

## **Meeting Notice**

**Missouri Board of Pharmacy  
Patient Safety Working Group  
Conference Call  
May 28, 2013 11:00 a.m. to 1:30 p.m.  
Professional Registration  
3605 Missouri Blvd.  
Jefferson City, MO 65109**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

If any member of the public wishes to attend the open conference call, s/he should be present at the Missouri Board of Pharmacy, 3605 Missouri Blvd., Jefferson City, Missouri, at 11:00 a.m. on May 28, 2013.

Please see attached tentative agenda for this meeting.

**TENTATIVE AGENDA**  
**May 28, 2013 11:00 a.m. to 1:30 p.m.**

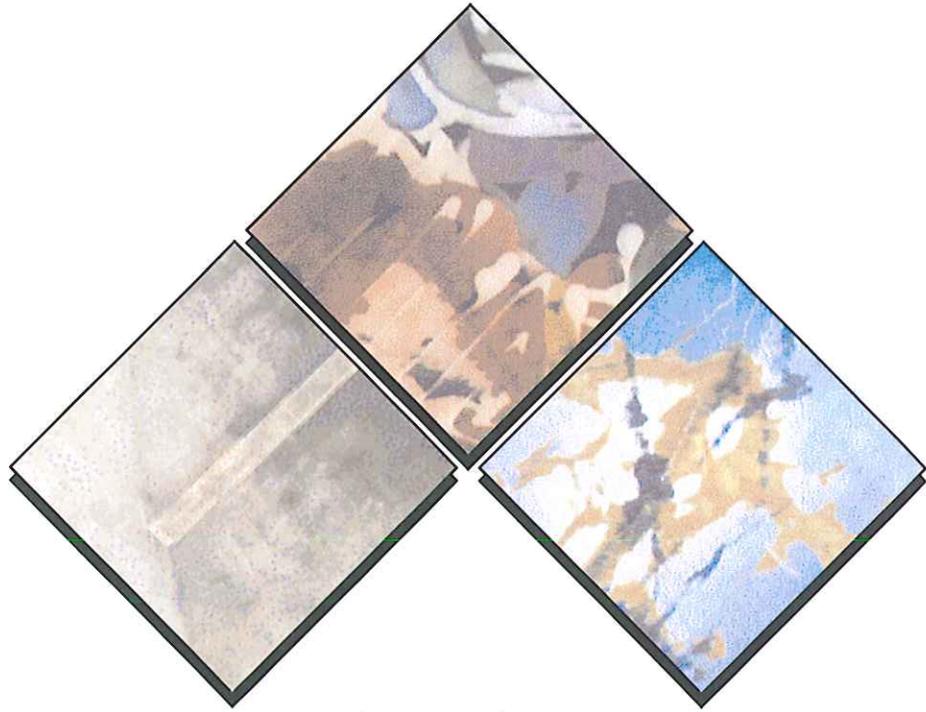
**Missouri Board of Pharmacy**  
**Patient Safety Working Group Meeting**  
**Professional Registration**  
**3605 Missouri Blvd.**  
**Jefferson City, MO 65109**

**OPEN SESSION**

- 1 Call to Order
- 2 Roll Call
- 3 Review of Patient Safety Suggestions
- 4 Review of Quality Assurance Programs
- 5 Future Meeting Dates
- 6 Adjournment



# HEALTH NOTES



Quality  
Assurance

COMMUNICATION AND  
PUBLIC EDUCATION  
COMMITTEE



Dedicated to building bridges of communication with those Californians whose health depends on proper drug therapy, compliance with a treatment regimen and a healthier lifestyle.

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# HEALTH NOTES

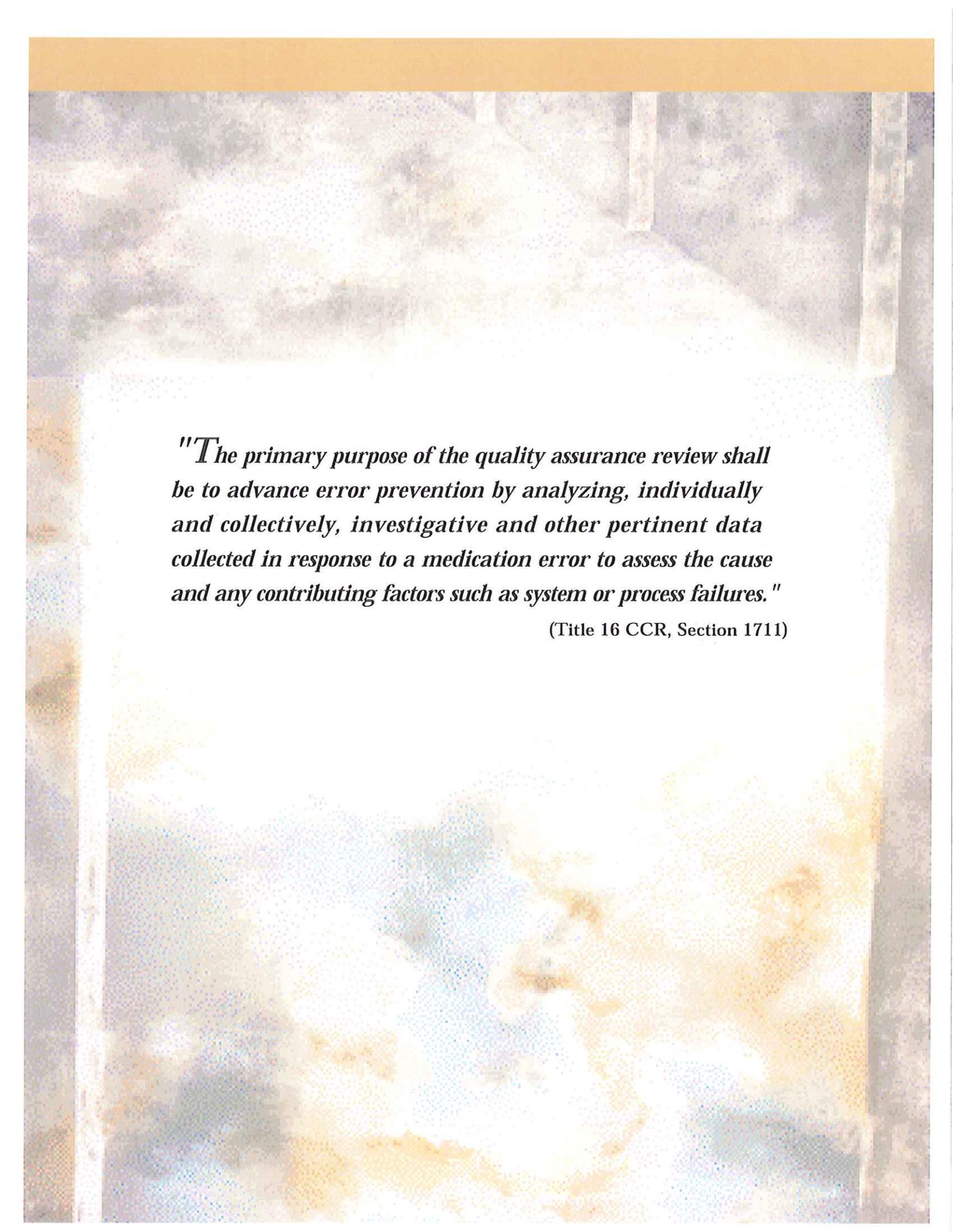
VOLUME 1, NUMBER 6



## Quality Assurance

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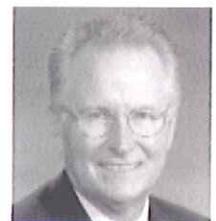
***"The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures."***

(Title 16 CCR, Section 1711)

*An Opening Note:*

# The Board of Pharmacy's Perspective

Steve Litsey, Pharm.D., FASHP  
*President, June 1, 2001 – May 30, 2002*  
California State Board of Pharmacy



**T**his edition of *Health Notes* will provide a starting point for learning about the application of quality assurance programs to pharmacy practice. The board has an absolute commitment to ensuring that patients receive quality pharmacists' care. The quality assurance requirement is the most important manifestation of that commitment since establishing mandatory patient consultation. The Board's goal for the quality assurance effort is to reduce the frequency of medication errors through the systematic study of those errors. Such study should provide pharmacists with the knowledge to improve pharmacy processes and systems to reduce the incidence of medication errors and to improve the overall quality of pharmacists' care provided to patients.

## Background on the Development of Title 16 CCR, Section 1711

In July of 1999, the Board considered a regulation requiring pharmacies to implement quality assurance programs to reduce the incidence of medication errors. The Board undertook this effort for a number of reasons. First, medication errors were, and still are, the most common consumer complaint received by the Board. Second, Board members were concerned by the growing body of evidence published in the professional literature documenting the threat of medication errors to patient health. Third, the Board believed that systems and process analyses were the most effective means to reduce the frequency and severity of medication errors.

While considering the 1999 regulation, the Board received extensive comments from the industry and the profession. These comments focused on the potential threat of quality assurance records if a civil suit resulted from a medication error. In response, the Board removed the pending regulation from consideration and instead sponsored Senate Bill 1339 to require quality assurance programs and provide a statutory exemption from discovery for quality assurance records. At the same time, *To Err is Human* was published by the Institute of Medicine (IOM) and focused the attention of policymakers around the country on the need to reduce medication errors and improve the quality of medical care. This report made a compelling case for establishing broad-based quality improvement efforts focused on improving systems and processes. The successful implementation of quality improvement processes requires moving away from blaming individuals and moving towards improving systems to minimize future occurrences of medication errors.

On September 24, 2000, Governor Gray Davis signed Senate Bill 1339. This law requires pharmacies to establish quality assurance programs to reduce the frequency of medication errors, exempts documents generated by quality assurance programs from discovery, and requires the Board of Pharmacy to adopt a regulation specifying the requirements of a pharmacy quality assurance program.

On behalf of the Board of Pharmacy, I wish to thank Senator Liz Figueroa (D – Fremont) for authoring this groundbreaking legislation. Without her leadership and advocacy, the bill would not have been possible.

It is also worth noting that Senate Bill 1875 (Speier) also was enacted in 2000, in response to the concern about medication errors. This bill requires hospitals and surgical centers to develop medication error reduction plans and submit those plans to the Department of Health Services as a condition of

licensure. Institutions that are subject to both Senate Bill 1875 and Senate Bill 1339 can comply with both laws with a single plan if that plan contains the elements required by the Board of Pharmacy's regulation.

Since Senate Bill 1339 was signed into law, the Board has been developing the regulation required to implement the quality assurance mandate established in Senate Bill 1339. The regulation has been the subject of extensive and vigorous debate and numerous modifications. That debate produced the essential elements of a pharmacy quality assurance program. It is important to keep in mind that the regulation represents the minimum required, not the most that can be done. The regulation provides each pharmacy considerable freedom to design and implement a quality assurance program that is adapted to its individual characteristics and needs. The Board trusts that pharmacies will use that freedom to innovate and find new methods for learning from medication errors.

## Requirements of Title 16 CCR, Section 1711

Under Section 1711, pharmacies must develop a quality assurance program to study medication errors and learn from them how to prevent recurrence of the error. The regulation:

- Defines "medication error" as any variation from a prescription or drug order not corrected prior to furnishing the drug to the patient.
- Requires the quality assurance program to be documented in written policies and procedures.
- Requires the pharmacist to notify the patient and the prescriber of the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
- Requires that the discoveries resulting from a quality assurance program be used to develop pharmacy systems and workflow processes to minimize the occurrence of medication errors.
- Requires that the investigation of each medication error commence as soon as is reasonably possible, but no later than two business days from the date the medication error is discovered.
- Requires that reviews of medication errors must include:
  - a) Date, location, and participants in the review;
  - b) Pertinent data and other information related to the medication error(s) being analyzed;
  - c) Documentation of patient and prescriber notification;
  - d) Findings and determinations resulting from the quality assurance review; and
  - e) Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

- Requires that records of the quality assurance review must be kept in the pharmacy for at least one year from the date the record was created.
- Requires that quality assurance records must be maintained by the pharmacy in an immediately retrievable form.
- Permits pharmacies to contract with qualified outside entities to develop and/or conduct their quality assurance program.

### Enforcement

Section 1711 took effect January 14, 2002, and this regulation may require some pharmacies to implement significant changes in their operations.

Quality assurance programs will be reviewed during board inspections. The Board regards failure to implement quality assurance programs in compliance with this regulation as an

extremely serious violation. The Board does not intend to use documents from a quality assurance program when investigating medication error complaints. However, when the investigation of a medication error has been completed, the inspector will review the pharmacy's quality assurance program and the pharmacy's assessment of specific errors. Failure to have a quality assurance program in place and/or failure to complete a quality assurance review in compliance with the regulation will result in enforcement action being taken.

In closing, this edition of *Health Notes* is the product of the combined efforts of an extraordinary group of people. The contributing authors and faculty of the University of California, San Francisco School of Pharmacy all bring a wealth of knowledge and an abiding commitment to improving the quality of care provided by pharmacists. The Board is grateful for their efforts in making this publication possible. I hope you will find it as enlightening as I did.

## EDUCATIONAL GOALS

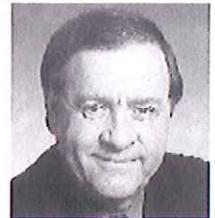
This issue of *Health Notes* will provide information about:

- The incidence, cost, and impact of medication errors;
- SB 1339 and its accompanying regulation;
- Quality assurance principles and strategies applicable to pharmacy;
- How to help consumers take an active role in preventing medication errors.



# It's Time for a New Model of Accountability

Michael R. Cohen, *R.Ph., M.S., D.Sc.*  
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Huntingdon Valley, PA



Healthcare is struggling to come to terms with the role of accountability in the non-punitive, system-based approach to error reduction recommended in *To Err is Human*, the landmark 1999 report from the Institute of Medicine. Even when we seem to understand the system-based causes of errors, it's still hard to let individuals off the hook. We ask, "How can we hold individuals accountable for their actions without punishment?" Some have even suggested that a non-punitive approach to error reduction could lead to increased carelessness as people learn that they will not be punished for their mistakes. However, a non-punitive, system-based approach to error reduction does not diminish accountability; it redefines it and directs it in a much more productive manner.

Typically, when an error happens, all accountability falls on individuals at the sharp end of an error where the caregiver/patient interaction occurs. But accountability – not for zero errors, but for making patient safety job one – should be equally shared among all healthcare stakeholders. In part, Webster's defines "accountability" as an obligation to provide a satisfactory explanation, or to be the cause, driving force, or source. These definitions offer a glimpse at a more appropriate patient safety accountability model. In this model, accountability lies not in performing perfectly, but in identifying safety problems, implementing system-based solutions, and inspiring and embracing a culture of safety. Below are examples.

Individuals in the workforce should be held accountable for speaking out about patient safety issues, voluntarily reporting errors and hazardous situations, and sharing personal knowledge of what went wrong when an error occurs. On the other hand, healthcare leaders should be held equally accountable for making it safe and rewarding for the workforce to openly discuss errors and patient safety issues. Hopefully, the new California quality assurance regulation will help to facilitate regular management safety briefings with staff to learn about improvement needs, discuss strategic plans, and identify new potential sources of error. When the workforce recommends error prevention strategies, leaders must support them and provide the means necessary, within a reasonable timeframe, to implement technology and other system enhancements to improve efficiency and safety.

Leaders should be held accountable for understanding and addressing barriers to safe practice, such as distractions and unsafe workloads. Likewise, the workforce must be empowered to ask for help when needed and be willing to change practices to enhance safety and quality. Leaders should position patient safety as a priority in the organization's mission and engage the community and staff in proactive continuous quality improvement efforts, including an annual self-assessment of patient safety.<sup>1</sup>

The workforce should be held accountable for working together as a team, not as autonomous individuals. Finally, leaders and staff alike need to follow the safety literature continuously and offer visible support to their colleagues whom have been involved in errors.

