharmacist as a problem. The important element is the examination of systems and processes in the pharmacy that may be improved to reduce the likelihood of an error’s recurrence. In many cases, the pharmacist involved in the error is one of the best individuals to participate in the review because of his/her knowledge of the error at hand.

She referred to a letter dated February 6, 2001, from Longs Drugs that included proposed language for the regulation. She stated that the language was not included in the board packet. She added that Longs’ proposed language simplified the regulation and made it easier to understand.

The board responds that the comments submitted by Longs Drugs on February 6, 2001, were based on the draft released for the informational hearing held at the January 2001 board meeting and predate the publication of the notice of proposed action on the subject of this rulemaking file. Those comments were reviewed by the Legislation and Regulation Committee prior to the publication of that notice. The letter referenced by Ms. Quandt was not included in the board packet because it did not address the draft of the regulations being considered by the board in this hearing.

Ms. Quandt referred to the last paragraph in section (e), “The pharmacy shall inform all personnel that the review process is completed.” She questioned whether this needs to be done after every prescription error or only in those instances where there are changes that need to be made.

The board responds that notification of pharmacy personnel is essential to any effective quality assurance program. Without feedback to daily operations and an understanding by staff of the results obtained by performing quality assurance

reviews, quality assurance efforts are likely to fail. The notification language has been altered to remove the requirement that notification of each result from the quality assurance review process.

Ms. Quandt stated that although the language has improved, Longs Drugs would like it simplified further.

The board responds that it is difficult to comment on a general request to “simplify” the regulation. The board would be willing to consider any specific recommendations to “simplify” the regulation.

Mr. Dan Wills stated that he is with a local community pharmacy and has a background in quality control with another organization. He noted that he has found that 95 percent of individuals want to do the right thing. The goal is to have something that will help those 95 percent to do better so there are fewer problems. He added that at some point, the board will be working on the other 5 percent. He stated that the best approach is never using quality assurance programs against someone punitively, but rather as a means to improve the process.

The board responds that the quality assurance program will not be used “punitively.” In fact, the regulation explicitly requires the board to consider compliance with the quality assurance requirements as mitigation in any disciplinary proceeding.

He added that if it were written in the regulations that the quality assurance data would not be used against the pharmacist, no one would mind keeping the records on site.

The board responds that this proposal is unworkable. The board needs access to quality assurance documents to verify the compliance of pharmacies with this regulation. If a pharmacy has not fully complied with the regulation, the board will need those documents to substantiate a case for failure to comply with the quality assurance regulation. Furthermore, the board provided numerous assurances during the hearings on this regulation that the quality assurance program will not be used to ferret out additional medication errors for enforcement action. Upon completion of the investigation, the board will look at the quality assurance program to determine if the pharmacy complied the regulation. However, it has also repeatedly indicated that it will take strong action against any pharmacy that fails to fully and faithfully comply with the quality assurance requirements.

Summary of Comments Received During the First 15 Day Public Comment Period

1. In a letter dated May 29, 2001, Bruce Young, Senior Vice President of the California Retailers Association (CRA), provided several comments in opposition to the regulation.

Mr. Young objects to the regulation because he believes the board failed to follow the direction of the Governor in the signing message of SB 1339. That signing message encouraged the board to use existing quality assurance programs as a model in developing the regulations.

The board responds that it did use elements of the “sentinel event” process required by the Joint Commission on the Accreditation of Health Care Organizations which is applied in hospital pharmacy settings. The board also used a quality assurance program implemented by a major pharmacy company as a model.

Mr. Young objects to the regulation because it is an enforcement tool and does not advance the “blameless” models of error reporting advocated in the literature.

The board responds that the regulation explicitly requires the board to consider compliance with this regulation as mitigation in any investigation of a medication error. Furthermore, the board provided numerous assurances during the April 2001 regulation hearing that the quality assurance program will not be used to ferret out additional medication errors for enforcement action. Lastly, the quality assurance program does not require medication errors to be reported to the board. Instead, it requires that pharmacies study their own errors to develop system and process improvements to prevent future errors. The existing regulation is entirely consistent with the “blameless” approach advocated in the quality assurance literature.

Mr. Young objects to the regulation because of the increased costs associated with maintaining quality assurance records including the diversion of inspector time from performing routine inspections.

