



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

(804) 367-4456 (Tel)

(804) 527-4472 (Fax)

Tentative Agenda of Meeting Ad Hoc Committee for Continuous Quality Improvement Program May 18, 2011 11:30AM

<u>TOPIC</u>	<u>PAGE(S)</u>
Call to Order: Brandon Yi	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
Review introduction of information and goal of meeting	1
Review HB2220	2-3
Review background information on patient safety organizations	4-7
Review NABP model rules	8-11
Review and discussion of other states' laws and regulations	
• California	12-14
• Florida	15-16
• Iowa	17-21
Discussion and development of draft regulations	22

Adjourn: The committee will adjourn at approximately 2:30PM.

***The Committee will have a working lunch at approximately 12 noon.**

CQI Taskforce 5/18/2011

Introduction

HB 2220 appears to mandate that every pharmacy comply with one of two requirements: either comply with Board regulations for implementing a continuous quality improvement program, or actively report to a patient safety organization (PSO) that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005. Therefore, the Board will need to adopt regulations for implementing a CQI program and probably for defining what it means to "actively report" to a PSO. These regulations must be effective within 280 days of the bill's enactment which means the Board must adopt proposed regulations at the September full board meeting.

Goal

Taskforce should evaluate what is required by the HB 2220, analyze approaches offered by NABP model rules and other states for meeting these requirements, and determine what specific information the Board should consider including in the draft regulations.

Included in this packet are:

1. copy of HB 2220;
2. background information on patient safety organizations;
3. model rules from the National Association of Boards of Pharmacy;
4. examples of current regulations in California, Florida, and Iowa; and,
5. thoughts to consider when drafting CQI regulations.

2011 SESSION

ENROLLED

1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 An Act to amend and reenact § 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia
3 by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03, relating to
4 continuous quality improvement of pharmacies.

5 [H 2220]
6 Approved

7 Be it enacted by the General Assembly of Virginia:

8 1. That § 54.1-3434.1 of the Code of Virginia is amended and reenacted and that the Code of
9 Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered
10 54.1-3434.03 as follows:

11 § 54.1-3434.03. Continuous quality improvement program.

12 Each pharmacy shall implement a program for continuous quality improvement, according to
13 regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of
14 dispensing errors that uses findings to formulate an appropriate response and to develop or improve
15 pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall
16 promulgate regulations to further define the required elements of such program.

17 Any pharmacy that actively reports to a patient safety organization that has as its primary mission
18 continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L.
19 109-41), shall be deemed in compliance with this section.

20 § 54.1-3434.1. Nonresident pharmacies to register with Board.

21 A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner,
22 Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be
23 considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in
24 charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance
25 with this chapter, and shall disclose to the Board all of the following:

26 1. The location, names, and titles of all principal corporate officers and the name and Virginia
27 license number of the designated pharmacist in charge, if applicable. A report containing this
28 information shall be made on an annual basis and within 30 days after any change of office, corporate
29 officer, or pharmacist in charge.

30 2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to
31 conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within
32 another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers
33 within the United States, in which it is a resident. The pharmacy shall also certify that it complies with
34 all lawful directions and requests for information from the regulatory or licensing agency of the
35 jurisdiction in which it is licensed as well as with all requests for information made by the Board
36 pursuant to this section.

37 3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of
38 the most recent inspection report resulting from an inspection conducted by the regulatory or licensing
39 agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the
40 inspection was conducted within the past five years. However, if the nonresident pharmacy has not been
41 inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past
42 five years, the Board may accept an inspection report or other documentation from another entity that is
43 satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized
44 agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

45 4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume
46 pursuant to an original prescription order received as a result of solicitation on the Internet, including
47 the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received
48 certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy
49 Practice Site, or has received certification from a substantially similar program approved by the Board.
50 The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy
51 that only does business within the Commonwealth in limited transactions.

52 5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to
53 patients in the Commonwealth so that the records are readily retrievable from the records of other drugs
54 dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents,
55 or any agent designated by the Superintendent of the Department of State Police upon request within
56 seven days of receipt of a request.

ENROLLED

HB2220ER

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57 6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in
58 violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a
59 prescription that he knows or should have known was not written pursuant to a bona fide
60 practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of
61 § 18.2-248.