This model of shared accountability spreads far beyond the walls of individual healthcare settings to encompass licensing, regulatory, and accrediting bodies; the federal government and public policy makers; the pharmaceutical industry; medical device and technology vendors; schools for medical and pharmacy training; professional associations; and even the public at large. These often-overlooked participants share equal accountability for doing their part to error-proof healthcare. For example, regulatory, accrediting, and licensing bodies should be held accountable for adopting standards related to error reduction recommendations that arise from expert analysis of adverse events and scientific research. Rather than experience the same mistakes happening again and again throughout the country, state pharmacy boards must work to identify the most common serious types of errors, work with licensees to develop prevention recommendations, and provide oversight to assure wide adoption at practice locations.

As an aside, I recently visited a practice site where, according to their internal error reports, Ortho-Cyclen<sup>®</sup> and Ortho-TriCyclen<sup>®</sup> were dispensed, in error, five times over the past two years. There were also errors involving confusion between Cortisporin<sup>®</sup> Ophthalmic and Otic Solutions – the same dispensing error I made myself over 25 years ago! Why does this happen? Here are some of the problems that may have contributed:

- Confusing drug names (and manufacturers' unwillingness to change to address problems that have been identified);
- Approval of look-alike packaging by the FDA;
- Overworked pharmacists and understaffed pharmacies;
- Workloads that exceed one's capability to provide safe care;
- Lack of dispensing technology (e.g., bar code, robotics, e-prescribing, image of original Rx on screen for refills, image on labels);
- Poor lighting in drug storage areas;
- Lack of safety alert to remind staff about potential errors

(e.g., auxiliary labels, highlighting portions of the manufacturer's label, reminders on the container or shelf);

- Overwhelming array of alerts when processing orders in the computer system;
- Lack of an independent check of each other's work by at least two staff members;
- Inefficient processes for adjudicating prescriptions with third party payers;
- Lack of patient counseling;
- Patients who are unaware of their role in error prevention;
- Risk management program in the pharmacy fails to address errors that have been reported by other pharmacies through the USP-ISMP Medication Errors Reporting Program; and
- Inadequate quality improvement program.

Others are also accountable for reducing errors. Purchasers of healthcare should provide incentives and rewards for patient safety initiatives. Companies that produce medical devices, pharmaceutical products, healthcare computers and software, and other health-related products should be held accountable for pre-market evaluation and continuous improvement in the design of devices, products, and labels and packages. Educators should seek out patient safety information and use it in curriculum design. (By the end of 2001, no pharmacy school had a course on medical error prevention as part of its core curriculum and only a handful provided it as an elective course.) Professional organizations should support local and national voluntary reporting systems and disseminate important patient safety information to their members. Finally, the public should ask questions and stay informed about their care and ways to avoid errors.

Who can argue with the multidimensional nature of medical care? Isn't it time to accept a multidimensional, shared accountability model for patient safety? Organizational leaders and other stakeholders who simply hold the workforce accountable when an error happens are inappropriately delegating their own responsibility for patient safety. We must stop blaming and punishing those closest to an error, and instead accept a model of shared accountability to collectively translate our sincere concern for patient safety into effective system-based error solutions.

<sup>1</sup> For this purpose, NACDS, APbA and ISMP partnered to produce the ISMP Medication Safety Self Assessment Tool for Community Pharmacy (see [www.ismp.org](http://www.ismp.org)). This tool provides nearly 200 safe practice characteristics for you to assess and compare your practice with other pharmacies around the nation. It should be considered a must for every community pharmacy to complete this tool.

# The Problem of Medication Errors

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## ***“First, do no harm.”*** Hippocrates

“Health care is not as safe as it should be.” This quote from the 1999 Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System*<sup>1</sup> summarizes the problem. *To Err is Human* broke the silence on medical errors and was the catalyst that focused national attention on patient safety. It was a call to understand the causes of medical errors and to search for solutions to reduce them. Still, errors continue to occur. What do we need to do to build a safer system for our patients?

## **Scope of the Problem**

According to the IOM report, medical errors (preventable adverse events) cause as many as 44,000–98,000 deaths each year.<sup>1</sup> The authors concluded – in effect – that the health care system kills more people each year than anything other than heart disease, cancer, stroke, and pulmonary disorders, exceeding the mortality due to motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

Adverse drug events (ADEs) are the single most common type of adverse event in hospitalized patients,<sup>2</sup> occurring at a frequency of 2–7 ADEs per 100 admissions.<sup>3,4</sup> Each year, an estimated 770,000 hospital patients annually experience an ADE.<sup>3</sup> Adverse drug events have been reported to cost hospitals between \$2.8 million and \$4.2 billion annually, depending upon hospital size.<sup>3,5</sup> These figures represent direct hospital costs only, and not those associated with outpatient care or disability. When all costs are included, one estimate of the cost of drug-related misadventures in the United States was nearly \$77 billion annually.<sup>6</sup>

Most adverse drug events are not life threatening or fatal.<sup>4</sup> Many are not preventable and reflect the intrinsic risks associated with drug therapy, such as when a life-threatening allergic reaction occurs in a patient not known to be allergic to the medication administered. However, when a patient receives an antibiotic to which he or she is known to be allergic, suffers an anaphylactic reaction and dies, a preventable ADE has occurred. One study found that almost one-third of ADEs were preventable.<sup>4</sup> Of the life-threatening and serious ADEs, 42 percent were preventable as compared to 18 percent of less serious ones.<sup>4</sup>

Medication errors occur much more frequently than ADEs, perhaps on the order of 100 times more often.<sup>7</sup> In one hospital study, investigators reported 5.3 errors per 100 orders, for a mean of 0.3 errors per patient day or 1.4 errors per admission.<sup>7</sup> Medication errors are not unique to hospitals. They also occur in other health care or practice settings, such as physicians' offices, pharmacies, and care delivered in the home. Unfortunately, there are very little data describing the extent of the problem outside of hospitals.

Fortunately, relatively few medication errors (about 1–2 percent) cause injury or an adverse drug event.<sup>4</sup> An additional 5 percent are “near misses,” which means they would have caused harm or injury if they had reached the patient.

## Why Do Errors Occur?

The health care system is complex, as is the medication use process within that system. Numerous discrete steps take place between the time a decision is reached to prescribe a drug and when a dose of that drug is administered to the patient. Practitioners representing more than one discipline participate in this process and can inadvertently introduce errors into it. Medication errors occur for various reasons, despite the good intentions of highly motivated and caring individuals.

Most medication errors are the result of faulty systems, not faulty people. Until recently, the prevalent culture in health care was one of blaming individuals. Poorly designed systems as an underlying cause of errors was not widely accepted.<sup>8</sup> To quote Michael Cohen of the Institute for Safe Medication Practices, a leading authority on medication errors, "The question of who was involved is of less importance than what went wrong, how, and why?"<sup>9</sup>

## Statutory and Regulatory Requirements

Medication errors deserve the heightened attention we are now beginning to see. As a result, new initiatives to prevent or significantly reduce medication errors are now in place.

**Legislation.** The California State Legislature recently enacted two bills, SB 1875 and SB 1339.

- SB 1875 requires hospitals to develop and implement plans to reduce medication errors. Hospitals were required to submit their plans to the state Department of Health Services by January 1, 2002 and are required to implement them by January 1, 2005.
- SB 1339, the subject of this issue of *Health Notes*,

requires all pharmacies to implement a quality assurance program to reduce medication errors.

**The JCAHO Patient Safety Standard.** The Joint Committee on the Accreditation of Healthcare Organizations (JCAHO) established a new safety standard for hospitals. It requires hospitals to:

- Designate one or more qualified individuals to manage an organization-wide patient safety program;
- Establish clear expectations for internal reporting of error information;
- Implement mechanisms to support staff members who have been involved in a sentinel event;
- Report annually to the governing body the actions that were taken to improve patient safety; and
- Implement a systematic assessment process that enables organizations to proactively identify points of risk in the medication use process.<sup>10</sup>

## The Pharmacist's Responsibility

This goal of this issue of *Health Notes* is to share the tools and safety strategies that will assist you in creating a "culture of safety" in the delivery of medications. Such a culture begins with an awareness that the "fault" for a medication error is often the result of a system failure, rather than a failure of an individual. This issue will help you to better understand the principles of quality assurance and error reduction; share lessons learned from low-error systems outside of pharmacy; provide tools and strategies for identifying, reporting, and analyzing errors; and empower consumers to do their part to prevent errors.

## References

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## *Building a Safer System:*

# Experience of Other Industries

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In U.S. hospitals, as many as 98,000 Americans die each year as a result of medical errors. This troubling statistic is one of the first statements from the Institute of Medicine Report, *To Err is Human*.<sup>1</sup> After the release of this report, several newspaper headlines equated these 98,000 annual deaths to a fully-loaded Boeing 747 crashing every working day, killing all those on board. Since our society would never tolerate such a terrible situation in the airline industry, why should it tolerate an error rate in the health care industry resulting in the same mortality?

Comparisons with the airline industry and others that demand safety systems are powerful and should motivate those of us within the health care industry to learn from them as we develop our own quality assurance programs. In reviewing the safety literature within these non-health care industries, there are three areas in which differences exist. They are the logic structure used to analyze errors, the methodology used to identify potential failures and their untoward effects, and the role of simulation in preventing errors. A description of each follows.

## The Logic Structure Used to Analyze Errors

The logic structure that has been used predominantly within the health care setting is *deductive logic*. The basic structure of deductive logic is to start with the consequences of an error and work backwards in order to draw an inference as to the possible causes.<sup>2</sup> For example, a physician calls the dispensing pharmacist to inform the pharmacist that her patient reported his latest prescription was dispensed erroneously. If this error occurred within the hospital, a multi-disciplinary task group would be established to identify the causes and possible solutions for preventing future occurrences. The task group would probably use a methodology called *root cause analysis (RCA)* to conduct the evaluation.

The physician then states that the prescription was mislabeled. Instead of the prescribed “take one tablet before each meal,” the label reads, “take two tablets before each meal.” In a root cause analysis, the sequence of events associated with the incident is identified and the root contributory factors are distilled from this examination. In our example of the mislabeled prescription, there may be many root contributory factors. For each factor, a corresponding action plan would then be identified.

Conversely, *inductive logic* starts with the causes or contributory factors in order to identify the possible consequences that may stem from each of them. Inductive logic is a *priori* (i.e., from cause to effect) and as such requires understanding of some key concepts. These are frequency, severity, and risk.

- Frequency is the probability that an undesired outcome will occur per a specified unit of time.
- Severity is the ultimate detriment that will result from the undesired outcome or event.
- Risk is the relationship between the severity of the consequence that results from an error and the frequency of that specific error.

Analyzing a system a *priori*, such as a medication use system, has the obvious advantage of identifying potential sources of error before an error occurs. The basic structure of inductive logic starts with the examination of a potential causative factor and then assessment of the consequences that can stem from it.<sup>2</sup> Using inductive logic optimizes the reliability and the safety of the stated system. Returning to our mislabeled prescription example, the possibility of getting a call from a physician describing an error would be lessened. The reason would be that mislabeling would have been identified as a logical consequence stemming from one or more

causative factors, such as illegibility of physician’s handwriting or dispensing prescriptions during peak demand periods. Actions that will prevent causative factors contributing to a mislabeled prescription would be identified and designed into a “fail safe” system in advance of an error.

## Methodology to Identify System Failures or Potential Failures

As described previously, root cause analysis uses deductive logic. A methodology containing the inductive logic structure is called *failure mode and effects analysis (FMEA)*. It is used in the military and has also been frequently used in the airline and the aerospace industries (e.g., National Aeronautical and Space Agency, NASA). This methodology provides an organized structure for identifying individual elements or operations within a system that will render the system vulnerable to failure. It identifies failure consequences and assists with an array of recommendations to mitigate each identified failure point. The methodology is generally used to identify points of failure in mechanical systems and not in systems where human beings are the main components within the system. However, the health care system is a complex mixture of both mechanical and non-mechanical elements, in which FMEA may play an important role at the nexus.

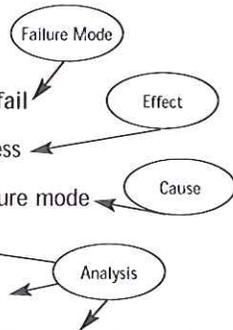
The FMEA process starts with three basic questions after the system under evaluation has been broken down into its various components or subsystems. These questions are:

1. Will a failure of the system or a subsystem result in an undesirable event?
2. For each of the systems or subsystems, what are the potential failure modes?
3. For each of the potential failure modes, what are the undesirable effects?

A FMEA worksheet is generally developed to document the evaluation, as well as to track and monitor the actions identified that address each failure mode. A typical worksheet would contain the following key elements: the system or subsystem, potential effect(s) of failure, severity of effect(s), potential cause(s) of failure, probability of failure, design controls to prevent failure, likelihood of detection, risk priority, recommended action and responsibility, and target date for completion.

### 12 Steps in Failure Mode & Effect Analysis (FMEA)

1. Form a multidisciplinary group
2. Understand the process
3. Brainstorm ways the process can fail
4. List effects of failure on the process
5. List root causes that generate failure mode
6. Estimate likelihood of failure
7. Estimate severity of failure affect
8. Estimate the probability of the failure being detected
9. Compute the criticality index
10. Brainstorm activities to reduce criticality index
11. Take action
12. Follow up



### OCCURRENCE RANKING

Likelihood	Definition	Probability	Rank
Remote	no known occurrence	1:10,000	1
Low	possible but no known data	1:5,000	2,3,4
Moderate	documented, but infrequent	1:200	5,6
High	documented and frequent	1:100-1:50	7,8

### DETECTION RANKING

Likelihood	Definition	Probability (10)	Rank
Very high	system will always detect error		1
High	likely to be detected before it reaches patient	7	2,3
Moderate	moderate likelihood of detection	4,5	4,5,6
Low	low likelihood of detection	1,2	7,8
Remote	detection not possible any time, any system	0	9

**Figure 1.**  
The systematic assessment of a process or product that enables one to determine the location and mechanism of potential failures

The FMEA worksheet may look like the following, where the top row illustrates an examination of the braking system within the automotive industry. The second row illustrates a medication dispensing subsystem using our mislabeled medication error.

System/ Subsystem	Potential Failure Mode	Potential Effect(s) of Failure	Severity of Effect	Potential Cause(s) of Failure	Probability of Failure
Braking Subsystem	Loss of Braking fluid	Cannot stop when needed	8	Break in fluid line	5
Transcribe	Misread MD order	Patient will receive wrong drug	10	Use of non-standard abbr.	3

For each identified potential effect of failure, the evaluator or evaluation team will assign a severity rating (1-10 with 10 being very severe). Similarly, a probability rating is given to each potential cause of failure (1-10 with 10 being very high).

The worksheet continues with identification of the design controls that are intended to prevent or mitigate the failure, as follows:

Current Design Controls	Likelihood of Detection	Risk Priority Number	Recommended Action(s)	Responsibility and Target Completion Date
Brake warning light	1	40	preventive maintenance of all brake fluid lines after every x miles	
RN double checks	2	60	Education on standard abbreviation	

A detection rating is given to each current design control (1-10 with 10 being highly undetectable). A risk priority number is then calculated for each potential failure mode. The risk priority number is the product of the severity rating multiplied by the probability rating and multiplied again by the detection rating. The potential failure mode with the highest risk priority number will have the highest potential to fail with severe consequences.

Applying this methodology to the pharmacy dispensing system would result in a FMEA worksheet as follows:

System/ Subsystem	Potential Failure Mode	Potential Effect(s) of Failure	Severity of Effect	Potential Cause(s) of Failure	Probability of Failure
Rx Dispensing	mislabeled dosage on prescription	Pt. will receive the wrong dose	10	Constant interruption via the phone	5
				Cannot read MD handwriting	5

Current Design Controls	Likelihood of Detection	Risk Priority Number	Recommended Action(s)	Responsibility and Target Completion Date
Double-check label against Rx	3	150	1. Reduce interruption by instituting a call triage process 2. Read the label out loud by a second person as one verifies Rx	
Call MD	1	50	Refuse to dispense and call MD for clarification	

Once the recommended actions are identified, they are accepted and implemented. If the recommendations are robust, the detection and/or the probability of failure ratings may be lowered. For example, if the two stated recommendations are successful in preventing mislabeling errors, the detection rating may be dropped to a lower number than 3 and the same for the probability rating. The lowering of ratings are not done unilaterally but are done under consensus using various identification methods, such as literature support, historical antecedents, modified Delphi<sup>i</sup> and others.