The board responds that the record maintenance required by this regulation is directly related to the number of errors in each pharmacy. Each error is subject to a quality assurance review and that review must be documented. If the pharmacy has few errors then there will be few records to maintain. Furthermore, the board reduced the record retention period from three years to one year to reduce the burden of maintaining the records. Lastly, the draft changes to the regulation permits pharmacies to retain these records in an immediately retrievable form (i.e., electronically) to reduce the burden of paper.

The concern expressed regarding routine inspections is also misplaced. The board has resumed routine inspections and that program will continue at the same pace under the quality assurance regulation. Contrary to the concern articulated in CRA’s letter, board inspectors will not have to spend “hours” reviewing every document in detail for each routine inspection. Rather, inspectors will briefly review policies and procedures for the pharmacy and any errors that have been subject to quality assurance review for that particular pharmacy. This undertaking will not require “hours” of inspector time. This evaluation will be designed to ascertain the pharmacy’s general compliance with the quality assurance requirement, not the detailed review that would be required when

investigating a consumer complaint. In either event, the board will be looking for compliance with the quality assurance regulation, not singling out specific pharmacists for enforcement action. The existence of a quality assurance program will be an important component in routine inspections.

Mr. Young objects to the regulation because it requires pharmacies to “detect and identify” medication errors.

The board responds that Mr. Young interprets this requirement as a mandate for development of novel technology systems or added staffing. The requirement was intended to require pharmacies to provide a mechanism for errors to be reported by pharmacy staff to pharmacy management. It was not the board’s intent to require the development of technological systems or increase staffing and the language has been removed to eliminate potential confusion.

Mr. Young objects to the regulation because the record keeping requirements will add \$13,000 per pharmacy per year in costs or over \$8 million per year industry-wide.

The board responds that record retention costs are directly related to the frequency of errors in the pharmacy. Pharmacies with many errors will have more workload from record retention and pharmacies with few errors will have virtually none. Furthermore, changes to the regulation permit records to be stored in a central electronic system that is accessible in the pharmacy which may reduce maintenance costs.

Mr. Young asserts that the board’s regulation will destroy existing quality assurance programs that are working well because they operate in a “blameless” system.

The board responds that the regulation was drafted to permit pharmacies to develop systems that work in their environments. Nothing in the regulation establishes “blame.” In fact, the regulation, as noted above, expressly requires the board to mitigate any medication error enforcement action if the pharmacy complied with the regulation.

2. In a letter dated May 29, 2001, David J. Fong, Senior Vice President – Pharmacy, Longs Drug Stores, provided several comments regarding the regulation.

Mr. Fong objects to the use of the term “proximate cause” because of the potential confusion with its use in judicial proceedings.

The board responds that this comment is appropriate and the language has been removed.

Mr. Fong objects to the existing regulation language requiring pharmacists to notify the patient and prescriber of any medication error. Longs suggests added language that would not require such notification when the patient or prescriber discovers the error.

The board responds that this comment is appropriate and the language has been added.

Mr. Fong objects to the definition of medication error. Longs suggests an alternate definition of medication error as follows: “Medication error means any preventable act or omission by the pharmacist that results in patient harm.”

The board responds that such a narrowing of the definition of medication error is not appropriate. In order to maximize the benefit of a quality assurance program, pharmacies need to evaluate all errors. While some errors may appear to be minor or insignificant, all errors are indicators of weaknesses in existing systems or processes. For instance, a simple misspelling of a patient’s name on the label may appear innocuous, that misspelling can result in providing the drug to the incorrect patient (Robert vs. Roberta, Jan vs. Jane, etc.). The fact that the error did not injure a patient at one time is largely a matter of good fortune rather than assurance that a “little” error won’t hurt anyone.

3. In a facsimile dated June 4, 2001, Diane J. Darvey, Director, State Pharmacy Affairs for the National Association of Chain Drug Stores (NACDS), provides several comments on the regulation.

Ms. Darvey objects to the use of the term “proximate cause” for the reasons stated by Longs above.

The board responds that this comment is appropriate and the language has been removed.

Ms. Darvey objects to the definition of medication error as overbroad. Alternatively, Ms. Darvey suggests a definition of medication error essentially identical to that proposed by Longs above.