62 7. *That it maintains a continuous quality improvement program as required of resident pharmacies,*
63 *pursuant to § 54.1-3434.03.*

64 The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not
65 apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

66 B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than
67 six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to
68 facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who
69 has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each
70 container of drugs dispensed to patients in the Commonwealth.

71 C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription
72 Monitoring Program as set forth in § 54.1-2521.

73 D. The registration fee shall be the fee specified for pharmacies within Virginia.

74 E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a
75 prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in
76 Virginia pursuant to regulations of the Board.

77 2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this
78 act to be effective within 280 days of its enactment.

79 3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas of
80 pharmacy practice in implementing the requirements of this act.

Background information on patient safety organizations from the Agency for Healthcare Research and Quality (AHRQ) found at:
<http://www.pso.ahrq.gov/psos/fastfacts.htm>

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs to improve quality and safety by reducing the incidence of events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) published the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule).

Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act): An Overview

The goals of the Patient Safety Act are to encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement. The Patient Safety Act:

- Encourages the development of Patient Safety Organizations (PSOs)—organizations that can work with clinicians and health care organizations to identify, analyze, and reduce the risks and hazards associated with patient care.
- Fosters a culture of safety by establishing strong Federal confidentiality and privilege protections for information assembled and developed by provider organizations, physicians, and other clinicians for deliberations and analyses regarding quality and safety.
- Accelerates the speed with which solutions can be identified for the risks and hazards associated with patient care by facilitating the aggregation of a sufficient number of events in a protected legal environment.

What is a PSO?

A PSO is an entity or a component of another organization (component organization) that is listed by AHRQ based upon a self-attestation by the entity or component organization that it meets certain criteria established in the Patient Safety Rule.

The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care. See 42 CFR 3.102 for the complete list of requirements.

What are "patient safety activities"?

There are eight patient safety activities that are carried out by, or on behalf of a PSO, or a health care provider:

- Efforts to improve patient safety and the quality of health care delivery
- The collection and analysis of patient safety work product (PSWP)
- The development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices
- The utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk
- The maintenance of procedures to preserve confidentiality with respect to PSWP
- The provision of appropriate security measures with respect to PSWP
- The utilization of qualified staff
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system

How does AHRQ ensure that a listed PSO is in compliance with the statutory requirements as outlined in the Patient Safety Rule?

The Patient Safety Rule establishes in Subpart B the requirements that an entity must meet to seek listing, and remain listed, as a PSO. The Patient Safety Rule relies primarily upon a system of attestations, which places a significant burden for understanding and complying with these requirements on the PSO. However, the Patient Safety Rule also authorizes AHRQ to conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ developed a *Patient Safety Organizations: A Compliance Self-Assessment Guide* to suggest approaches for thinking systematically about the scope of these requirements and what compliance may mean for an individual PSO.

Listing Process and Requirements

Who can seek listing as a PSO?

The Patient Safety Rule permits many types of entities—either an entire organization or a component of an organization, a public or private entity, a for-profit or not-for-profit entity—to seek listing as a PSO. Both the *mission* and the *primary activity* of the entity (or component) must be to conduct activities to improve patient safety and the quality of health care delivery (42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)).

The Patient Safety Rule requires an entity to certify that it meets 15 distinct statutory requirements; a component of another organization must attest that it meets another three

statutory requirements; and each entity or component organization must comply with several additional regulatory requirements.

What are the requirements to be a PSO?

Every entity seeking to be a PSO must certify to AHRQ that it has policies and procedures in place to perform the eight patient safety activities specified in the Patient Safety Rule.

In addition, an entity must also, upon listing, certify that it will comply with the following seven additional criteria specified in the Patient Safety Rule:

- The mission and primary activity of the entity are to conduct activities that improve patient safety and the quality of health care delivery
- The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals
- The entity, within each 24-month period that begins after the date of the initial listing as a PSO, will establish two bona fide contracts, each of a reasonable period of time, with more than one provider, for the purpose of receiving and reviewing PSWP
- The entity is not, and is not a component of, a health insurance issuer
- The entity shall fully disclose—
 - i. any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and
 - ii. if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity
- To the extent practical and appropriate, the entity collects PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers
- The entity uses PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk

The Patient Safety Rule also establishes several additional requirements (see 42 CFR 3.102(a)).