### Advantages

The FMEA methodology adds another perspective to error analysis and management. Its primary advantages are that it enables:

- Prioritization of system weaknesses requiring attention;

- Identification and development of redundancies within a system or subsystem;
- Development of design change to increase system reliability;
- Development of better monitoring or detection systems; and
- Reduction or elimination of service and/or environmental stresses, such as constant computer system outages.

### Limitations

Obtaining, interpreting, and applying severity, probability of failure, and detection ratings can be difficult and tedious. This is one of the limitations associated with FMEA. Three other major limitations to the FMEA methodology are as follows:

- It only examines individual faults of system elements; the combined effects of simultaneous failures are not considered;

<sup>i</sup> A method to reach consensus by polling experts and collecting data in a structured manner.

- It takes time to complete a full analysis, especially for complex systems; and
- It is not geared to identify human frailties.<sup>3</sup>

### Role of Simulation in Preventing Errors

Complex systems, like the medication delivery system, have gaps between processes, subsystems, people, and information. In many analyses of mistakes made in the medication delivery systems, gaps (especially information gaps) are identified as contributing factors to the error. For example, our mislabeling error can be categorized as an informational gap error. If the dispensing pharmacist had been aware of the patient's diagnosis, would the mislabeling error have been caught?

In the military and other industries (e.g., aviation), units use simulation as one of the bridges to span the gaps in complex systems. Simulation games can be useful learning tools, because individuals learn to work with other team members in order to accomplish a stated mission. As a result of being tested together within the simulation, team members develop a strong teamwork ethic and *esprit de corps*.

Working under simulated, but realistic, conditions pushes the team to "storm" together before they can "perform."<sup>ii</sup> Conflicts among and between team members become real, but highly useful to fostering and strengthening communication channels before the team is actually deployed. Conflicts arise that deal with informational gaps, forcing the team to work through these situations. A wonderful byproduct of "storming" is the establishment of a new culture among the team members. Even though there may be an established hierarchical structure within the team, as in the military, the constant testing under simulated conditions allows junior members to speak up when a senior member is about to make a grave error.

<sup>ii</sup> Refers to the process of teams coming together as originally described by Henry Mintzberg: forming, storming, norming, performing.

This latter point is very important in the health care industry, because there is a definite hierarchy. Physicians generally dictate the action (treatment) plans for the patients. If the physician was about to make a grave error that could result in harm to the patient, would we be able to speak up? If not, perhaps, simulated scenarios among health care team members may be helpful in developing the ability to speak up to prevent harm. Constant simulated play by a health care team can result in bridging gaps created by the hierarchical structure.

The key advantage of simulation is that it develops tacit knowledge among team members. There is instant feedback on how an individual and the team performed. The saying that "we should learn from our mistakes" is the norm in simulated games. During these simulated situations, unforeseen scenarios are created for the individual member and team to negotiate. Errors are constructively criticized and changes are made. Correct actions are reinforced.

In today's health care industry, there is a tremendous shortage in our labor force and it is working in a stressful, ever-changing environment. Simulation is very important in these situations and would help protect patient safety. Would you fly in an airplane knowing that the pilot had never before flown with the aircrew assigned to your flight?

### Conclusion

In health care, the obvious adverse consequences that should be avoided in our patients are injury, iatrogenic illness, and death. Other adverse consequences could be loss of reputation, loss of money, and medical-legal lawsuits. In the final analysis, the approach used by other industries to reduce errors differs significantly from that used in health care. The health care industry, and more specifically the pharmacy profession, has much to learn from them.

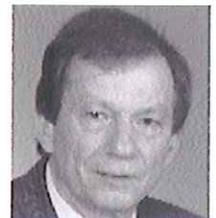
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# *Tools for the Reflective Practitioner:* Using Self-Monitoring, Personal Feedback and Goal Setting to Reduce Error

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In a recent letter that I received, a pharmacist remarked, "Part of the reason for errors is that filling prescriptions is like an assembly line operation. It seems like a never-ending task. We get so busy that we often don't have time to think. Pharmacists become like robots with our brains on the back burner!"

Pharmacists are not alone. Researchers estimate that 70-80 percent of our waking life uses the mental equivalent of an automatic pilot.<sup>1,2</sup> This is particularly true of familiar tasks such as driving cars, exercising, and performing the repetitive and routine parts of our jobs. Our conscious awareness drops and largely automatic modes of thinking and behaving take over. Harvard University psychologist, Ellen Langer, labels this mental state *mindless thinking* and contrasts it with what she calls *mindful* or conscious and reflective thinking.<sup>3</sup> Each mode of thinking has its advantages and disadvantages.

On the positive side, our ability to engage our “auto-pilots” saves time and energy for reflective thinking on interesting and challenging tasks. Thus, when asked whether a combination of three medications could have side effects, a pharmacist switches into a mindful mode of thinking. Since most of the dispensing process largely occurs automatically, additional time is available for a thoughtful answer. Reflective thinking and processing of information reduces accident and error rates, lessens anxiety and stress, and gives people a sense that they have more control in their lives.<sup>4,5</sup>

On the negative side, mindless thinking creates a mental fog with less conscious attention paid to the task at hand. Rules and procedures may not be used properly, and normal checkpoints may not be thoroughly conducted. In a pharmacy, these short cuts can translate into a variety of mistakes. Familiar examples include the misspelling of patient or physician names during data entry, placing incorrect directions on a label, selecting the wrong drug or strength, rushing the final verification of a prescription, or failing to counsel patients on new prescriptions.

Clearly, devoting additional conscious attention to tasks, especially during normal checkpoints, will be helpful. Also, periodic analysis of the strengths and weaknesses associated with how tasks are conducted and the outcomes of any changes can improve the safety and quality of work. The new quality assurance regulation to reduce medication errors (Title 16 CCR, Section 1711) encourages the analysis of mistakes and the development of remedies.<sup>6</sup> It is *reflective practitioner-friendly* legislation. It provides permission, protection, and an incentive for pharmacists to learn from their mistakes.

There are two sides to most things in life and the new quality assurance law in California is no exception. While it will undoubtedly yield dividends in improving patient safety, *it may inadvertently limit what can be learned and achieved.* The problem lies in how a medication error is defined in the new regulation. Specifically excluded from the definition of an error is “any variation that is corrected prior to furnishing the drug to the patient or patient’s agent or any variation allowed by law.”<sup>6</sup> This definition of a medication error is reasonable, but it may limit the focus of analysis to *those adverse outcomes that account for a minority of the mistakes that pharmacists make.*

In contrast, errors made and corrected in the process of achieving a correct outcome, or “near misses,” provide extremely valuable information about conditions producing errors. I label such mistakes *process errors*. Analyzing process

errors produces information about the causes of error and suggests how they might be managed. These lessons are less likely to emerge from a study of outright medication errors alone.

## Important Characteristics of Process Errors

### *Process Errors Are “Real-Time” Errors*

Currently, several strategies are used to analyze the cause of errors. But they are initiated either after an error has occurred (e.g., root cause analysis and pharmacy incident report analysis) or in advance of a potential problem. The latter strategy is used to assess potential risk in new procedures or changes in drug use and distribution systems (e.g., failure mode and effects analysis). A drawback of such techniques is that some dispensing errors are not easily reconstructed after the fact and conditions likely to produce errors that are not totally predictable beforehand. For example, consider what normally occurs when patients discover errors. Such mistakes are often called to the pharmacist’s attention hours or even days after the event happened. Memories for events fade with time, facts are remembered and assembled selectively, and emotions associated with a medication error can interfere with an accurate reconstruction of what actually happened.<sup>7,8</sup> When asked about the causes of errors on incident reports or in focus groups, pharmacists typically respond with such statements as, “I was busy,” “I was distracted by a customer’s question,” “It happened out of the blue like a bolt of lightning,” or “Must have been a bad roll of the dice.”<sup>9</sup> These and similar statements do not help to identify underlying causes.

In contrast, because process errors are monitored in *real time*, additional sensitivity to psychosocial factors and the nuances of environmental, workflow, and other factors can be obtained. Recent cases of serious errors suggest that mental distraction, following rigid rules, and emotional states affected the error, but were largely ignored in traditional analyses of the problems. The medication errors occurred when a pharmacist was preoccupied with the recent death of a spouse, when a nurse invoked a cultural injunction to “not challenge authority and thus I assumed the doctor knew what he was doing,” and while a pharmacist was worried about her children on a camping trip as a severe storm approached.<sup>9,10,11</sup> Psychosocial factors can lead to specific interventions. In the cases mentioned here, a company bereavement leave policy should be in place; assertiveness training for employees in managing authority would teach valuable skills; and a culture

encouraging workers to ask colleagues to help check their work when emotional levels are high could have prevented the errors. Such lessons learned can be combined with traditional root cause and failure-mode analyses to provide a comprehensive picture of the causes of medication errors.

***Increases in Process Errors are Precursors to Medication Errors***

There are many more process errors than outright mistakes. As they increase, so do the chances of a mistake getting past normal verification checkpoints.<sup>12</sup> On average, for every six process errors, one mistake will find its way into the “will-call bins” waiting to be picked up or directly into the hands of patients. This ratio of process errors to mistakes that get past normal verification processes is remarkably stable and has been observed in retail pharmacy field-sites, an outpatient hospital pharmacy study,<sup>13</sup> and in a pharmacy simulation laboratory.<sup>14</sup>

***Process Errors are Like a Double-Edged Sword***

They are good, because a mistake was caught and corrected. Unfortunately, process errors are bad as well, because they signal that mental processes drifted into an error mode. Too many of them are a sign that the *fog of mindless thinking is emerging*. Pharmacy personnel should take precautions. *A rule of thumb is that six or more processes errors per hour should be treated as an alarm.*<sup>i</sup> This lesson is easily applied. One pharmacy manager told me that she watches herself and her staff carefully. “When I notice them fumbling about and making too many corrections, I require a break or a shift in their tasks and require additional checks of their work.” A pharmacist remarked, “When they increase, I take a break or do a non-dispensing task for awhile.” Such actions lessen the chances of patients receiving incorrect prescriptions.

**Capturing Process Errors**

***Periodic Self-Monitoring of Performance***

In a study of 84 pharmacists in 36 retail pharmacy field-sites, pharmacists monitored themselves for 9 hours a week over a 4-week period, equally dividing their time between early, middle, and late parts of their shifts.<sup>12,16</sup> The form used

to document critical events is shown in Figure 1. It was part of a 4 x 6 inch booklet the pharmacists carried with them or kept close by in the workspace. Multiple copies of the form were available in the booklet to cover the periods of time on the shift they would spend monitoring performance. The pharmacists placed a hatch mark or check in the proper space on the form whenever a critical event occurred (e.g., a change in data entry or final verification). Everyone was instructed to make an entry only when it was safe to do so. The monitoring packet also included forms for recording emotional states and perceptions of subjective workload. The latter included ratings of perceptions of mental demand, time demand, physical demand, concern for doing well, effort required, and frustration with their work.<sup>ii</sup>

This form can be used as shown, or adapted to reflect aspects of particular pharmacy environments or any specific

SELF-MONITORING OF PROCESS ERRORS				
Day ____	Part of Shift	(Early)	(Middle)	(Late)
Time of day you began ____ ended ____				
# Scripts you helped to fill during this time ____				
Correcting information to patient on telephone				
<input type="text"/>				
Correcting script information when copying from a telephone call or FAX transmission				
<input type="text"/>				
Date-entry changes				
<input type="text"/>				
Product selection changes				
<input type="text"/>				
Count & pour changes				
<input type="text"/>				
Corrections during normal checkpoints				
<input type="text"/>				
Counseling patient or answering patient questions				
<input type="text"/>				
Correcting script after it was placed in “will-call”				
<input type="text"/>				

Figure 1: Form used to monitor process errors

<sup>i</sup> Author's opinion and not necessarily that of the California State Board of Pharmacy.

<sup>ii</sup> The National Aeronautical and Space Administration – Task Load Index was used. This tool allows people to judge the amount of subjective workload they are experiencing during different parts of a task or during various times of the day. Judgments are made of a scale that ranges from 1 – 100 where one indicates a low level of task tension and 100 a very high level of task tension. Scores on each of the subscales are also combined to yield an overall composite of subjective workload. It is one of the most highly reliable measures of subjective workload available.

information needs the pharmacy might have. For example, the categories could be modified to include look-alike or sound-alike product confusion, number of times the work of a technician was corrected, process errors associated with working on third-party insurance requirements, specific data-entry mistakes made, or environmental or workflow conditions present. Also, the amount of time monitored could vary based upon individual circumstances (e.g., three times a week every month, one day a week, or for several hours after an increase in process or other errors are noticed). Finally, monitoring forms could be used to periodically check 10 percent of the prescriptions in will-call bins against the original prescription for mistakes. In the latter case, monitoring for

a wrong prescription in the bag, incorrect directions and other label information, incorrect count/amount, wrong strength, and wrong drug could be examined.

Process error monitoring is best used for personal development. As such, individuals or teams might conduct such analyses. The goal is to provide information for personal use and professional development. There is no need to archive any records gathered since the objective is to use what is learned immediately.

### Outcomes of Monitoring

Table 1. summarizes several patterns in process errors that were observed in the study of 84 pharmacists across 36 retail field sites.

Percentage of Process Errors **	Percentage of Process Errors **
Overall (8.4 percent)	Ratings of Pharmacy Lighting
Scripts Worked on Per Shift	Rated Adequate (11.8 percent)
Low [40-105] (11.2 percent)	Rated Inadequate (8.5 percent)
Medium [106-192] (7.9 percent)	Percent Reduction due to
High [193-327] (6.1 percent)	Eye-level script-holder (35 percent)
Distribution in Monitoring Form	Each independent check
Patient on Telephone (4.2 percent)	after final verification (95 percent)
Copying Information (8.6 percent)	Subjective Workload
Data Entry (41.3 percent)	Low Error- 6.6 percent- (60 of 100 pts)
Product Selection (12.5 percent)	High Error -10.2 percent- (40 of 100 pts)
Count & Pour (14.4 percent)	Supervisory Effectiveness
Normal Checkpoints (14.2 percent)	Rated Effective (<4.8 percent)
Counseling Patients (2.6 percent)	Rated Ineffective (>11.6 percent)
After Prescription Placed in Will-Call (2.2percent)	Workload & Error Change***
High to Low Vol (7.1 percent to 10.2 percent)	High to Low Vol ( 7.1 percent to 10.2 percent)

Table 1. Summary of Findings from Monitoring Process Errors. \*

\* Adapted from references 16 – 18

\*\* All percentages based upon the number of process errors observed divided by the number of prescriptions filled.

\*\*\* Low workload was (< 15 prescriptions per hour). High was (> 25 prescriptions per hour).

## Learning from Process Errors

### *Using Patterns in Process Errors to Design Interventions*

While interesting in their own right, analysis of the outcomes shown in Table 1, led to development of the following strategies to improve patient safety.<sup>12,16-18</sup>

**Data entry:** Use scanning technology. Keep information at eye level when typing it into a computer data base. Use copy or monitor-stands to hold a prescription at a comfortable visual angle to decrease errors.

**Verification:** Use independent double checks of work completed. Control interruptions of people when verifying work. Use adjustable task lights and magnification devices to increase visual acuity during verification.

**Patient Counseling:** Take more time to counsel patients and use a “show and tell” technique when dispensing new prescriptions, as follows. Open the vial of medication when counseling the patient, shake one tablet or capsule of the medication into the cap of the vial, and tell patients the name of the drug and the directions for its use. For refills, ask “is this what you expected to get?” This forces the patient or caregiver to consciously reflect on what was received, to ask questions, or to find out what was received the last time.

**Negative perceptions of lighting:** Take complaints about light levels or equipment seriously and take immediate steps to improve them. Perceptions that pharmacy lighting was adequate were associated with fewer process errors. This mirrors what happens when illumination levels were actually increased in research studies.