The board responds that such a narrowing of the definition of medication error is not appropriate. In order to maximize the benefit of a quality assurance program, pharmacies need to evaluate all errors. While some errors may appear to be minor or insignificant, all errors are indicators of weaknesses in existing systems or processes. For instance, a simple misspelling of a patient’s name on the label may appear innocuous, that misspelling can result in providing the drug to the incorrect patient (Robert vs. Roberta, Jan vs. Jane, etc.). The fact that the error did not injure a patient at one time is largely a matter of good fortune rather than assurance that a “little” error won’t hurt anyone.

Ms. Darvey objects to the requirement that pharmacies have a process for detecting medication errors.

The board responds that Ms. Darvey interprets this requirement as a mandate for development of novel technology systems or added staffing. The requirement was intended to require pharmacies to provide a mechanism for errors to be reported by pharmacy staff to pharmacy management. It was not the board’s intent to require the development of technological systems or increase staffing and the language has been removed to eliminate potential confusion.

Ms. Darvey interprets the language in subdivision (a) to require each individual pharmacy in a chain of pharmacy stores to maintain a unique program. Ms. Darvey suggests language to clarify that chain pharmacies may comply by participating in a company-wide program.

The board responds that this comment is appropriate and the language has been altered to remove any concern about the ability to implement a company-wide program.

Ms. Darvey objects to the requirement that policies and procedures for quality assurance programs be maintained in the pharmacy. Alternatively, NACDS suggests allowing the policies and procedures be readily retrievable.

The board responds that policies and procedures need to be immediately available in a pharmacy. In the event a medication error is detected, the pharmacist on duty should have the policies and procedures available to refer to in fulfilling his/her responsibilities. Also, the board must have immediate access to these documents to enforce the quality assurance program requirement during unannounced inspections and investigations. The language has been altered to require simply that policies and procedures be immediately available in the pharmacy. If a chain has the capacity to make such documents available via their electronic data systems, then that would be sufficient to meet this standard. Permitting the electronic distribution of policies and procedures would simplify the implementation of this new requirement for the owners of chain pharmacies.

4. In a letter dated June 4, 2001, R. Bruce Gordon, Director, Litigation & Pharmacy Law for Albertson's, provided several comments.

Mr. Gordon interprets the requirement that "each pharmacy" establish a quality assurance program to mean that chain pharmacies could not implement a single company-wide quality assurance program. Albertson's requests that subdivision (a) be amended to expressly permit chain pharmacies to implement a company-wide program.

The board responds that this comment is appropriate and the language has been altered to remove any concern about the ability to implement a company-wide program.

Mr. Gordon expresses a preference for replacing the proposed definition of medication error with a reference to Title 16, Section 1716 of the California Code of Regulations.

The board responds that this comment is appropriate and the language has been added.

Mr. Gordon objects to the requirement that policies and procedures describing the quality assurance program be maintained in the pharmacy.

The board responds that policies and procedures need to be immediately available in a pharmacy. In the event a medication error is detected, the pharmacist on duty should

have the policies and procedures available to refer to in fulfilling his/her responsibilities. Also, the board must have immediate access to these documents to enforce the quality assurance program requirement during unannounced inspections and investigations. The language has been altered to require simply that policies and procedures be immediately available in the pharmacy. If a chain has the capacity to make such documents available via their electronic data systems, then that would be sufficient to meet this standard. Permitting the electronic distribution of policies and procedures would simplify the implementation of this new requirement for the owners of chain pharmacies.

Mr. Gordon objects to the requirement that the policies and procedures be reviewed and revised, if necessary, prior to renewal of the pharmacy license.

The board responds that the comment is appropriate and the language was removed.

Mr. Gordon objects to the requirement that pharmacists be required to notify the patient and the prescriber when they become aware of a medication error. Albertson's believes that exceeds the authority of the statute.

The board responds that the first obligation of a pharmacist is to take whatever steps necessary to remove any threat to the patient's health. There is no circumstance where a pharmacist should not take steps to prevent harm to a patient from a medication error. Furthermore, the board has the statutory authority to establish such a requirement in regulation. In addition to the authority to issue quality assurance regulations in Senate Bill 1339, the board has a general authority to issue regulations for the "protection of the public." (Section 4005 (a) of the Business and Professions Code) That authority is sufficient to mandate patient notification. It is also worth noting that the Joint Commission on Accreditation of Health Care Organizations (JCAHO) recently adopted a standard requiring hospitals to report medical errors to patients and the family of patients.