Does a PSO listing expire?

A PSO is listed for a period of 3 years. To renew its listing for an additional 3 years, the PSO will be required to complete and submit a *PSO Certification for Continued Listing* form before the expiration of its period of listing. The PSO must certify that it is performing, and will continue to perform, each of the patient safety activities and that it is complying with, and will continue to comply with, the other requirements of the Patient Safety Rule. The PSO's 3-year period of listing will automatically expire at midnight of the last day of the PSO's listing period if AHRQ has not received and approved the PSO's continued listing form.

What are the privacy and confidentiality protections for PSWP?

The Patient Safety Act and Rule make PSWP privileged and confidential. Subject to certain specific exceptions, PSWP may not be used in criminal, civil, administrative, or disciplinary proceedings. PSWP may only be disclosed pursuant to an applicable disclosure exception (see 42 CFR 3.206).

What is the importance of the privacy and confidentiality protections for PSWP?

The Patient Safety Act makes PSWP privileged and confidential. The Patient Safety Act and the Patient Safety Rule generally bar the use of PSWP in criminal, civil, administrative, or disciplinary proceedings except where specifically permitted. Strong privacy and confidentiality protections are intended to encourage greater participation by providers in the examination of patient safety events. By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

If a PSO is revoked for cause (i.e., noncompliance with the requirements that each PSO must meet) and a health care provider inadvertently submits data to that entity, is the data protected?

If a PSO's listing is revoked for cause, health care providers may continue to submit data to the delisted PSO for 30 calendar days, beginning on the date and time that the PSO is delisted and ending 30 days thereafter. Data submitted during this 30 day period are treated as PSWP and are subject to the confidentiality and privilege protections of the Patient Safety Act.

For example, if a PSO is delisted for cause at midnight on March 1, a health care provider can continue to submit data to the delisted PSO until midnight on March 31 and the data will be protected. Data submitted to the former PSO after midnight on March 31 would not be protected. All PSWP submitted to a former PSO in accordance with provisions of the Patient Safety Act and Patient Safety Rule remains protected after the PSO ceases operations.

Will the general public ever have access to the trending data collected or aggregated from PSOs?

The Patient Safety Act authorizes AHRQ to facilitate the development of a network of patient safety databases (NPSD), to which PSOs, health care providers, or others can voluntarily contribute nonidentifiable PSWP. The Patient Safety Act directs AHRQ to incorporate the nonidentifiable trend data from NPSD in its annual *National Health Care Quality Report (NHQR)*. The NHQR is available in hard copy and electronically on the AHRQ Web site at <http://www.ahrq.gov/qual/qrd08.htm>.

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From Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy - August 2010

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 105(cc) Comment

States should continue efforts to develop and implement requirements for Continuous Quality Improvement (CQI) Programs in pharmacies, recognizing that CQI Programs enhance patient safety and operate most effectively when privilege of discovery laws and/or regulations protecting CQI data and information are enacted and included as a component of the CQI process.

Section 105(uuuu) Comment

A Peer Review Committee may be established to evaluate the quality of Pharmacy services or the competence of pharmacists and suggest improvements in Pharmacy systems to enhance patient care. Peer Review Committees may review documentation of quality-related activities in a pharmacy, assess system failures and personnel deficiencies, determine facts, and make recommendations or issue decisions in a written report that can be used for Continuous Quality Improvement purposes. A Peer Review Committee may include the members, employees, and agents of the committee, including assistants, investigators, attorneys, and any other agents that serve the committee in any capacity.