**Workload Shifts:** Work on non-dispensing tasks or review work completed in order to “get back into the task” or warm-up after a break or lull in workflow. Shifts from conditions of high to low workload and working under conditions of low workload led to more process errors. One reason is that low workload leads to boredom and people begin to think about non-task related items. Also, dramatic shifts from high to low workload disrupt normal work-rhythms. In both cases, engagement with the task drops.

Active attempts to regulate workload should be initiated. Consider prioritizing work to be completed by using different colored baskets and computer guided work priority systems to separate prescriptions needing immediate attention from those that can be filled later. Or, if possible, have some filled centrally when overloads occur, and always ask patients in outpatient and community pharmacy settings to state when they need to have their prescription ready.

**Supervision:** Use effective supervision skills. Ineffective supervision was seen as overly controlling, which did not allow people appropriate autonomy on the job. It led to job dissatisfaction, stress, and mental distractions that interfered with accurate and productive performance.<sup>20</sup> Similar finding have also been observed among nurse-pharmacist-physician teams.<sup>21</sup> Under such conditions people intercept and report fewer errors.

The most helpful supervisors have the following attributes:

- Set clear goals and directions for the work that people do;
- Help establish a climate for excellence and professionalism;
- Provide clear expectations;
- Delegate appropriately the freedom to do a job;
- Seek the opinions of those affected before making decisions;
- Insure that the reasons why something is done are clearly stated;
- Provide sufficient answers to questions;
- Adjust supervisory style to accommodate differences among people; and
- Make people feel involved and important.

### **Use Feedback from Self-Monitoring to Set Performance Goals**

After the first two weeks of the project, pharmacists working in 12 of the field-sites were asked to calculate the percentage of process errors they observed before sending their booklets to the research team. Based upon a chart showing them the average percentage of process errors that all pharmacists in the study made, they set a performance goal for the following two weeks. Their choices were:

- “I am satisfied and will maintain my current level of work performance.”
- “I am dissatisfied and want to improve my ability to detect mistakes.”

The outcomes of this intervention are shown in Figure 2.

The data clearly show that attending to feedback and setting goals were helpful. Compared to a control group of participants working in 12 stores where no feedback was provided, those who set a goal to maintain their performance detected 22 percent more process errors. On the other hand, those who set a personal goal to improve what they did increased their detection of process errors by 103 percent. *They became more mindful of their actions on the job and were better able to notice problems.* While comparing one’s performance to others is useful, establishing personal improvement goals based on monitoring behavior also should have beneficial effects.

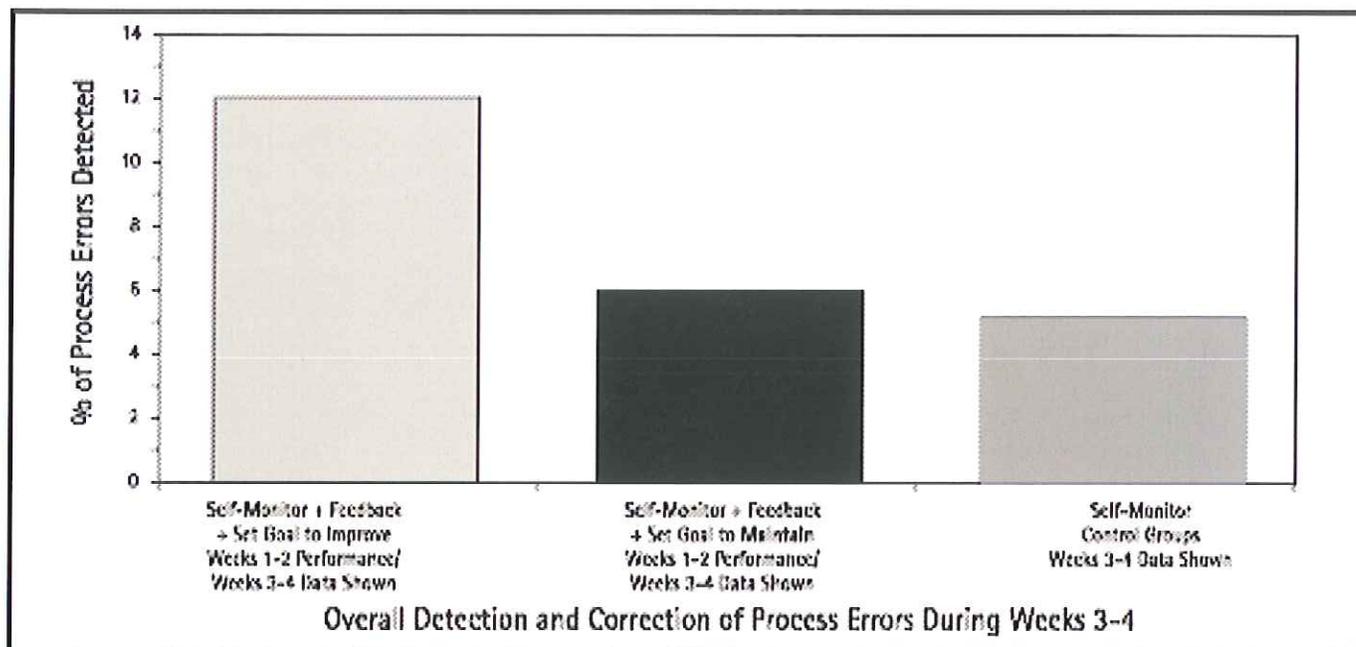


Figure 2: Effects of performance feedback provided after self-monitoring process errors during the weeks 1-2 of the protocol. Participants were asked to set a goal of either maintaining or improving process error detection during weeks 3-4. Chart shows performance improvement during weeks 3-4 compared to a control group than did not receive feedback or set goals.

## Conclusion

Taking more time to become mindful or to consciously focus on work in process or completed benefits patient safety. This entails increasing the time spent as a reflective practitioner and using processes that actively facilitate such

thinking. A general sensitivity to the interplay between cognitive and other psychosocial factors and pharmacy practices should be a part of such analyses.

More detailed information on how to accomplish such goals is available in several recent publications for pharmacy personnel.<sup>iii</sup>

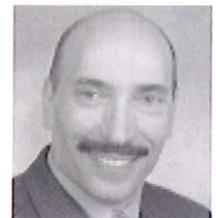
<sup>iii</sup>There are innovative self-study materials that cover the practical applications of the interplay between cognitive, psychosocial factors and traditional pharmacy practices in reducing error, risk management, and promoting patient safety. Ten self-study modules on the latter topics were supported from an unrestricted educational grant from the McKesson Foundation and will be available to pharmacy personnel worldwide beginning in July 2002. Interested readers should view the non-commercial website ([www.pharmsafety.net](http://www.pharmsafety.net)) where the modules can be downloaded free of charge. CE credit is available for US and Canadian Pharmacists. The development team included Anthony Grasha, Ph.D., David Brushwood, R.Ph., J.D., Michael O'Neill, R.Ph., and Krnig Schell, Ph.D.

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# *Documenting Medication Errors:* Tools for Performance Improvement

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**T**he United States Pharmacopeia (USP) is a practitioner-based organization that sets standards for the identity, strength, quality, purity, packaging, and labeling of therapeutic products. USP's standards-setting body is the Council of Experts, formerly the Committee of Revision. This committee maintains and continuously revises the *United States Pharmacopeia and National Formulary (USP-NF)* and the *USP-DI*<sup>®</sup>. As a non-profit corporation working in the public interest, USP also operates several public health programs that further help to assure that practitioners and patients/consumers have access to high quality therapeutic products and that they are used wisely. Patient Safety is one of these programs.

USP's interest in patient safety began with the understanding that names and labels of therapeutic products can either reduce or enhance the likelihood of a medication error. Reports from practitioners were and continue to be critical to this understanding. To facilitate practitioner reporting, USP now operates two complementary error-reporting programs. These are the USP Medication Errors Reporting (MER) Program, which operates in cooperation with the Institute for Safe Medication Practices (ISMP), and MedMARx<sup>SM</sup>. Both yield information that has been highly useful to USP's standards-setting activities, to practitioners and patients or consumers, and to regulatory bodies such as the Food and Drug Administration (FDA). USP's Council of Experts has two expert committees that focus specifically on information from the MER Program and MedMARx. These are the Labeling and Nomenclature Expert Committee and the Safe Medication Use Expert Committee. While both programs collect essential data on medication errors submitted by health care practitioners, there are some important differences.

### The Medication Errors Reporting (MER) Program

The MER Program allows health care professionals from any practice site (e.g., retail pharmacy, hospital, clinic, nursing home) to spontaneously report both actual and potential medication errors in a confidential and, if desired, anonymous manner (Figure 1). Reports can be submitted by mail, fax, phone, or online ([www.usp.org](http://www.usp.org)) and are compiled into a national database. USP reviews each report for health hazards and forwards all information to the ISMP, the FDA, and the product manufacturer. The MER database is not accessible to individual practitioners. However, pertinent findings are disseminated to practitioners primarily through the USP Quality Review and Practitioner's Reporting News releases, as well as through ISMP newsletters.

By sharing experiences through the MER program, pharmacists contribute to the collective learning about the types and causes of medication errors. This understanding in turn leads to recommendations and actions to prevent recurrence. Reports collected through the MER Program are reviewed by USP's Safe Medication Use Expert Committee, which can recommend changes or additions to USP standards. USP's Labeling and Nomenclature Committee can also consider name and labeling changes. USP can also implement error-prevention strategies by working collaboratively with partners such as ISMP, FDA, and the United States Adopted Names

Council. Depending upon the nature of the medication error, MER Program reports become the basis for ongoing discussions between the FDA and manufacturers, and if warranted, regulatory action. The reported concerns of practitioners have prompted USP, FDA, and various drug manufacturers to institute numerous changes and improvements to drug products and have contributed to safer medication prescribing and use. Over the last five years, USP has received about 5,000 reports to the MER Program, most of which were submitted by pharmacists.

The following case study, abstracted from an MER report, illustrates how reporting identifies issues and concerns that need to be brought to the attention of product manufacturers.

*A female patient was prescribed a topical anesthetic cream with three refills. The prescription stated only that the cream should be applied before her scheduled laser procedures. Fearful of pain, the patient obtained all allowable refills (having the prescription refilled approximately every 7-10 days) and applied all the medication to the skin before the first procedure. The patient experienced a drug overdose that required intubation. She suffered an extended unconscious period and spent several days in the hospital. At discharge, the patient was put on diltiazem and had to use a walker.*

This example demonstrates how patients can be put in a precarious position if the product's packaging or the prescription label does not contain specific dosing instructions. California's law now requires pharmacies to implement a process for documenting and analyzing medication errors. Pharmacists can use the MER form as one way to document and trend error incidents. Moreover, review of published news items from the MER database should help pharmacists identify potential error-prone areas and analyze causes for error.

### The MedMARx Program

Based on the experiences from the MER program, USP developed MedMARx, an Internet-accessible, performance improvement tool designed for hospitals and health systems.<sup>1</sup> California's SB 1875 requires all general acute care hospitals, clinics, and specialty hospitals to develop effective reporting mechanisms to ensure that medication errors are reviewed by a multidisciplinary group. Hospitals using MedMARx are able to anonymously collect, track, and analyze medication errors in a standardized format. Subscribing hospitals can access the MedMARx database program, which enables them to compare their own medication error data with other hos-

pitals on a national level. The database also provides hospitals with a powerful tool to concurrently and proactively assess error-prone areas, identify opportunities for systems improvements, and apply risk prevention strategies by taking steps to “error proof” their hospital based on the unfortunate experiences of others.

The MedMARx program uses a medication severity index created by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as the basis for categorizing errors.<sup>2</sup> (Figure 2) USP provides secretarial support to NCC MERP, which is a working coalition of seventeen organizations that promotes the reporting, understanding, and prevention of medication errors. The NCC MERP medication error category index consists of nine categories, ranging in severity from A (the potential for error existed) to I (the error resulted in patient death). Categories also differ on the basis of whether the error reached the patient and if the error caused temporary or permanent harm.

In addition to the severity index, NCC MERP has developed other related error nomenclature, including the following definition for a “medication error:”<sup>i</sup>

*A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.*

Standardized definitions, indexes, and nomenclature help pharmacists to more uniformly collect, track, and compare medication error data. MedMARx allows the user to enter detailed information related to a medication error incident. This includes the error category; date, time, and type of error; possible cause(s); contributing factors (e.g., workload, staffing shortages); location of error; product(s) involved; general patient data (e.g., age, gender); and type of staff involved.

MedMARx is designed for use as a multidisciplinary tool to capture medication errors in any hospital area. It allows users to search medication error records within their facility as well as from other participating facilities, using various data fields to capture specific areas of interest (e.g., category/type/location/staff). All information reported to

MedMARx is anonymously submitted and the submitters identity is unknown both to the USP and to other hospitals in the system. MedMARx provides users the ability to document where in the medication use process (i.e., prescribing, transcribing, dispensing, administration, monitoring) errors occur allowing targeted assessment of specific process components. It enables users to review the causes and contributing factors (e.g., computer entry) associated with errors facility-wide, thereby identifying specific “problem-prone” systems or processes that may need changing.

Currently, there are over 500 MedMARx subscribers; approximately 40 of these are based in California. Hospitals in MedMARx have begun creating a valuable database, with over 6000 reports submitted in its first year of operation (1999) and over 40,000 more reports in its second year (2000). Now in its third year, over 175,000 reports have been submitted to the MedMARx database since its inception.

## What Has Been Learned

Research by USP on both the MER and MedMARx databases has yielded valuable information that can help guide pharmacists and other healthcare practitioners in their quality assurance and performance improvement initiatives. A recently published article detailing errors identified in pediatric patients is an example of such research.<sup>3</sup> The study found that 31 percent of MER and 5 percent of MedMARx reports identified as involving pediatric patients were cited as harmful errors. *Improper dose/quantity* (47 percent) was the most frequently reported type of pediatric error in the MER database, while *omission* (27 percent) and *improper dose/quantity* (25 percent) were cited as the most frequent pediatric error types in MedMARx. The top products most often involved included intravenous fluids (including premixed and extemporaneously compounded preparations), acetaminophen, and gentamicin.

Other data compiled from MedMARx and publicly released last year<sup>4</sup> found that:

- Reported errors that cause harm are an extremely low percent of total errors—approximately 3 percent
- “Omission” (29 percent) and “failure to follow a procedure or protocol” (12 percent) were the two main *causes* of a medication error.
- Distractions and workload increases were most frequently cited as *contributing factors* related to the top two causes of error.

<sup>i</sup>This definition is more inclusive than that used by the California State Board of Pharmacy.

- Insulin, morphine, and heparin were the drugs most frequently reported as being associated with errors causing harm

The finding that most reported errors do not cause harm supports a widely held view that “near misses”— as well as errors that can cause harm—should be collected and can be extremely useful in promoting patient safety. Many hospitals currently have some type of patient safety or medication safety/error committee as part of their overall quality assurance program. MedMARx is structured to capture key details in a manner that allows for a more thorough analysis (including a root cause analysis) of the error incident. The customized reports generated through the MedMARx program are beneficial in focusing multidisciplinary attention and resources on the issue of medication errors.

## The JCAHO Safety Standard

Implementing a multidisciplinary, blame-free, proactive approach to medication errors is also part of the intent of the patient safety standards implemented in July 2001 by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). The standard requires hospitals to establish a defined safety program – including systems for internal and external reporting of medical and health care errors. Data collected through internal and external reports are then to be used to identify risk and improve patient safety.

Although the role of the pharmacist is not identified specifically in these standards, medication use has been identified as a high-risk process.<sup>5</sup> However, given the complexity of the medication use system within hospitals and the frequent occurrence of adverse drug events, it is widely accepted that

Figure 1.  
The form used to submit errors  
to the USP Medication Error  
Reporting Program.\*

\*Source: USP Medication Errors Reporting Program, Rockville, MD. Used with permission.