Mr. Gordon objects to the requirement that pharmacies have a system designed to detect medication errors.

The board responds that Albertson's interprets this requirement as a mandate for development of novel technology systems or added staffing. The requirement was intended to require pharmacies to provide a mechanism for errors to be reported by pharmacy staff to pharmacy management. It was not the board's intent to require the development of technological systems or increase staffing and the language has been removed to eliminate potential confusion.

Mr. Gordon objects to the requirement that pharmacies begin investigating a medication error within two business days of discovering the error.

The board responds that this requirement is key. Any investigation is greatly aided by gathering information as soon as possible. As time passes from the event, memories fade, events are confused, documents are lost or destroyed. All of this impairs the ability to

reconstruct the events completely and accurately. It is important to note that this language simply requires the investigation to commence, not be completed, within two business days.

Mr. Gordon objects to the requirement that quality assurance reviews only be conducted for those errors attributable in whole or in part to the pharmacy or its personnel. Albertson's suggests that all medication errors be subject to quality assurance reviews.

The board responds that this comment was appropriate and language has been changed to reflect it.

Mr. Gordon objects to the use of "proximate cause" for the same reasons expressed by Longs above.

The board responds that the comment is appropriate and the language has been removed.

Mr. Gordon suggests recasting the provisions of subdivision (e) to clarify the purpose of quality assurance review.

The board responds that the comment is appropriate and the language has been altered to reflect it.

Mr. Gordon objects to the requirement that pharmacy personnel be informed of the completion of the review and any changes that resulted from the review. Albertson's believes that this could interfere with any related personnel actions and that operational issues should not be included in the quality assurance regulation.

The board responds that the comment is appropriate in part. This requirement should not interfere with any personnel action. However, it is important to communicate the results of quality assurance processes to pharmacy personnel to demonstrate the value of an effective ongoing program. Accordingly, the language has been changed to eliminate the reporting of the results of specific quality assurance reviews, and instead require that the pharmacy make a periodic report of changes generated by the quality assurance program to pharmacy personnel.

Mr. Gordon objects to the requirement that quality assurance records be maintained in the pharmacy for one year. Alternatively, Albertson's suggests that records be readily retrievable in the pharmacy for one year.

The board responds that quality assurance reviews need to be immediately available in a pharmacy so that the board may have immediate access to these documents to enforce the quality assurance program requirement during unannounced inspections and investigations. The language has been altered to require simply that policies and procedures be immediately available in the pharmacy. If a chain has the capacity to make such documents available via their electronic data systems, then that would be sufficient

to meet this standard. Permitting the central electronic storage of these records could simplify the implementation of this new requirement for the owners of chain pharmacies.

Mr. Gordon objects to the requirement that pharmacies make quality assurance records available to the board as a condition of mitigating any enforcement action.

The board responds that the comment is appropriate and the language has been removed.

Summary of Comments Received During the second 15 day Public Comment Period

1. In a letter dated August 22, 2001, Ms. Teresa Ann Miller, Executive Vice-President of the California Society of Health System Pharmacists (CSHP), provided several comments.

Ms. Miller states that CSHP supports notifying patients regarding the occurrence of medication errors but argues that the requirement that the pharmacist perform that notification is impractical because it would require rewriting existing hospital procedures on this subject.

The board responds that it appreciates the potential impact this regulation may have on existing hospital procedures, but it believes strongly that it is the professional obligation of the pharmacist to make the notification to patients and prescribers regarding medication errors. Communicating such information through an intermediary creates the possibility of miscommunication and delay in relaying the information to the patient and prescribers. Either miscommunication or delay have the potential to expose the patient to additional harm and should be minimized by any means practically possible.

Ms. Miller states that the CSHP believes that only medication errors with the potential to cause harm should be subjected to a quality assurance review.

The board responds that it is essential to examine all errors. The same error can result in disparate outcomes on different patients. This is particularly true when considering children and seniors, where standard adult dosages can be fatal. Furthermore, comment received from Albertson's preferring the examination of all errors regardless of patient harm reinforced the board's position.