Definitions

- (a) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. All information, communications, or data maintained as a component of such a system shall be privileged and confidential and not subject to discovery in civil litigation.
- (b) "Peer Review" means a process that is part of an outcome-based, continuous quality improvement process that involves:
 - (1) the setting and periodic re-evaluation of standards for quality by which a pharmacy operation will be evaluated;
 - (2) the collection of data necessary to identify when those standards are not being met and data necessary to evaluate the reason(s) the deficiency occurred;
 - (3) an objective review of the data by an appropriate peer review committee to make recommendations for quality improvement; and
 - (4) an appropriate feedback mechanism to ensure that the process is operating in a manner that continually improves the quality of care provided to patients.
 - (i) Peer review should not be a punitive activity or a performance evaluation.
- (c) "Peer Review Committee" means:
 - (1) a committee that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care; or

- (2) a committee established by a person who owns a pharmacy or employs pharmacists that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.
- (d) "Quality-Related Event" means any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication. The term "Quality-Related Event" includes:
 - (1) a variation from the prescriber's prescription drug order, including, but not limited to:
 - (i) incorrect Drug;
 - (ii) incorrect Drug strength;
 - (iii) incorrect dosage form;
 - (iv) incorrect patient; or
 - (v) inadequate or incorrect packaging, labeling, or directions;
 - (2) a failure to identify and manage:
 - (i) over-utilization or under-utilization;
 - (ii) therapeutic duplication;
 - (iii) drug-disease contraindications;
 - (iv) drug-drug interactions;
 - (v) incorrect drug dosage or duration of drug treatment;
 - (vi) drug-allergy interactions; or
 - (vii) clinical abuse/misuse.
 - (3) The term also includes packaging or warnings that fail to meet recognized standards, the Delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.
- (e) "Quality Self-Audit" means an internal evaluation at a pharmacy to assess the effectiveness of the Continuous Quality Improvement (CQI) Program.

Continuous Quality Improvement Program

Each Compounding Pharmacy shall implement a Continuous Quality Improvement (CQI) Program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this document. Emphasis on the CQI Program should be placed on maintaining and improving the quality of systems and the provision of patient care. The CQI Program should ensure that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions are performed. The CQI Program should adhere to the provisions set out in the NABP Model Rules for the Practice of Pharmacy.

A CQI Program shall be documented through written policies and procedures and shall include the following:

- (a) consideration of all aspects of the preparation and dispensing of products as described in the NABP Model Rules for Sterile Pharmaceuticals and the USP Chapter 797 "Pharmaceutical Compounding – Sterile Preparations;"
- (b) description of specific monitoring and evaluation activities;
- (c) specification of how results are to be reported and evaluated;
- (d) collection of complaints, returns, or recalls that are the result of issues concerning the identity, strength, quality, and/or purity of Compounded Drug products;
- (e) identification of appropriate follow-up mechanisms when action levels or thresholds are exceeded; and
- (f) delineation of the individuals responsible for each aspect of the CQI Program.

In developing a specific plan, focus should be on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone, provided that Compounding of Drug products with these attributes are appropriate. Proper evaluation of

environmental monitoring might include, for example, the trending of an indicator such as settling plate counts.

The selection of indicators and the effectiveness of the overall CQI Program plan should be reassessed as needed or on an annual basis.

Pharmacy Practice

Continuous Quality Improvement Program

- (1) Compliance with this section may be considered by the Board as a mitigating factor in the investigation and evaluation of a Quality-Related Event (QRE).
- (2) Each Pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing QREs. At a minimum, a CQI Program shall include provisions to:
 - (i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;
 - (ii) initiate documentation of QREs as soon as possible, but no more than three days, after determining their occurrence;
 - (iii) analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;
 - (iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;
 - (v) provide ongoing CQI education at least annually to all pharmacy personnel.
- (3) As a component of its CQI Program, each Pharmacy shall ensure that periodic meetings are held, at least annually, by staff members of the Pharmacy to consider the effects on quality of the Pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Pharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients.
- (4) Appropriately-blinded incidents of QREs shall be reported to a nationally recognized error reporting program designated by the Board.
- (5) **Quality Self-Audit**
Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.
- (6) **Consumer Survey**
As a component of its CQI Program, each Pharmacy should conduct a Consumer Survey of patients who receive pharmaceutical products and services at the Pharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Pharmacy should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.
- (7) **Protection from Discovery**
All information, communications, or data maintained as a component of a pharmacy CQI Program are privileged and confidential. This shall not prevent review of a pharmacy's CQI Program and records maintained as part of a system by the Board, pursuant to

subpoena, as necessary to protect the public health and safety. All information, communications, or data furnished to any Peer Review Committee, and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any Peer Review Committee, are confidential and shall be used by such committee, and the members thereof, only in the exercise of the proper functions of the committee and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged Peer Review Committee information during advocacy, or as a report to the Board of Pharmacy, or to the affected Pharmacist or Pharmacy auxiliary personnel under review does not constitute a waiver of either confidentiality or privilege.