The image shows a detailed form titled "USP MEDICATION ERRORS REPORTING PROGRAM". The form includes sections for:
 

- Date and time of event:** A field for recording the date and time.
- Please describe the error:** A large text area for describing the incident, including details like drug name, dose, and patient information.
- Did the error reach the patient?** A checkbox section with "Yes" and "No" options.
- What the incorrect medication, dose, or dosage form administered to or taken by the patient?** A text field.
- What the appropriate (over-the-counter) product was also involved in the error?** A text field.
- Describe the direct result of the error to the patient:** A text field.
- Indicate the location of the error:** A text field.
- What type of staff or health care practitioner made the error?** A text field.
- What type of staff or health care practitioner discovered the error or recognized the potential for error?** A text field.
- How was the error prevented from occurring again?** A text field.
- Product information:** A section for Product #1 and Product #2, including fields for Brand Name, Generic Name, Manufacturer, Labeler, Dosage Form, Strength/Concentration, and Type and Size of Container.
- Reports are most useful when returned, and/or if a copy of product label, copy of prescription/order, etc., are to be returned.** A checkbox section.
- Suggest any recommendations to prevent recurrence of this error, or describe policies or procedures you implemented or plan to implement to prevent future similar errors.** A text field.
- Name and Title:** A text field.
- Facility Name, Address, and Zip:** A text field.
- Your center and a copy of this report are routinely stored with the Institute for Safe Medication Practices (ISMP). Copies of reports will be sent to this portion with the manufacturer's label, and to the Food and Drug Administration (FDA). You have the option of including your name on these copies.** A text field.
- USP may release my identity to those third parties as follows (check boxes that apply):** A checkbox section.
- Signature:** A text field.
- Date:** A text field.

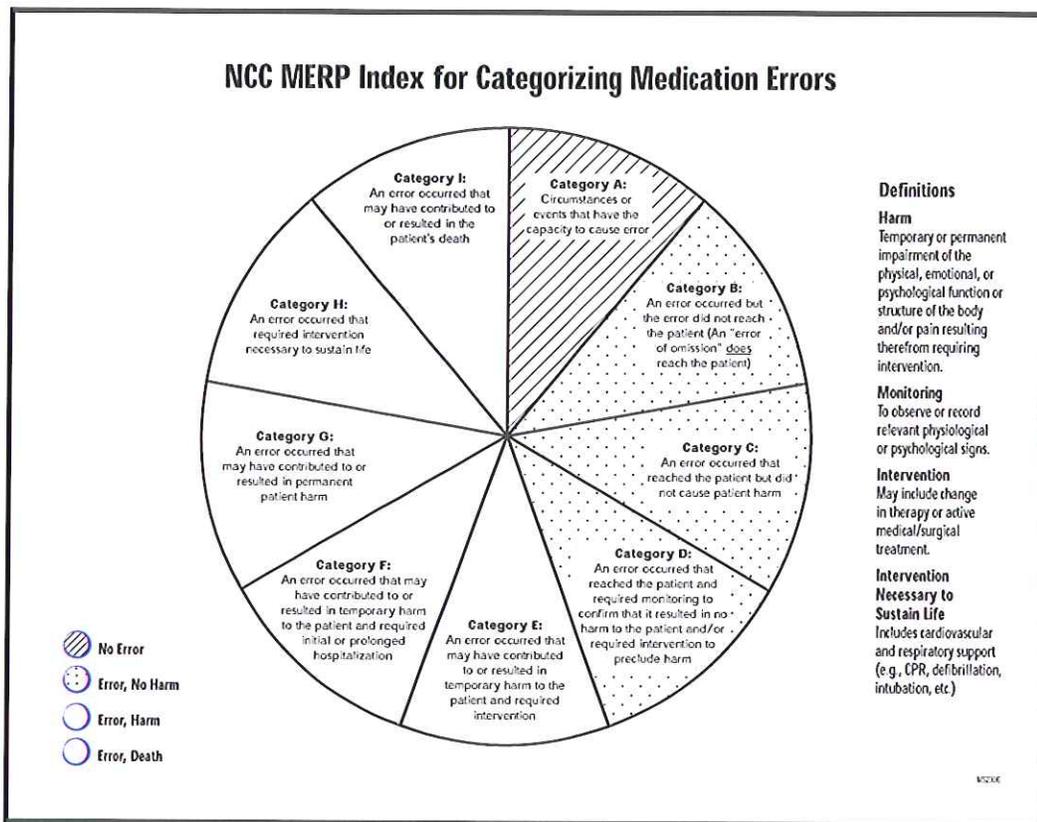


Figure 2.  
2001 National Coordinating Council for Medication Error Reporting and Prevention.

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the intent of the JCAHO standards supports both a focus on medication safety and the role of pharmacists in improving safety. MedMARx supports hospitals' compliance with the new JCAHO standards by prospectively identifying areas of the medication use process that are high-risk/problem-prone, facilitating both internal and external confidential reporting, facilitating root cause analysis of sentinel events, and determining opportunities for system improvements.

### Conclusion

The United States and other countries around the world are focusing to an increasing degree on quality

enhancement systems that improve the quality of care and promote patient safety. This focus has been heightened by reports from the Institute of Medicine and elsewhere indicating that errors in a health care system can be a significant cause of morbidity and mortality.<sup>6</sup> A key component of any quality enhancement system is reporting. For this reason, USP expects its MER and MedMARx programs to have a positive impact upon public health. Building a national medication-error database can contribute to the establishment of "better practices," reduce medical costs, and improve medication use systems that ultimately lead to better patient care.

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# *The Quest for Quality:* A Basic Review

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The ultimate goal of a pharmacy quality assurance program is to promote medication safety. Quality and patient safety terms, concepts, and principles are continually being redefined as professional and regulatory standards and expectations change. Many of these terms are used interchangeably, which can be confusing for those less familiar with their precise definitions, meanings, and nuances. For example, terms such as “quality assurance,” “total quality management,” and “continuous quality improvement,” are frequently used interchangeably. Yet, each has a slightly different meaning and implication within the context of health care.<sup>1-4</sup> Nevertheless, to minimize confusion here, continuous quality improvement (CQI) will be used, as it best captures the intended meaning of the term “quality assurance” used in SB 1339. The intent of this article is to provide a brief review of CQI principles and the steps necessary to implement a successful quality improvement program to meet California’s quality assurance requirement.

## What is Quality?

We all have a basic understanding of the word “quality” and most of us would probably recognize it if we saw it. But, what exactly does it mean? One definition of quality, as it applies to health care, is “meeting or exceeding valid customer requirements” when providing a product or service.<sup>1</sup> Thus, to provide quality services, we must know who our customers are and what they need or require of us.

Quality can be transparent and therefore may not be easily recognized. This is especially true in pharmacy, where there is a lack of established quality standards or thresholds against which to measure performance. For example, what is the quality standard or safety threshold for ensuring safe medication use? Is there a safe number of prescriptions to be filled per hour? Is there an acceptable time frame for medications to reach the patient once prescribed? Is there an acceptable number of medication-related errors that can be allowed per shift, or per day?

Medication errors can occur during the medication use process for many reasons. Decisions are made under tremendous time constraints or during high levels of stress. Health care providers may be faced with information overload, limited resources, or inadequate, ambiguous, incomplete, or even erroneous information. These may all be viewed as circumstances beyond our immediate control. A quality improvement program provides a structure in which problems can be identified, documented for pattern recognition, and then analyzed for better understanding. What is learned through the process can then be shared and used to propose strategies or methods to prevent future occurrences. Ideally, this is a continuous effort, requiring commitment from all of the participants in a given process or service, such that system flaws are transformed into improvement opportunities. A CQI process allows us to reflect on what was experienced, conceptualize what happened, and put the lessons learned into practice to prevent future mishaps.

## Where to Start?

### *Designate a process improvement team.*

One of the first steps when implementing a quality improvement program is to identify those individuals who will participate. Ideally, that should include all members of the pharmacy staff – pharmacists, pharmacy interns, pharmacy technicians, and clerks. Everyone who contributes to

the process of dispensing and furnishing medications to patients should be included, because quality requires a team effort. Bring everyone together regularly to discuss problems that have occurred and brainstorm solutions that are likely to be effective. Depending upon the size of the pharmacy or organization, the whole team, selected members, or administrative staff will be responsible for further analysis and implementation of process changes.

People involved in all stages of the process need to understand how important their contributions are to the whole effort. All members of the pharmacy team should understand the entire workflow process. In the community pharmacy this includes how prescriptions are taken in, how they are filled, how they are stored, and how they are dispensed. In the hospital it might include how drugs are procured, how orders are written and processed, how drugs are stored, and how medications administered. Every pharmacy will be unique in this regard, but it is imperative that all participants in dispensing or drug distribution understand the whole process.

### *Create a culture of safety*

Blaming is not productive. Employees will feel more inclined to report errors and participate in resolving problems if the environment is non-punitive. No one makes an error on purpose, but health professionals are human beings. The rigorous education and training of licensed health care providers emphasizes error-free practice, where mistakes are unacceptable.<sup>5</sup> These high standards of practice result in blaming individuals when errors occur, which creates pressure to hide or cover up mistakes. An environment of trust and a willingness to learn from mistakes, either our own or those of others, is important to preventing the same types of errors from reoccurring.

### *Think in terms of systems and not individuals*

Rarely can one individual alone cause an error. Focus on the process or system design and look for ways to improve it. Look for steps that can be eliminated or simplified and ways that procedures can be standardized. When possible, implement protocols and checklists to minimize or avoid reliance on memory. Improve access to important information and take advantage of computer forcing functions and alerts.

Recognize that there are multiple causes that contribute to any error. Systematically collect data and base decisions on that data, not on opinions. A multi-disciplinary approach to problem solving or process redesign is often necessary.

## Methods and Tools

There is a whole body of literature devoted to CQI methods and tools, which is beyond the scope of this article. The reader is referred to one of the many texts in this field for further study.<sup>1-4</sup> Quality improvement experts generally agree the following key steps are part of any CQI initiative:

- The process is described and sources of variation from the intended outcomes are identified
- The team conducts an in-depth analysis to clarify the sources of variation and extent of problems
- The team weighs alternatives and makes decisions about how to reduce variations
- The team implements one or more of these alternatives and measures how that affects the process

Many texts in the industrial and health care literature refer to the "seven quality tools." These are flow charts, cause-and-effect diagrams, checksheets, histograms, Pareto charts, control charts, and correlation analysis. The most useful of these and some of the more common CQI method are briefly described below.

### Quality improvement tools

*Flow charts and diagrams* help members of the team visualize all the steps in a given process. For example, when an error occurs and a meeting is convened to look at possible causes and solutions, the main steps leading up to the error can be

diagrammed in the order in which they occur. These may be further subdivided, focusing on the points where decisions are made or where errors are likely to occur.

*Cause-and-effect diagrams* are useful when brainstorming the underlying causes of an event (see Figure 1.). They are also known as Ishikawa diagrams (after Kaoru Ishikawa who introduced a method for evaluating root causes of problems in the 1960s) or fishbone diagrams (because when completed, they resemble the skeleton of a fish). This technique begins with identifying the problem and drawing it as the end result, as if backbone of a fish. Once the main stem has been identified, contributing factors leading up to the end result can be added as branches off the main stem. For each of these, root causes can then be identified. This type of schematic is especially useful, because it enables a group to visualize multiple contributing factors and underlying root causes in one diagram.

*Checksheets* are another common tool and are used to record data in a way that facilitates analysis. The number or frequency of an occurrence can be tabulated, for example, by time of day or day of week, to identify peak periods when an event occurs. An example of a checksheet is the form used to document process errors, which appears as Figure 1. in the previous article, "Tools for the Reflective Practitioner: Using Self-Monitoring, Personal Feedback and Goal Setting to Reduce Error."

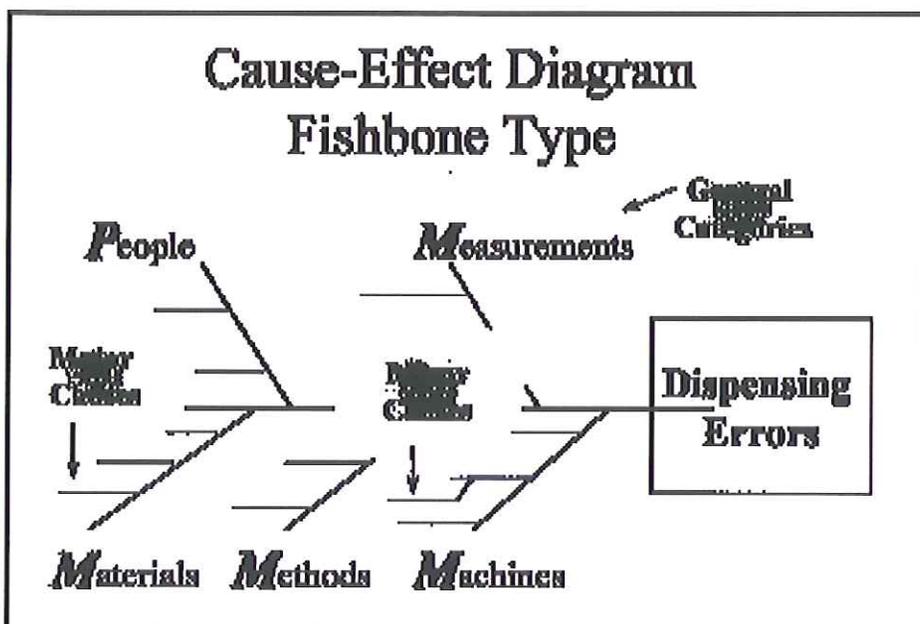


Figure 1. Cause-and-effect Diagram

### Quality improvement methods

Depending upon the size and resources available to the pharmacy or pharmacy organization, the methods selected for CQI may be simple or fairly complex. It is important to focus on what is manageable for a given pharmacy to avoid getting bogged down in the process.

**FOCUS-PDCA.** W. Edwards Deming, one of the first American proponents of quality improvement in the business arena, popularized the “plan-do-check-act” (PDCA) cycle, which was originally published by Walter Shewhart at Bell Laboratories.<sup>3,4</sup> During the 1980s, the Hospital Corporation of America (HCA, now part of Columbia Health Care Corporation) incorporated Deming’s concepts into its FOCUS-PDCA model, providing the healthcare industry

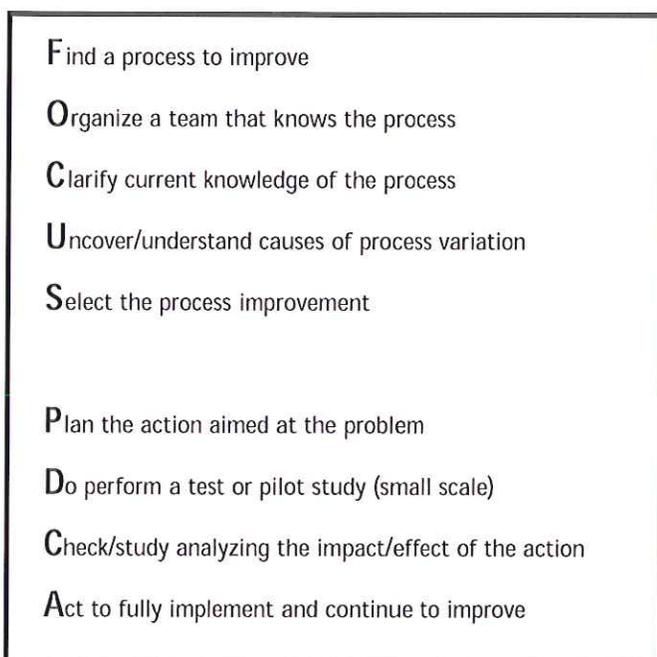


Figure 2. FOCUS-PDCA Model

with a common language and framework for CQI.<sup>1,3,4</sup> (See Figure 2.)

**Root Cause Analysis (RCA).** This is a method for identifying the basic or causal factors that underlie variations in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual per-

formance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist. Healthcare organizations are required by JCAHO to perform RCA's for sentinel events and reporting of these events to JCAHO is encouraged, but not required. JCAHO's RCA statistics have shown medication errors (12 percent) to be the third most commonly reported or discovered category, after suicide (17 percent) and operative or post-operative complications (12 percent). Therefore, since the initial publication of the Joint Commission's *Sentinel Event Alert* in 1998, several issues have been devoted to the topic of medication errors. These include the identification, prevention, and reporting of specific types of medication errors either reported to JCAHO as part of the sentinel event reporting system or identified by JCAHO at the time of survey.