Ms. Miller states that CSHP is concerned that the board define which records are subject to the immediately retrievable requirement in the regulation.

The board responds that those records required by the regulation must be immediately retrievable. Because each pharmacy has the ability to develop its own quality assurance system, it is impossible for the board to specify which documents must be immediately retrievable in each pharmacy with the precision requested by Ms. Miller.

Ms. Miller states that the CSHP opposes the rescission of language in the regulation regarding the discoverability of records in the quality assurance program.

The board responds that the language addressing the discovery exemption was removed on the advice of counsel. Counsel believes that inclusion of that language may violate the non-duplication standard and the clarity standard of review for regulations. After discussion with counsel and extensive deliberation and comment by the board, it was determined that the discovery exemption provision of the regulation was not necessary because the enabling statute contained provisions regarding the discovery exception.

Ms. Miller states that the board's self assessment forms should be updated to indicate the new quality assurance requirements.

The board responds that it will update the self assessment form through a subsequent rulemaking procedure.

2. In a letter dated August 22, 2001, R. Bruce Gordon, Director, Litigation & Pharmacy Law for Albertson's, provided several comments.

Mr. Gordon states that paragraph (c) of the regulation is confusing because it contains two separate mandates.

The board responds that the inclusion of two requirements in a single paragraph does not impair the clarity of otherwise clear language. Furthermore, the board prefers its formulation of the patient notification provision because it explicitly requires immediate communication with the patient and the prescriber and the Albertson's formulation does not. Immediate notification is essential to minimize patient harm and the ultimate purpose of this regulation is to minimize patient harm from medication errors.

Mr. Gordon states that the current language in paragraphs (c) and (d) are counterproductive and inconsistent with the purpose of the regulation.

The board responds that it does not agree that the provisions of paragraphs (c) and (d) are inconsistent with and counterproductive to the purpose of the regulation. These paragraphs outline essential requirements in any quality assurance system:

1. Policies and procedures defining the system.
2. Patient and prescriber notification of errors.
3. Require the improvements identified by quality assurance review to be implemented.
4. Require the initiation of an investigation as soon as possible.
5. Review all errors.

Without policies and procedures, there is no systematic evaluation of errors that is the essential element of quality assurance systems and this regulation.

Mr. Gordon further states that complete quality assurance programs contain components other than the reduction of medication errors through improvements in pharmacy processes and systems.

The board responds that this regulation seeks solely to reduce the frequency of medication errors. The regulation is a minimum required, not the maximum allowed. Pharmacies that wish to expand their quality assurance programs to address other quality issues or to add broader medication error reduction strategies such as trend analysis, human factors analysis, or other quality assurance techniques are encouraged to do so. The board drafted this regulation broadly to permit each pharmacy to innovate and establish a quality assurance program that suits its particular circumstances and in full recognition that the regulation applies to a wide range of pharmacy settings from the independently owned pharmacy, large chain pharmacies (such as Albertson's), hospital pharmacies, home care pharmacies and compounding pharmacies.

Mr. Gordon states that the requirement of maintaining the accessibility of quality assurance documents in the pharmacy is unnecessary unless the board intends to use them punitively and increases the risk of their disclosure.

The board responds that the documentation requirements in the regulation are the minimum required for the board to enforce the quality assurance mandate established by SB 1339. Without this minimum documentation, the board has no means to verify the existence of policies and procedures, the existence of quality assurance reviews, or the implementation of any changes to pharmacy procedures or systems in response to quality assurance reviews. The board has frequently stated that it does not intend to bring enforcement action on medication errors discovered in the review of quality assurance records. However, it has also repeatedly stated that it will punish the failure of pharmacies to implement quality assurance programs. Regarding the risk of disclosure by maintaining the accessibility of documents in the pharmacy, the board responds that it is the obligation of each pharmacy to train its own staff regarding pharmacy policy. If the pharmacy is concerned about the disclosure of pharmacy records by pharmacy personnel, it needs to address that concern through its internal systems and training programs. The ability to maintain these records in a central electronic storage system does permit pharmacies to use the myriad security and access restrictions that are available in many software systems to control access and disclosure of pharmacy documents. The discovery protections contained in SB 1339 address the documents created solely as a part of the pharmacy's quality assurance program and do not vary based on the location of the documents.