(8) Compliance with Subpoena

All persons shall comply fully with a subpoena issued by the Board for documents or information as otherwise authorized by law. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege associated with a CQI Program. Failure to comply with the subpoena is grounds for disciplinary action against the Person by the appropriate licensing board.

Suggested Language (highlighted) from NABP for Central Filling and Central Processing

Centralized Prescription Processing and Filling

- (1) A Pharmacy may perform or outsource Centralized Prescription Filling or Centralized Prescription Processing services provided the parties:
 - (i) have the same owner; or
 - (ii) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and State laws and regulations; and
 - (iii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a Prescription Drug Order.
- (2) The parties performing or contracting for Centralized Prescription Processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:
 - (i) a description of how the parties will comply with federal and State laws and regulations;
 - (ii) the maintenance of appropriate records to identify the responsible Pharmacist(s) in the Dispensing and counseling processes;
 - (iii) the maintenance of a mechanism for tracking the Prescription Drug Order during each step in the Dispensing process;
 - (iv) the maintenance of a mechanism to identify on the prescription label all Pharmacies involved in Dispensing the Prescription Drug Order;
 - (v) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of Protected Health Information;
 - (vi) the maintenance of a Continuous Quality Improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.



Current State Laws/Regulations from California, Florida, and Iowa

California

NABPLAW Online 2009/NABPLAW/CALIFORNIA/CALIFORNIA Pharmacy Practice Act/CA PracAct Business & Professions Code/CA PracAct Division 2. Healing Arts. Chapter 9. Pharmacy/CA PracAct Article 7. Pharmacies/CA PracAct 4125. Quality assurance program.

CA PracAct 4125.

Quality assurance program.

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

History: Added by Stats.2000, c. 677 (S.B.1339), Section 1, operative Jan. 1, 2002.

NABP 01/2009

NABPLAW Online 2009/NABPLAW/CALIFORNIA/CALIFORNIA State Board of Pharmacy Regulations/CA BReg Title 16. Professional and Vocational Regulations/CA BReg Division 17. California Board of Pharmacy /CA BReg Article 2. Pharmacies/CA BReg 1711. Quality Assurance Programs.

CA BReg 1711.

Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

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(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Section 4125, Business and Professions Code.

History: 1. New section filed 1-14-2002; operative 1-14-2002 pursuant to Government Code section 11343.4 (Register 2002, No. 3). For prior history, see Register 96, No. 5. 2. Repealer of subsections (c) and (i) and new subsections (c)-(c)(4) filed 9- 22-2004; operative 10-22-2004 (Register 2004, No. 39).

NABP 02/2009

Florida

NABPLAW Online 2009/NABPLAW/FLORIDA/FLORIDA Board of Pharmacy Regulations /FL BReg Title 64. Chapter 64B16-27. Pharmacy Practice /FL BReg 64B16-27.300. Standards of Practice -- Continuous Quality Improvement Program.

FL BReg 64B16-27.300.

Standards of Practice -- Continuous Quality Improvement Program.

(1) CONTINUOUS QUALITY IMPROVEMENT PROGRAM means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) QUALITY-RELATED EVENT means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions; or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which

program shall be described in the pharmacy's policy and procedure manual and, at a minimum, shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, pharmacy interns, pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;
2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality-Related Events at least every three months;
3. A planned process to record, measure, assess, and improve the quality of patient care; and
4. The procedure for reviewing Quality-Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

History: New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07.

NABP 4/2008

Iowa

**NABPLAW Online 2009/NABPLAW/IOWA/IOWA Pharmacy Practice Act/IA
PracAct Chapter 155A. Pharmacy Practice Act/IA PracAct ICA 155A.41.
Continuous Quality Improvement Program**

**IA PracAct ICA 155A.41.
Continuous Quality Improvement Program**

1. Each licensed pharmacy shall implement or participate in a continuous quality improvement program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors and for improving patient use of medications and patient care services. Under the program, each pharmacy shall assess its practices and identify areas for quality improvement.