**Failure Mode and Effects Analysis (FMEA).** FMEA, as described in the previous article, “Building a Safer System: Experience of Other Industries” is a proactive method to prevent errors with potential harm from reaching the patient. It is a systematic assessment of a system or process that enables one to determine the location and mechanism of potential failures. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is now requiring organizations to use proactive techniques such as this to identify potential risk points or failure modes.<sup>5</sup>

**IMADIM.** This is a method used by one academic medical center in California. It somewhat parallels the FOCUS-PDCA method and meets the intent of performance improvement. (see figure 3.)

### Conclusion

There are numerous CQI tools and methodologies available that may be used or adapted for use by individual pharmacies. The goal of each is to provide a structure for identifying system problems and recognizing opportunities for improvement. The most successful of these quality improvement models move quickly from problem identification to problem resolution and prevention, without exhausting resources or team members.

IMADIM	
IDENTIFY	<p>Identify the process for improvement</p> <ul style="list-style-type: none"> <li>• Develop your problem statement using clear, concise, and measurable terms.</li> </ul> <p>Identify the Team</p> <ul style="list-style-type: none"> <li>• Identify individuals involved in the project.</li> </ul>
MEASURE	<p>Measure current performance</p> <p>Identify data sources for measurement of the problem</p> <p>Benchmark</p> <ul style="list-style-type: none"> <li>• Use comparative data when possible</li> </ul>
ANALYZE	<p>Analyze current processes</p> <ul style="list-style-type: none"> <li>• Look at all steps in the process</li> <li>• Include input from a cross section of project members</li> <li>• Analyze the data using CQI tools</li> </ul>
DESIGN	<p>Design the improvement</p> <ul style="list-style-type: none"> <li>• Using your data, analyze and design a specific course of action</li> </ul>
IMPLEMENT	<p>Implement Process Improvement</p> <ul style="list-style-type: none"> <li>• What are the implementation steps?</li> <li>• Who will be involved? <ul style="list-style-type: none"> <li>• What are the milestones?</li> </ul> </li> </ul>
MEASURE	<p>Measure Performance</p> <ul style="list-style-type: none"> <li>• What will be the methods for monitoring progress?</li> <li>• How will you make conclusions as to whether the implementation actions were effective?</li> </ul>

Figure 3. The IMADIM Method

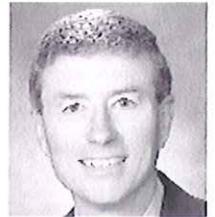
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*Continuous Quality  
Improvement Programs:*  
**Experiences In Different  
Pharmacy Settings**

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Continuous quality improvement (CQI) programs exhibit commonalities across various business settings. All CQI programs, independent of methodology, involve the identification of a problem, analysis of the problem, implementation of a process to minimize the problem, and then testing the outcomes of implemented processes. CQI programs that have been established by others may be reviewed and possibly modified for use in our individual practice settings. Distribution and dispensing of medications share common processes, regardless of practice settings, and review of CQI programs from hospitals, chain drug stores, independent community pharmacies, and long-term care facilities can provide useful roadmaps. This article is intended to share experiences that pharmacies in different settings have had with their CQI programs.

## Experiences of A Chain Store Pharmacy.

### *Background*

Organizations commonly utilize policy and procedure documents to record the rules and regulations governing the operations of their enterprise. Policies are general statements of an organization's philosophy on specific operational issues and procedures define a step-by-step process for the implementation of those policies. Policies and procedures are often identified by a title, a particular coding system, date of implementation, date of revision, and some indication that the particular policy and procedure of a unit meets the approval of the organization.

One chain store pharmacy began its quality assurance (QA) program by assembling individuals to develop a plan and then wrote policies and procedures to support that plan. After review and feedback from various individuals, this chain pharmacy developed an instructional video to describe the company's new QA program. It focused on the management and prevention of pharmacy errors related to the dispensing of medications. Although preparation of a videotape is not necessary for the dissemination of a QA program, this approach was selected because of a need to facilitate communication of information to a large number of employees. The videotape also facilitated standardization of the presentation. Employees were subsequently instructed to read the relevant policies and procedures and to acknowledge formally, by means of their signatures, that these were read and understood. These procedures also described a process for educating future new employees on this QA program.

### *Specifics*

In this QA program, pharmacy incidents or errors were defined. Demographic data (e.g., patient information, nature of incident, personnel involved, date and time of incident, outcomes) is also collected, not for the purposes of affixing blame, but to assist in analyses to identify contributing factors. After appropriate study of the probable cause(s) of the incident and action(s) undertaken, the specific pharmacy error is reviewed with the individuals who were involved. Subsequently, this information is shared with other staff members to reinforce the utilization or improvement of proper procedures.

An investigative form was developed for the collection of pertinent information related to a pharmacy error. The pharmacist who is notified of the incident is responsible for

completing the form and submitting it to a central location. Instructions for these steps are provided in the videotape and in the written policies and procedures. This pharmacist also is responsible for notifying other managers (e.g., the district pharmacy manager, store manager, and the pharmacist in charge) that the investigative form had been completed. An electronic summary of the report is available to the pharmacist at the store level and is password protected.

The procedures for this QA program provide guidance for sharing information related to a specific pharmacy error with the California State Board of Pharmacy. They also provide reassurance that the Board of Pharmacy's review of the error is to assure the safe distribution of prescription medications by adherence to established procedures. The QA program establishes a process for management oversight to identify trends in prescription incidents to assist in the development of both new procedures and better systematic processes. In addition, a process for communication of these findings to affected units in the organization was established.

### *Best Practices used by this Pharmacy*

This chain pharmacy's QA program emphasizes the prevention of prescription errors through several checks and balances:

#### 1. Standardized procedures during the dispensing process

- Verify all telephoned prescriptions by verbally confirming the patient's name, medication name, quantity to be dispensed, directions for use, and the name of the authorized prescriber.
- Fill the prescription from the hard copy of the prescription rather than from the generated label accompanying the prescription.
- Verify that each filled prescription involved a process for comparing the NDC number on the filled prescription label against the stock container.
- Develop a bar code scanning process that tracks and verifies that "systematic" checks are in place throughout the dispensing process.

#### 2. Standardized procedures at the time the medication is presented to the patient

- At the time of the patient consultation, ask the patient for his or her full name and the name of his or her authorized prescriber (e.g., physician) for comparisons against the label affixed to the medication container.
- Visually inspect the medication against the hard copy of the prescription before giving the patient the medication for all new prescriptions.

## Experiences of An Independent Community Pharmacy.

### *Background*

The policies and procedures for an independent community pharmacy should be similar to that described above for a chain store pharmacy. In essence, policies and procedures are written after front-line personnel have developed a plan. The plan must then be communicated appropriately to all affected personnel, who should acknowledge their understanding of it. Procedures for data collection and for analyses of the processes surrounding a medication error also need to be clearly understood. Again, the issues of problem identification, analyses, implementation, monitoring outcomes, and subsequent reevaluation of the procedures to further improve the program are similar to those for all QA programs.

### *Best Practices used by this pharmacy*

In the independent community pharmacy, the following practices demonstrate that procedures for minimizing medication errors can be standardized.

#### 1. Generation of prescription order.

- Use facsimile (fax) machines to minimize errors from verbal telephoned orders.
- Use fax servers that utilize computer-generated transmission of prescription orders to alleviate the problems associated with illegible handwriting.
- Be careful with computerized physician order entries (CPOE). While they alleviate problems with illegible handwriting, they are still susceptible to errors (e.g., incorrect selection from menu-driven screens of drug, dosage forms, doses, or directions for use). CPOE can also create errors because of incompatibilities at the interface between the hardware and software of the physicians' office systems and the pharmacy system.

#### 2. Interpretation of prescriptions.

- Obtain clarifications whenever the prescription order is unclear and requires an interpretation (e.g., "look-alikes" and "sound-alikes").
- Enter the diagnosis on the prescription label (e.g., one tablet daily for hypertension) to lessen the potential for error.

#### 3. Obtain pertinent patient data

- Obtain allergy histories while gathering insurance and other demographic data.
- Obtain information on concurrent disease states to facili-

tate collaborative drug therapy management and prevent potential adverse effects (e.g., ulcerogenic medications in a patient with an active peptic ulcer).

#### 4. Computer data input

- Use the NDC (National Drug Code) from the medication stock bottle wherever possible to assist in the identification of the correct medication. The effort to input the NDC of a drug into the data entry process necessitates review of the medication prior to computer entry. In addition, write the NDC from the medication bottle on the prescription order for each new and refill prescription, especially if the NDC can be printed on the computer-generated label that is to be affixed to the medication container.
- Be careful when using menu-driven screens to select drugs, doses, and dosing instructions and initiate a process for a double check whenever possible.

#### 5. Medication packaging

- Fill one prescription at a time, especially when medication orders are grouped together on one prescription blank and accompanied by multiple labels.
- Read the written prescription before reading the computer-generated label, and then check the label for accuracy.
- Do not leave a medication container unlabeled (i.e., complete the labeling task before responding to interruptions).
- Place completed multiple prescriptions for a patient banded or packaged together in an uncluttered storage area to minimize the delivery of a medication vial to the wrong patient.

#### 6. Delivery of medication to the patient.

- When consulting with the patient, ask the patient for his or her first and last names and the name of the physician, and compare this information to the information on the label that is affixed to the medication container.
- Open the container and place several tablets or capsules onto the cap of the medication vial to show the patient and visually ascertain that the identity of the medication is consistent with the labeled contents of the medication vial.
- If your pharmacy system has bar code scanning capabilities, utilize this technology to confirm that the right patient is about to receive the right drug.

Many of the above best practices can be rewritten as procedures in support of a pharmacy's quality assurance policy. Adherence to written procedures is intended to standardize a process (e.g., dispensing drugs) and to maximize the outcomes

from that process (e.g., decreasing the probability of a medication error). Although deviations from standardized procedures may be associated with ethical, professional, and legal implications, a standardized approach can decrease liability by decreasing the potential for adverse outcomes. Standardized procedures that are analyzed and updated periodically can improve the quality of pharmaceutical care to patients, decrease errors, decrease costs, and increase profitability.

### Experiences of a Community Pharmacy's QA Implementation

The following describes a community pharmacy's implementation of a quality improvement program that addressed dispensing accuracy and medication errors. The pharmacy was notified by its customers of several medication dispensing errors, which occurred over a two-month period. As a result, pharmacy management instituted quality improvement principles to implement a system of improved internal surveillance of dispensing practices and process analysis of dispensing data.

A well-designed quality improvement program must be based on high standards and grounded in established standardized procedures. In this case, there were no clear standardized procedures for checking the accuracy of dispensed prescriptions and no consistency in how the small staff of pharmacists and technicians documented that the prescription was filled with the correct medication. These pharmacists developed with the staff procedures that not only achieved the purpose of content verification, but that were also acceptable to each staff member. In this case, a procedure utilizing NDCs was added to the prescription filling process. The NDC for a drug was to be placed on the label of the medication vial and compared against the NDC on the manufacturer's stock container that was used to fill the prescription. The pharmacist's initials on the hard copy of the prescription signified that this step occurred.

Analysis of the medication dispensing errors that had occurred revealed that sound-alike drugs were inaccurately dispensed in two cases and fast-moving drugs confused in two others. The pharmacy's dispensing process allowed for accumulation of manufacturers' containers of fast-moving drugs on the dispensing counter. On a busy day, this could clutter the dispensing area and lead to inaccurate product selection. A new practice of re-shelving items at least every 15 minutes was instituted. A reference listing of common sound-alike

drugs was also shared with staff and posted. Additionally, selected items were assigned new locations on the shelves to prevent two sound-alike drugs from being shelved in close proximity to one another.

Most importantly, two forms were developed and implemented. A form for errors that are identified *after* prescriptions are dispensed captures detailed information about the medication error and patient sequelae. These infrequent occurrences can now be tracked and analyzed for common causes and possible solutions. When a dispensing error is reported, the results of the pharmacy's investigation and resultant process changes are shared with the "customer" reporting the error, whether a patient, nurse, or physician. Although resistant at first, the staff later agreed that sharing this information would be helpful in re-establishing credibility with their customer(s).

The second form, named a discrepancy diary, captures errors that occur and are corrected *during* the dispensing process. Occurring more frequently than actual dispensing errors, compiling this data can result in a relatively quick identification of dispensing processes that are vulnerable to the introduction of errors and opportunities for improvement. This not only prevents future errors, but can increase efficiency by eliminating the workload associated with correcting them.

Discrepancies logged in the diary over a two-week period revealed that labels for topical medications prescribed by a dermatology practice were frequently re-generated when one specific technician was at the computer. The pharmacists met with this technician and together they developed a process to better meet the expectations for labeling these medications. Further review of the diary also noted that pharmacists frequently rejected prescription labels for liquid medications. Again, the pharmacists met with the pharmacy technicians and developed a new standardized labeling format.

The pharmacy staff now meets regularly as the Quality Improvement Team to review both the prevented errors in the discrepancy diary and the medication-dispensing errors. These meetings have resulted in the implementation of new procedures to improve services, beyond the medication error program. The dispensing staff has coalesced and now considers itself more of a team. This positive attitude and management's perspective that errors and discrepancies should be embraced as opportunities for analysis and improvement, have led to a decrease in discrepancies and medication errors as well.

## Experiences of A Long-Term Care Pharmacy

Skilled nursing facilities, assisted-living communities, and residential-board and care homes commonly contract with one pharmacy to provide pharmaceutical services and prescription medications for the majority of their residents. These extended care facilities and their professional staff members are, therefore, important customers of the pharmacy in addition to its more obvious customers (i.e., patients, authorized prescribers).

Nursing facility operations are highly regulated by both federal and state agencies. One California requirement calls for timely administration of certain medications such as anti-infective agents and drugs that are critical to symptomatic relief (e.g., analgesics, anti-emetics, anti-diarrheal agents). Unless ordered "stat," these agents should be administered within four hours of being ordered. Medications NOT administered within four hours can be deemed medication errors by state health licensing surveyors during annual inspections or whenever a complaint is investigated. Although not strictly within the purview of the pharmacy and despite timely dispensing by the pharmacy, late administration of the medication can lead to a medication error for the pharmacy's customers, the facility and its patients.

Pharmacies within long-term care facilities are uncommon. Although emergency supplies of medications are allowed, the content and quantities are tightly controlled. Pharmacies design their emergency supplies to best serve the needs of their customers and a timely delivery process is critical to their success. Distance and traffic can be significant challenges to optimal outcomes. Without clear standards, procedures, and on-going monitoring of timeliness, a pharmacy can jeopardize its patients and the facilities it serves.

A Southern California institutional pharmacy exclusively serving long-term care facilities conducted a customer satisfaction survey to assess the level of satisfaction with their services and to determine which services were most important to their customers. Results clearly indicated that in addition to medication dispensing, timeliness of delivery was of prime importance. Several facilities indicated that they had received state deficiencies for medication errors resulting from medications not being available on time. The findings of the pharmacy's own consultant pharmacist the previous quarter reinforced the problem of timely delivery and administration of medications.

This pharmacy is located in a large metropolitan area with access to freeways that are becoming increasingly congested.

With business growing at farther distances from the pharmacy, delivery became an issue. The pharmacy staff understood the importance of the four-hour requirement, but until the customer satisfaction results identified this as an issue, the pharmacy had not developed an ongoing system to measure performance. They now knew they had a problem, but did not know how serious it was or what might be the underlying cause(s).