Mr. Gordon also states that maintaining these records with highly confidential information in a pharmacy exposes that information to improper disclosure.

The board responds that all pharmacies contain confidential medical information and are bound to preserve its confidentiality pursuant to the Confidentiality of Medical Information Act (Civil Code 56 et seq.). Pharmacies currently maintain this information in their prescription records. The board fails to understand how thousands of pharmacies that maintain the confidentiality of this information would be unable to preserve the confidentiality of quality assurance records. Use of passwords in computer systems or locked storage cabinets are two examples of ways a pharmacy can keep these records

confidential.

Mr. Gordon states that maintaining records in an electronic storage system accessible in the pharmacy creates additional risk of disclosure of quality assurance records.

The board responds that most every pharmacy in California uses a computer system for its mission critical functions, including the storage and transmission of confidential patient information for payment purposes. Again, it is unclear to the board how pharmacies that so ably create and maintain such systems for hundreds of millions of prescriptions each year are unable to safely manage the quality assurance records for a few dozen (at the upper extreme) medication errors each year.

3. In a letter dated August 22, 2001, Mr. Alan Pope, Vice President and Assistant General Counsel for Longs Drugs, provided several comments.

Mr. Pope objects to the removal of language from the regulation addressing the discovery exemption.

The board responds that the language addressing the discovery exemption was removed on the advice of counsel. Counsel believes that inclusion of that language may violate the non-duplication standard and the clarity standard of review for regulations. After discussion with counsel and extensive deliberation and comment by the board, it was determined that the discovery exemption provision of the regulation was not necessary because the enabling statute contained provisions regarding the discovery exception.

Mr. Pope objects to the language requiring pharmacies to make a determination of the cause of the error subject to quality assurance review because Section 4125 of the Business and Professions Code does not require that determination be made.

The board responds that Section 4125 was added by SB 1339. SB 1339 requires the board to adopt regulations specifying the requirements of quality assurance programs required by Section 4125. The board believes, and is supported by the substantial majority of the professional literature on quality assurance in pharmacies, that reaching an understanding of what caused a medication error is vital to developing system and process improvements that will prevent its recurrence. Without a determination of cause, quality assurance would accomplish little reduction in medication errors which is the purpose of this regulation.

Mr. Pope objects to the inclusion of language referring to the improvement of the quality of pharmacy service.

The board responds that improving the quality of pharmacy service is the express purpose of the regulation and the language is appropriate.

Mr. Pope states that most of the contents of paragraph (e) are redundant, unnecessary and nonsensical and should be removed.

The board responds that the provisions contained in paragraph (e) are essential to the purpose of the regulation and should be retained. The first sentence is a statement of purpose for the quality assurance review process. It stresses the need to examine data to assess the cause or causes of a medication error and other contributing factors. The second sentence requires the maintenance of quality assurance records, the need for which has been discussed at length in this document above. The remainder of the paragraph spells out the documentation requirements and the need to implement process and/or system improvements based on the findings of the quality assurance review.

Mr. Pope objects to the documentation requirements in paragraph (e) as “micro-managing” and “dictating” the review process for pharmacies in disparate settings.

The board responds that the documentation requirements are elementary and leave each pharmacy broad authority to structure its own quality assurance process. The regulation does not specify who shall conduct the quality assurance review, where it shall be conducted, when it shall be conducted, in what manner it shall be conducted, and for how long it shall be conducted. All the regulation requires is recording basic information regarding the incident, who conducted the review, the findings of the review and any changes made to pharmacy systems or processes based on the review. These requirements do not, in the board’s opinion, impose a micromanaging of the quality assurance review by the board. Rather, these requirements are general and can easily be incorporated into virtually any quality assurance process.

4. In a letter dated August 22, 2001, Diane L. Darvey, Director of State Pharmacy Affairs for the National Association of Chain Drug Stores provided several comments.

Ms. Darvey states that the regulation exceeds its statutory authority by requiring that pharmacists notify patients of medication errors and that each pharmacy has the right to use its professional judgment regarding the components of its quality assurance program. Ms. Darvey further states that the board exceeded its statutory authority by establishing documentation requirements for quality assurance programs.