2. The board shall adopt rules for the administration of a continuous quality improvement program. The rules shall address all of the following:

- a. Program requirements and procedures.
- b. Program record and reporting requirements.
- c. Any other provisions necessary for the administration of a program.

History: Added by Acts 2005 (81 G.A.) ch. 179, H.F. 882, Section 189.

NABP 10/2008

**NABPLAW Online 2009/NABPLAW/IOWA/IOWA Board of Pharmacy Examiners
Regulations/IA BReg 657. Pharmacy Examiners Board/IA BReg Chapter 8.
Universal Practice Standards/IA BReg 657-8.26 (155A). Continuous quality
improvement program.**

**IA BReg 657-8.26 (155A).
Continuous quality improvement program.**

Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall

implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

- a. An incorrect drug;
- b. An incorrect drug strength;
- c. An incorrect dosage form;
- d. A drug received by the wrong patient;
- e. Inadequate or incorrect packaging, labeling, or directions; or
- f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

- a. Train all pharmacy personnel in relevant phases of the CQI program;

- b. Identify and document reportable program events;
- c. Minimize the impact of reportable program events on patients;
- d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;
- e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and
- f. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

- a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;
- b. Identifying and communicating directions or processes for correcting the error; and
- c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

- a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

NABP 11/2008

NABPLAW Online 2009/NABPLAW/IOWA/IOWA Board of Pharmacy Examiners Regulations/IA BReg 657. Pharmacy Examiners Board/IA BReg Chapter 18. Centralized Prescription Filling and Processing/IA BReg 657-18.10 (155A). Policy and procedures.

**IA BReg 657-18.10 (155A).
Policy and procedures.**

18.10(1) *Manual maintained.* A policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) *Manual contents.* The manual shall:

a. Outline the responsibilities of each of the pharmacies;

- b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing;
- c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and
- d. Include, but not necessarily be limited to, policies and procedures for:
- (1) Protecting the confidentiality and integrity of patient information;
 - (2) Protecting each patient's freedom of choice of pharmacy services;
 - (3) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function;
 - (4) Complying with federal and state laws, rules, and regulations;
 - (5) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and
 - (6) Reviewing, at least annually, the written policies and procedures and documenting that review.

Thoughts to consider when drafting CQI regs:

- Need to define “dispensing error”. Most states appear to not include errors corrected prior to patient receiving, but NABP and Agency for Healthcare Research and Quality recommends including these near misses. Additionally, many states define an error to include issues only related to the act of accurately dispensing a drug. However, NABP model rules and at least one state define an error to also include the clinical appropriateness of dispensing the drug – refer to d2 of NABP model rules (ex: over-utilization, under utilization, therapeutic duplication, etc.)
- Within what timeframe should staff be required to report a dispensing error to the pharmacist on-duty?
- Within what timeframe and who should be required to document the dispensing error?
- What type of information shall be documented about the dispensing error?
- Within what timeframe and who shall perform the analysis of the dispensing error(s)?
- Should a peer review committee review findings or an individual pharmacist? Who would make up a committee?
- Are all pharmacies required to have a CQI policy and procedure manual?
- What type of information should be included in a CQI Policy and Procedure Manual?
- How often must staff be educated to the pharmacy’s CQI program and any system changes? (Ongoing, at least annually recommended by NABP); could require incoming PIC to review information upon taking over??
- Is PIC ultimately responsible for ensuring compliance with CQI program or may this be delegated?
- What records must be maintained to document compliance with the statute and regs, i.e., what will inspectors review for compliance?
- Should it include a “quality self-audit” or “consumer survey” as suggested in NABP model rules?
- Do regs need language required for protection from discovery?
- Should the regs for central filling and central processing include requirement for CQI in the P&P manual as suggested by NABP model rules?
- Do regs need to define what it means to “actively report” to a PSO? If so, should the regs go beyond simply defining the frequency at which a pharmacy must report to be considered actively reporting, i.e., should “actively reporting” include a requirement for improving pharmacy systems and workflow processes to prevent or reduce future errors?
- How will inspectors check for compliance with regs?