Multiple steps in the medication use process must be completed in a timely and coordinated manner to achieve the desired outcome of timely administration. These steps involve many different individuals and include timely noting of the order by the facility nursing staff, properly notifying the pharmacy (i.e., fax, phone) of a time-sensitive order, consistent pharmacy intake and dispensing procedures that properly differentiate a time-sensitive order from routine and refill orders, and staging of deliveries. The latter involves taking medication administration times at the facility and traffic into consideration when determining facility delivery order within a certain delivery run. Additionally, at the facility level, staff must recognize when there is a time-sensitive order included in a delivery and must administer the medication in a timely manner. Although the last two steps are not technically within the pharmacy's control, they are important to achieving optimal outcomes when assessing performance. The complexity of the process illustrates several areas of vulnerability that might contribute to overall success.

To address this problem, pharmacy management first established an indicator of timely processing of time-sensitive orders and a system to monitor performance. The goal was to deliver 100 percent of time-sensitive orders well within the four-hour window. The pharmacy first designed a method for identifying and tracking of these orders as they progressed through the dispensing process. The time orders were received by phone or fax was already being documented for every order, but time-sensitive orders were not differentiated in any way. Pharmacy staff responsible for data input were then instructed to highlight time-sensitive orders. On a daily basis, dispensing times were calculated for time-sensitive orders delivered the previous day. This was done by noting the time an order was received by the pharmacy and the time the staff at the facility signed for the delivery. Orders outside of the four-hour window were noted. The consultant pharmacists were given a list of these so they could follow-up on the actual administration of medications, on a random basis, when they were in the facilities.

## TALKING TO PATIENTS FOLLOWING A PRESCRIPTION ERROR

### Do

1. Involve the pharmacist immediately.
2. Apologize – speak to the patient directly.
3. Ask if any of the incorrect medication was taken. If so, find out how much the patient took and for how long.
4. Ask how the patient is feeling – Show your concern with you tone of voice and body language.
5. Communicate to the patient that he/she received incorrect medication or the wrong strength of medication.
6. Ask the patient to return the incorrect medication.
7. Take immediate action to provide correct medication to the patient.
8. Counsel the patient.
9. Notify the prescriber with the details of the error and what the pharmacist has done to correct the error.
10. Follow up with the patient the next day.
11. Explain that the pharmacy is investigating how this happened so that it will not happen again.

### Don't

1. Make excuses.
2. Use a defensive tone of voice.
3. Take any error or potential error lightly.
4. Delegate the responsibility to handle the error to a non-pharmacist.
5. Require the patient to make the effort to obtain the correct medication.
6. Violate patient confidentiality.
7. Apologize via a voice mail or answering machine.
8. Underestimate the concern of the patient.
9. Assume the patient is okay.
10. Make the patient wait.

After identifying that a prescription error has occurred, some pharmacies deliver the appropriate medication to the patient, pick up the inappropriate medication, refund the original prescription copay or price, and provide the correct medication without charge.

The data were surprising. Timely delivery was a larger problem than previously realized. The indicators of timely delivery ranged from 70 to 100 percent, with the former being more common than the latter. The prevalence of time-sensitive orders was much higher than the staff realized and several specific antibiotics that were not currently in the emergency supply were more commonly dispensed than previously thought. Certain delivery times and days of the week were more problematic. When delivery personnel were matched with the indicator data, it appeared that certain staff seemed to perform much better than others.

In order to identify root causes and solutions, the management shared the results with all staff involved in the various steps necessary for timely delivery. The consultant pharmacist shared the results of the quality improvement study. The pharmacy staff was amazed at the complexity of the overall task and how many individuals were involved. The consultant data revealed that a number of facilities had higher prevalence of orders outside the four-hour window than others, despite timely pharmacy delivery. A further investigation determined that in many of these cases, especially later in the day, the delivery containing the time-sensitive orders was not checked in by facility staff until after the four-hour window. Delivery staff with excellent indicator data shared their procedures for determining order of delivery. It became apparent that the pharmacy did not have a procedure for notifying delivery personnel that timed orders were within their delivery. Some already took this into account as part of their routine, but it was not standardized. Since the pharmacy business and traffic had grown, this inconsistency was leading to inconsistent outcomes.

Discussion by this “team” of involved pharmacy staff recommended several possible solutions, which were implemented sequentially while continuing to monitor performance. Procedures were added to better mark time-sensitive orders as they progressed through the dispensing process, to mark delivery bags containing time-sensitive orders with brightly colored stickers, to design delivery runs around these orders, and to notify nursing staff at the facility when a delivery contained time-sensitive medications. In addition, the emergency supplies of oral medications at the facilities were revised to better meet the facilities needs.

The pharmacy continues to measure this quality indicator, although now on a more random and periodic basis. What was initially identified as a problem through a customer satisfaction survey resulted in changes in process for both the

pharmacy and the facility, yielding higher quality of care for the ultimate customer, the patient.

## Experiences of a Hospital Pharmacy

### *Background*

One of the first steps of a quality assurance plan involving documentation/assessment of medication errors is an effective reporting mechanism. In 1999, a hospital pharmacy implemented an on-line incident reporting system, which significantly improved the management of medication errors. Timely reporting of medication errors is essential for accurate data gathering while memories are still fresh and documents such as medication orders or faxes are still easily retrievable. Once a staff member submits a medication-related incident report, an e-mail notice with a link to the incident is immediately sent to the manager of the person who reported the medication error and to the Medication Safety Pharmacist. The Department of Risk Management also has access to all incident reports. These steps help to ensure that a medication-related incident will be reviewed within 48-72 hours. If another manager needs to see a copy of the report, the e-mail link can be forwarded. All who review the incident report have an opportunity to add comments pertaining to follow up actions or additional investigation. The system also documents those who review the incident report, but make no comments.

Gathering all the information needed to assess the cause and severity of an incident is an important aspect of the reporting process. Asking specific questions instead of relying on a written account of the incident is a good way to capture essential information. For medication errors or delays in medication administration, information is requested on date, time, location, as well as the name, age, and gender of the patient. Further information is requested of the individual who reports the medication error as shown below.

- 1) Name of the medication
- 2) Where in the medication process the initial error occurred. One of the following choices is selected from a drop down menu: prescribing, documenting, dispensing, administering, or monitoring.
- 3) Type of Error. One of the following choices is selected from a drop down menu: extra dose, improper dose/quantity, omission, wrong administration technique, wrong dosage form, wrong drug, wrong drug preparation, wrong patient, wrong route, wrong time, or other.

- 4) Possible Causes of Error. One of the following choices is selected from a drop down menu: calculation error, contraindicated or allergy, decimal point, illegible handwriting, look alike or sound alike products or product name, pump improper use, transcription, or other.
- 5) Whether the error reached the patient.
- 6) The result of the error on the level of care e.g., antidote administered, code blue, death, drug therapy-initiated or changed, hospitalization-initial, hospitalization-prolonged, lab tests performed or increased, oxygen administered, reversal agent administered, surgery performed, transferred to a higher level of care, or vital signs monitoring initiated/increased.
- 7) Results of any tests/lab data if relevant to the outcome of the error.

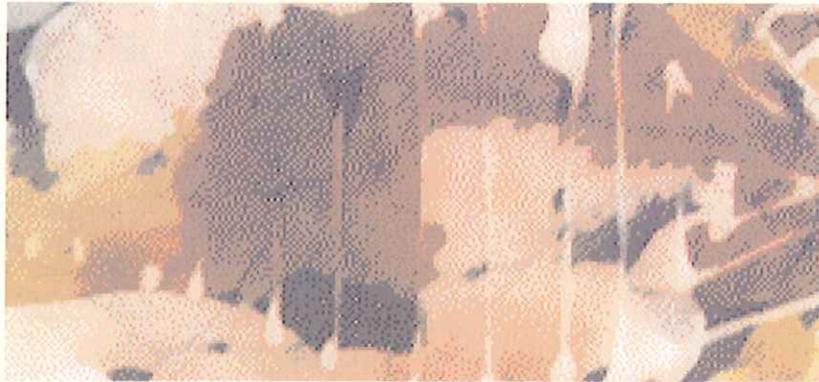
This hospital chose to focus on some of the more common causes of an error and provided an "other" option to capture the less frequent types of errors. To encourage voluntary reporting, a blame free environment is promoted by establishing hospital policies that prevent incident reports from being used as part of performance evaluations. "Performance deficit" as a cause of error was intentionally omitted in order to reinforce the non-punitive, systems approach to error reduction.

The on-line system has undergone multiple changes since its first implementation at this hospital pharmacy. Some manual transfer of the data must still occur in order to generate quarterly and annual reports. Plans to expand the report-generating potential of this system are under development.

### *The Medication-Related Events Management Program*

When this hospital had the reporting mechanism in place, the next questions were, "Who should take responsibility for reviewing the errors?" "What do we do with the incident reports?" "How do we improve care?" The answer was to implement a Medication Related Events Management Program to reduce medical errors attributed to the medication use process. Two important committees were appointed, the Medication Safety Steering Committee and the Medication Process Improvement Committee. The first, a multidisciplinary subcommittee of the Pharmacy and Therapeutics Committee, has oversight responsibility for medication safety. The latter is a pharmacy-nursing committee that deals with specific issues related to these two departments.

The first phase of the plan was to develop a definition of an error, recognizing that there is value in looking at both the



### HOW NOT TO HANDLE AN ERROR SITUATION:

Mrs. Jones walks up to the pharmacy counter on a Tuesday morning to question why the refill she picked up the night before was a light blue tablet instead of a white tablet. The pharmacy clerk looks inside the bottle and agrees that the tablets are blue and suggests that it is probably a different generic manufacturer.

Mrs. Jones explains that the medication is for her diabetes and that she took one of the tablets last night at bedtime and is feeling ill this morning. She wasn't paying attention to the color of the tablet when she took the drug last night. The clerk mentions that they were very busy yesterday and then calls the pharmacist to the counter.

The pharmacist talks to Mrs. Jones who again explains her concerns and is visibly upset. Meanwhile, several people have gathered around the cash register area waiting to be helped. The pharmacist says that they had a new technician working yesterday and then excuses himself while he goes to retrieve the prescription from the files for review.

Upon looking at the Rx hard copy, he sees that Rx called for Glipizide,\* which is what is on the Rx label. However, he recognizes the light blue tablet to be Glyburide,\* and fully understands that a prescription error has occurred.

The pharmacist tells the patient that a mistake has occurred and that he will fix the problem and dispense the correct drug right away. Before Mrs. Jones can say anything, he prepares the correct medication in a hurried fashion and hopes that no one else will notice that the pharmacy made an error.

Mrs. Jones tells the young pharmacy clerk that she is very upset about this situation and that she is not feeling well.

The pharmacist comes back to the counter with the correct medication, thanks the customer for bringing the error to their attention, and assures the patient that this error will never happen again.

Mrs. Jones says that she no longer trusts the pharmacy and will never be coming back there again.

errors that reach the patient and those that do not. In this hospital, *potential* errors are defined as mistakes that are corrected through intervention by the health care professional or the patient. *Actual* errors are errors that result in administration of a drug that deviates from the order or is given due to a prescribing error. Omission errors are considered exceptions to this definition and are considered actual errors.

Both types of errors are useful and indicate a point of vulnerability in the system. Consider the warfarin prescription that is filled with 10 mg tablets when 1 mg tablets were ordered. The patient notices the pills are a different color than usual and questions the pharmacist prior to leaving the pharmacy, thus an error is avoided. Even though the error did not leave the pharmacy, multiple system problems may be identified that caused this error (e.g., use of trailing 0, transcribed incorrectly, storage of the 1 mg and 10 mg next to each other on the shelf).

The Medication Related Events Program document includes an outline of the medication reporting process and incorporates other medication related policies (i.e., Sentinel Event Policy and the Incident Report Policy). Most pharmacy system improvements are the result of staff and management "brainstorming" sessions. Due to the complexity of the medication use system, many of the pharmacy system improvements are discussed by the Medication Process Improvement Committee to insure that changes in pharmacy procedures will have little or no negative effect on nursing processes.

## Conclusion

As noted above, quality assurance programs in various practice settings have commonalities. While there may be different processes used, the steps involved when developing a quality assurance program are similar. These include:

- Developing policies and procedures – Map out your current medication use process, critically analyze it, and incorporate safety practices that are readily available in the medication safety literature.
- Developing a reporting mechanism. There is no need to re-invent the wheel. Network with other pharmacists and use the tools that are currently available, editing these to fit your practice site.
- Educating the employees who will be participating in the system.
- Fostering a blame-free environment. Use the information from errors to identify system issues or education/training issues.
- Tracking the near misses – They provide valuable information.
- Utilizing technology to minimize errors.

Fostering open, honest communication about errors. Ensure that staff all understand the results of error reporting and are involved in developing solutions.

## HOW TO BETTER HANDLE THE SAME SITUATION.

Mrs. Jones walks into the pharmacy on a Tuesday morning complaining to the young pharmacy clerk that her refill for her diabetic medication that she picked up last night appears to be the wrong drug, because it is a light blue tablet instead of a white tablet.

The pharmacy clerk immediately calls the pharmacist to the counter. The pharmacist walks over and introduces himself and asks her to tell him about the problem.

Mrs. Jones tells the pharmacist that she took one of the tablets last night, not realizing it was light blue, and is now not feeling well. The pharmacist apologizes for her not feeling well and tells her that he is going to look at the prescription again to determine what the doctor ordered and what is in the bottle. He escorts her to the waiting area and suggests that she sit down while he immediately follows-up on the situation.

The pharmacist reviews the patient profile and determines that the patient has been maintained on Glipizide® for almost a year. The bottle is labeled correctly, however he looks at the light blue tablets and determines the drug is Glyburide®. The pharmacist calls Dr. Smith, Mrs. Jones' endocrinologist, and explains what happened. Dr. Smith tells the pharmacist he will note it in her chart. He confirms with the pharmacist that the correct medication will be dispensed, but that no patient harm should be caused by this error.

The pharmacist corrects the mistake and takes it over to Mrs. Jones. He explains what happened. He also tells her that while the incorrect drug is also used to treat diabetes, it was an incorrect drug for her and apologizes for the error. He assures Mrs. Jones that the pharmacy takes several precautionary steps while filling every prescription in their pharmacy.

He mentions that he has spoken to her doctor about the error and that there shouldn't be any harm from taking the one tablet. The pharmacist refunds the \$25 copay that Mrs. Jones paid for the refill the night before, retrieves the incorrect medication from Mrs. Jones, and asks her if there is anything else that he could do for her now. She says "no" and thanks him for his help, but suggests they be more careful when filling prescriptions in the future.

The next day the pharmacist calls Mrs. Jones to see how she is feeling. She reports to him that she is feeling much better and is glad that nothing more serious happened due to the mistake.

A month later Mrs. Jones calls the pharmacy for a refill on her Glipizide.® She continues to be a patient of the pharmacy.



# What Can Consumers Do To Protect Themselves From Medication Errors?

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Teaching consumers to be more knowledgeable about their medications is one way to protect them from medication errors. Consumers can be taught to play a greater role in their health care by encouraging them to speak up and routinely question their physicians and pharmacists about all their prescription medications, over-the-counter medications, herbals, and vitamins. As time with providers grows shorter, consumers must be advocates for their own care. They can do so if they have the tools and take responsibility for getting the proper questions answered about their medications.

Unfortunately, 96 percent of patients never ask any questions about their medications.<sup>1</sup> They assume that everything their doctor prescribes is correct and they believe their pharmacists will always dispense the right medicines. But this may not be the case, because physicians have less time to do their jobs and pharmacists are often overwhelmed with hundreds of prescriptions to fill. Thus, consumers must be educated to ask questions of both their doctors and pharmacists to better assure that they get the right medication and to know how to take it properly.

## What questions should consumers ask?

A number of health care and consumer organizations have developed lists of the basic questions that consumers should ask when given a new prescription.<sup>1-6</sup> The California State Board of Pharmacy recommends:<sup>1</sup>

Before taking any prescription medication, talk to your pharmacist; be sure you know:

- What is the name of the medication and what does it do?
- How and when do I take it and for how long? What if I miss a dose?
- What are the possible side effects and what should I do if they occur?
- Will this new prescription work safely with the other medicines and herbal supplements I am taking?

<sup>i</sup> [www.smartcoalition.org](http://www.smartcoalition.org)

- What food, drinks or activities should I avoid while taking this medicine?