The board responds that Senate Bill 1339 (Chapter 677, Statutes of 2000) expressly requires the board, not individual pharmacies, to determine the requirements of quality assurance programs,

“The California State Board of Pharmacy shall adopt regulations on or before September 1, 2001, specifying the requirements and implementation of quality assurance programs established pursuant to Section 4125 of the Business and Professions Code.”

Section 4005 of the Business and Professions Code reads in pertinent part,

“The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; and pertaining to the sale of drugs by or through any mechanical device.”

The authority granted by that provision and the board’s basic rulemaking authority contained in Section 4005 of the Business and Professions Code grant it wide discretion in adopting rules to protect the public safety. In the board’s opinion, the provisions of this regulation fall well within the bounds of that statute and the board is unaware of any statute that prohibits it from requiring either patient notification of a medication error or the maintenance of documents.

Summary of Other Comments Received

1. In a letter dated July 17, 2001, Senator Liz Figueroa provided several comments.

Senator Figueroa states that the language requiring “each” pharmacy to establish its own quality assurance program is potentially confusing to chain pharmacies, however, the recommendation simply requiring pharmacies to “participate” is insufficient.

The board responds that it recognizes the potential confusion created by the use of “each” in this context and has altered the language to resolve the confusion by requiring each pharmacy to establish or participate in an established quality assurance program.

Senator Figueroa states that the revised definition of medication error should not be altered to exempt variations in the prescription authorized by law.

The board responds that it concurs with the spirit of Senator Figueroa’s comment, however, there is one specific circumstance where a pharmacist may legally vary from the physician’s prescription. Section 4073 of the Business and Professions Code permits pharmacists to substitute a therapeutically equivalent generic drug for a brand name drug. Such a substitution is safe and does not constitute an “error” because the patient is receiving the same dose of the appropriate active ingredient(s). In addition, legislation has recently been enacted (Senate Bill 340, Chapter 631, Statutes of 2001) which would permit pharmacists to lawfully dispense a drug in a different form (i.e., liquid, chewable tablet, capsule, etc.) than that prescribed. Again, this change does not alter the dose or the active ingredient prescribed and is not an “error.” Given these appropriate “variances” or substitutions would qualify as “errors” under a strict reading of the definition, the board felt it was appropriate to add the language exempting these substitutions.

Senator Figueroa states that the use of “well being” as a qualifier in subdivision (c) is vague and should be removed.

The board concurs and the language has been altered.

Senator Figueroa states that “described” should be replaced with “managed” per the request of another commenter.

The board concurs and the language has been altered.

Senator Figueroa states that the use of “proximate cause” may cause some confusion but that the regulation should continue to require some determination of “cause.”

The board concurs and the language was altered.

2. In a letter dated July 24, 2001, R. Bruce Gordon, Director of Litigation and Pharmacy Law for Albertson’s provided several comments.

Mr. Gordon requested a change to subdivision (c) permitting the written policies and procedures to be retained in an immediately retrievable form instead of in a written form.

The board concurs and the language has been altered to reflect this comment.

Mr. Gordon requested the elimination of the requirement that patients be notified by the pharmacist when an error is detected.

The board responds that patient and prescriber notification are essential. Medication errors can have serious health consequences for patients (both through the direct effect of the drug and through the consequences of not being treated with the correct drug). Patients have a right to this information and pharmacists have a professional, moral and ethical obligation to take whatever steps are required to prevent harm to their patients. Furthermore, prescribers need to be informed so that the prescriber can assess the impact of the error on the patient’s condition and the consequences for the patient’s course of treatment.

Mr. Gordon requested the elimination of the requirement that investigations of medication errors begin no later than 2 business days following their discovery.

The board responds that it is important to begin investigation quickly after the incident is discovered. By beginning the investigation rapidly, the investigator is more likely to find relevant information and the recall of the individuals involved will be more comprehensive and accurate. The quality of information obtained in the investigation is an essential variable in the success of such a program.

Mr. Gordon requested that the records not be maintained in the pharmacy but by the entity

conducting the review.

The board responds that the records need to be maintained in the pharmacy so that they may be reviewed by board inspectors. There is no requirement that the quality review be performed by an entity in California and the board lacks the jurisdiction to enter locations outside California to review documents. Furthermore, the complexity of interstate travel for state employees and the cost associated with such travel make such a storage arrangement impractical from an enforcement standpoint. Lastly, even for locations in California, board inspectors do not have a right of entry into premises that are not licensed by the board. By requiring that these documents be immediately available in the pharmacy, the board ensures its ability to enforce the requirements established by this regulation.

Mr. Gordon requested that the quality assurance review documents not be required to contain pertinent information regarding the medication error.

The board responds that such information is essential for enforcement of the regulation. Without the facts of the error at hand, the board is unable to evaluate whether the review has been performed faithfully and whether the quality assurance review should yield improvements to existing systems and processes. Also, without such information the board will be unable to ascertain whether the pharmacy conducted a quality assurance review on a medication error when the board receives a complaint regarding that error. Without information relating to the specific factual situation, a pharmacy could simply draft a general quality assurance review which could be applied to all errors in that pharmacy.

Local Mandate:

None.

Business Impact:

The board has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives:

The board has determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Addendum to the Final Statement of Reasons

Summary and Response to Comments

At the April 25, 2001 Public Hearing:

Mr. Greg Schapansky, representing Costco Pharmacy, stated that the amendments to the regulation are appreciated. He stated that he has concerns about the implementation of the quality assurance programs.

The board responds that it is difficult for the board to respond without articulating more specific concerns with the proposed regulation.

Mr. Schapansky stated that currently his pharmacists fear the board's inspectors and reporting errors.

The board responds that it is difficult to address the subjective emotional state of pharmacists in the context of this regulation.

In a letter from the National Association of Drug Stores (NACDS) dated June 4, 2001:

NACDS requests that the board should allow further oral testimony and hearings on the proposed regulation.

The board responds that additional testimony was taken at the July 25, 2001 board meeting.

NACDS states that the 15 day comment period is too short given the significant changes to the proposed regulation in the board notice.

The board responds that the 15 day comment period is consistent with the notice requirements in the Administrative Procedures Act.

NACDS states that the board has not taken the Governor's signing message into account when drafting this regulation and that existing voluntary quality assurance programs should be permitted to continue.

The board responds that it carefully considered the Governor's signing message in drafting this regulation. However, the essence of Senate Bill 1339 was to require, not permit, pharmacies to implement quality assurance programs consistent with requirements established in regulations adopted by the board.

In a letter from Albertson's dated June 4, 2001:

Albertson's states that the effective date chosen does not provide pharmacies without quality

assurance programs enough time to comply.

The board responds that it sought a January 1, 2002 implementation date to correspond with the statutory requirement established in SB 1339. Without the proposed regulation pharmacies would be subject to the quality assurance requirement with no regulation to guide their implementation of this new requirement. Furthermore, pharmacies cannot claim the discovery exemption provided for quality assurance documents until the documentation requirements of quality assurance programs are established. The proposed regulation has been available in its various forms since October 2000 and firms are already offering programs to comply with the quality assurance requirement for sale. Lastly, the effective date of the proposed regulation will be January 14, 2002, not January 1, 2002.

In a letter from Longs Drug Stores dated August 22, 2001:

Longs Drug Stores questions the clarity of language in subdivision (e) ‘advance error prevention by analyzing, individually and collectively, investigative and other pertinent data’.

The board responds that it does not find that sentence to lack clarity.

In a letter from Albertson’s dated July 24, 2001:

Albertson’s requested a change in the regulation to permit documents to be retained in the pharmacy in an immediately retrievable form.

The board responds that the regulation was changed to permit documents to be maintained in the pharmacy in an immediately retrievable form. The board believes that this change addresses the substantial concern expressed in the comment relating to the immediately retrievable form and not any distinction between retained or maintained. Accordingly, the board retained the usage of maintained.

Underlying Data

In developing its policy on quality assurance the board conducted an extensive review of the healthcare literature. This literature review provided the board with the principles of quality assurance in the health care setting upon which the regulation is based. However, this is a novel regulation and the board did not rely on any particular document or documents in developing the regulation text.

Nonsubstantive Changes to Text

The text of the regulation had two nonsubstantive changes, as follows:

- Strike the “Sanitary Standards for Pharmacies” heading.
- Strike the existing authority and reference citations.