In addition, the Board recommends that consumers be instructed to also tell their health care professionals:

- The names of all prescription and non-prescription medicines they are taking and for what conditions they take them;
- If they are allergic to any medicines;
- If they have any problems with any medicines;
- If they are or could be pregnant.

### Taking Responsibility

In addition to educating consumers to ask the right questions, pharmacists should also emphasize the other things that patients can do to play a greater role in their health care. Pharmacists should encourage patients to:

- Maintain a list of all of their prescription and over-the-counter medications, as well as any vitamins, herbal products, nutritional supplements, or home remedies they take. This list should be kept up to date and carried with them at all times.
- Insist on being counseled about any new medication. It is state law for the pharmacist to provide consultation in such cases.
- Ask the pharmacist to “show and tell” every time patients receive a new or refilled medication. Have the pharmacist open the bottle and show the medication inside. Customers should question anything that looks different – a different color, shape, name, or strength of their medicine.
- Tell their doctor and pharmacist about everything they take, including herbs, nutritional supplements, and vitamins.
- Read the information that is provided with their medication and ask the pharmacist to explain anything that they don’t understand.
- Follow the directions for use on the prescription label or

on the bottle or container. They should not take more or less than instructed and should continue to take the medication as long as it is indicated.

- Write down any suspected problems that occur when taking any medication and report these to their doctor or pharmacist.
- Keep a list of medications that have caused problems or allergic reactions in the past and make sure their doctor and pharmacist includes this information in their medical record and patient profile.

### Helping Seniors Take Control

Seniors are particularly vulnerable to adverse effects associated with medications. On average, they consume more medications than younger individuals and suffer a disproportionately higher percentage of adverse effects. One program that is available to help seniors learn to take responsibility for their medications is the Senior Medication Awareness & Training Program, SMARxT. (For more information see [www.smartcoalition.org](http://www.smartcoalition.org).) The SMARxT Coalition of California is a consortium of statewide grassroots organizations. In the SMARxT workshops seniors are taught the basic questions to ask of their pharmacists and physicians. They are also instructed to never make decisions about their medications, over-the-counter meds, herbals, and vitamins without first asking questions of their health professionals. A handy SMARxT wallet card is given to participants for easy reference to these questions and the seniors are taught to show this card listing all their medications, herbals, over-the-counter drugs, and vitamins to their physician every time they visit the doctor or get a new prescription. The SMARxT workshop teaches them that even if they are taking only one prescription drug, they should never buy anything else over-the-counter without first asking the pharmacist if it is safe to take along with the list of medications listed on their SMARxT card.

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# Resources for Additional Information

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## *Bibliography*

### **To Err is Human: Building a Safer Health System**

LT Kohn, JM Corrigan, and MS Donaldson (Eds.), Institute of Medicine. Washington D.C.: National Academy Press (2000)

*The Institute of Medicine has drawn national attention to medical errors.  
This book truly was the catalyst for bringing attention to medication safety issues.*

**Comments:** This book provides a great overview of the medication error problem. Pertinent topics covered include reporting systems, protecting voluntary reporting systems from legal discovery, and creating safety systems in health care organizations.

**Advantages:** Great summary of medication error reduction strategies, including recommendations from multiple organizations. Includes summaries of medication-related studies, including descriptions of samples, data sources, results, definitions and causes/types of errors.

**Disadvantages:** Many of the medication error reduction strategies are pertinent for health care organizations and/or hospitals. Limited reduction strategies for independent community pharmacies.

### **First Do No Harm: A Practical Guide to Medication Safety and JCAHO Compliance.**

Marblehead, MA: Opus Communications (1999)

*As the title indicates, this book is a helpful reference for hospitals  
in developing a medication safety program to meet Joint Commission standards.*

**Comments:** Useful for the hospital pharmacists. Topics include applying systems approaches to error prevention, performing root cause analysis, designing and implementing improvement proposals and complying with JCAHO standards.

**Advantages:** Explains tools necessary for any quality improvement program. Includes a suggested reading list at the end of each chapter.

**Disadvantage:** Independent/community pharmacists may find little value in the chapters that cover JCAHO standards. However, the pharmacist-in-charge may review these chapters as many of the practice guidelines could be adapted to an out-patient pharmacy.

## **Medication Errors: Causes, Prevention and Risk Management**

MR Cohen (Ed.) Sudbury, MA: Jones and Bartlett Publishers (2000)

*Provides practical examples of risk assessment and process improvements. Identifies those medication adverse events that have resulted in patient deaths as well as specific weaknesses in the medication use processes and suggests system changes to prevent these.*

**Comments:** Topics include identifying poor distribution practices, dosing miscalculations, packaging problems, incorrect drug administration, and patient education issues.

**Advantages:** This book has something for everyone. Of particular interest to all pharmacists is Chapter 9: "Preventing Dispensing Errors." This chapter does an excellent job of covering both the common causes of dispensing errors and their solutions. There is also a chapter that discusses effective use of dispensing automation that will be useful to outpatient and inpatient pharmacists alike.

**Disadvantages:** There are none! Great reference...it's a must have.

## **Medication Use: A Systems Approach to Reducing Errors.**

DD Cousins (Ed.) Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations (1998)

*Provides a good overview of using the "systems approach."*

**Comments:** Chapter 6, "Case Study on Measuring and Improving the Medication Use System," is a good reference for those attempting to outline their own reporting system.

**Advantages:** Explains many of the tools utilized in examining processes and identifying opportunities for improvement. Describes the process and provides a case study as an example.

**Disadvantages:** Primarily geared to the hospital pharmacy; however, some portions could easily be adapted to outpatient pharmacy areas.

## **Preventing Medication Errors: Strategies for Pharmacists**

Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations (2001)

*Defines the pharmacist's role in preventing medication errors in all aspects of the medication use process (prescribing, dispensing, administering, and monitoring drugs).*

**Comments:** The tendency to compartmentalize the medication use system is sometimes difficult to overcome. Pharmacists will sometimes focus on their piece of the medication use pie, which is dispensing errors. This book does an excellent job of encouraging the pharmacist to look at all stages of the process to improve medication use.

**Advantages:** Illustrates the pharmacists' ability to impact medication use at all levels.

**Disadvantages:** Focused primarily on hospital practice.

# Web Sites

## American Pharmaceutical Association

[www.aphanet.org](http://www.aphanet.org)

*Comments: Offers a variety of books and products and has useful links to other pertinent sites.*

## American Society of Health-System Pharmacists

[www.ashp.org](http://www.ashp.org)

*Comments: Offers products and services. The Practice Resource Section includes a new Patient Safety site. This site includes an extensive bibliography as well as a newly developed "Medication Use System Safety Strategy (MS3): Phase I of the ASHP Medication Safety Officer Project." The document provides a systematic approach for healthcare organizations wishing to design, implement, and maintain safe medication use systems.*

*Most useful: The bibliography*

## Institute for Safe Medication Practices

[www.ismp.org](http://www.ismp.org)

*Comments: Offers products and services. On-line "Medication Safety Alert" identifies reported medication related safety problems. Message Board gives health care professionals the opportunity to post questions and receive advice from other health care providers who have had similar problems. Offers a medication safety self-assessment to both hospitals and community pharmacies. Many links to other sites are provided.*

*Most useful: Everything is a must see at this site. For community pharmacists, the community self-assessment may be the most useful tool for evaluating your current practice.*

## Joint Commission on Accreditation of Healthcare Organizations

[www.jcaho.org](http://www.jcaho.org)

*Comments: Sentinel Event Alerts provide useful information for hospitals; however, these alerts deal with more than just medication related events. These alerts identify underlying causes and suggest steps for prevention.*

*Most useful: Hospitals will find the Sentinel Events Alert useful.*

## California Institute for Health Systems Performance

[www.cihsp.org](http://www.cihsp.org)

*Comments: This is a medication safety collaborative (CISHP in partnership with California Healthcare Association). Provides a medication safety checklist (more applicable to hospital practice). Also provides a compendium of suggested practices, an 86-page document outlining strategies for improving patient safety. The compendium was developed to assist hospitals in preparing their medication error reduction plan (as required by SB1875) and covers prescribing, dispensing, administering, and monitoring medications. Also provides links to other sites.*

*Most useful: Community and hospital pharmacies will find the compendium of suggested practices useful.*

## National Coordinating Council for Medication Error Reporting and Prevention.

[www.nccmerp.org](http://www.nccmerp.org)

*Comments: Independent body comprised of 17 national organizations. This site provides the taxonomy for medication errors and is useful for the pharmacy implementing a new medication related events reporting system. Also provides council recommendations for various processes (e.g. bar coding).*

*Most useful: This site provides essential definitions for medication errors and sets up a severity ranking as well as possible breakdown points.*

## VA National Center for Patient Safety

[www.patientsafety.gov](http://www.patientsafety.gov)

*Comments: Safety topics section provides straightforward clear explanations of commonly used QA tools (e.g. failure mode and effects analysis, root cause analysis). Has a "papers and publications" section that includes "TIPS" (Topics in Patient Safety) as well as a NCPS patient safety handbook.*

*Most useful: Both the Safety topics section and the TIPS newsletter have useful information.*

## American Hospital Association

[www.aha.org](http://www.aha.org)

*Comments: Quality and Patient Safety section is very useful. Both the AHA initiatives and the successful safety practice sub-sections contain information on some of the most "pioneering and innovative efforts" going on in health care.*

*Most useful: The Successful Safety Practice section is a "must bookmark". Contains many pertinent articles relating to patient safety.*

## US Pharmacopeia

[www.usp.org](http://www.usp.org)

*Comments: Drug information on over 11,000 generic and brand name drugs. Patient education information also available on this site. Practitioner reporting news includes examples of reported medication errors.*

*Most useful: The examples of reported medication errors serve as a great source of information to prevent similar errors from occurring.*

## Pharmsafety.net

[www.pharmsafety.net](http://www.pharmsafety.net)

*Comments: Contains self-study materials that cover the practical applications of the interplay of cognitive, psychosocial factors and traditional pharmacy practices in reducing error, risk management, and promoting patient safety. Available to pharmacy personnel worldwide beginning in July, 2002 and can be downloaded free of charge. CE credit is available for US and Canadian pharmacists.*

# Reporting Programs

## FDA Medwatch

[www.fda.gov](http://www.fda.gov)

Comments: *Voluntary reporting of serious adverse events, potential or actual medication product errors, and product quality issues.*

*Can submit on-line, download form and fax, or call.*

Fax: 1-800-FDA-0178

Phone: 1-800-FDA-1088

## USP Medication Errors Reporting Program

[www.usp.org/practrep/mer.htm](http://www.usp.org/practrep/mer.htm)

Comments: *Voluntary reporting system.*

Phone: 1-800-233-7767

## MedMaRX (USP)

[www.medmarx.org](http://www.medmarx.org)

Comments: *Web-based reporting system. Fee to participate.*

## JCAHO Sentinel Event Hotline

[www.jcaho.org](http://www.jcaho.org)

Comments: *Encourages hospitals to report sentinel events to the JCAHO as well as the root cause analysis performed in order to identify "lessons learned".*

Hotline Phone: 1-630-792-3700

# Glossary

**Adverse Drug Event (ADE):** *An injury related to the use or non-use of a medication.*

**Adverse Drug Reaction (ADR):** *A subset of ADE. It includes any undesirable, unintended, or unexpected clinical manifestation associated with use of a medication.*

**Adverse Event (AE):** *An untoward, undesirable and usually unanticipated event, such as injury to or death of a patient.*

**Continuous Quality Improvement (CQI):** *A quality assurance program that is integrated into normal daily activities in order to obtain sufficient or improved quality on a continuous basis.*

**Failure Mode Effects Analysis (FMEA):** *A method for proactive assessment of a system or process that enables one to determine the location and mechanism of potential failures in advance.*

**Medication Error:** *any variation from a prescription or drug order not corrected prior to furnishing the drug to the patient (CCR, Title 16, section 1711).*

**Outcome:** *The result of the performance (or non-performance) of a function(s) or process(es).*

**Potential ADE:** *A hazardous situation that fails to cause injury by chance or because it is intercepted (caught) before the medication is administered to the patient. Sometimes referred to as "process errors" or "near misses."*

**Process:** *A goal-directed, interrelated series of actions, events, mechanisms, or steps.*

**Quality Assurance:** *A process used to ensure that a product or service meets appropriate or pre-determined standards.*

**Root Cause Analysis (RCA):** *A method for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. Often initiated after an event has occurred (reactive)*

**Risk Management:** *Clinical and administrative activities to identify, evaluate, and reduce the risk of injury to patients, staff, visitors and the organization itself.*

**Sentinel Event:** *An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.*

# California Code of Regulations

## Titlle 16, Division 17

### Quality Assurance Programs

**1711. (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.

**(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 this 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)** Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

**(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. recommended 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.

This section shall become operative on January 14, 2002.

# “Quality Assurance”

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### LEARNING OBJECTIVES

After reading the articles in this issue, you should be able to:

1. Describe at least five requirements of the pharmacy quality assurance regulation (Title 16 CCR, Section 1711).
2. List five items that must be documented whenever a medication error is investigated.
3. Describe three tools that are applicable to a pharmacy quality improvement program.
4. Describe three methods that are often used in continuous quality improvement.
5. Describe the differences between root cause analysis and failure mode and effects analysis and how each is applicable to continuous quality improvement.
6. Discuss three reasons why process errors (errors that do not reach the patient) should be tracked.
7. List three benefits derived from a national medication error-reporting program.
8. Describe seven best practices that would reduce the potential for medication errors.
9. Describe an effective strategy for dealing with patients after a medication error has been discovered.
10. List five steps consumers can take to protect themselves from a medication error.

### DIRECTIONS FOR OBTAINING CE:

- Read the articles and take the test to receive three (3) hours of continuing education credit. Return the entire test page and include a self-addressed, stamped envelope. Please note that the passing grade is 70%. If necessary, one test will be readministered.
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- Please include check for \$15, payable to Regents of the University of California
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Additional comments are appreciated: \_\_\_\_\_

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### CONTINUING EDUCATION CERTIFICATE OF COMPLETION

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# TEST QUESTIONS

1. Medication errors are the most common consumer complaint to the Board of Pharmacy.
  - a) True
  - b) False
2. California's quality assurance regulation defines a medication error as any variation from a prescription or drug order that is not corrected prior to furnishing the drug to the patient or patient's agent.
  - a) True
  - b) False
3. A prescription filled with the wrong medication that is corrected when counseling a patient is NOT a medication error.
  - a) True
  - b) False
4. Which one of the following is NOT required for a pharmacy to be in compliance with the pharmacy quality assurance regulation:
  - a) The QA program must be documented in written policies and procedures
  - b) Process errors that are corrected prior to furnishing the drug to the patient must be documented, but do not need to be formally reviewed.
  - c) Discoveries resulting from a QA review of medication errors must be used to redesign systems and workflow processes to minimize the occurrence of medication errors.
  - d) Investigations of medication errors must commence as soon as reasonably possible, but no later than 2 business days from the date of discovery.
  - e) The pharmacists must notify both the patient and the physician when an error is discovered.
5. A record of quality assurance review must be immediately retrievable in the pharmacy for at least one year from the date it was created.
  - a) True
  - b) False
6. When a medication error is investigated, all of the following must be documented, except:
  - a) The name and license number of the person who made the error.
  - b) Date, location, and participants in the review.
  - c) Pertinent data and other information related to the error being analyzed.
  - d) Findings and determinations resulting from the QA review.
  - e) Recommended changes to pharmacy policy, procedure, systems or processes, if any.
7. Simulation, a technique often used in aviation, is not helpful for improving safety in organizations where a hierarchy exists, such as in healthcare.
  - a) True
  - b) False
8. The advantages of monitoring process errors (errors that are corrected prior to reaching the patient) include all of the following, except:
  - a) They occur in real time, when memories are still fresh.
  - b) They signal that mindful thinking is emerging.
  - c) They signal that mindless thinking is emerging
  - d) They are precursors to actual medication errors
  - e) None of the above.
9. Process errors are more likely to occur when the number of prescriptions being filled per hour increases.
  - a) True
  - b) False
10. A root cause analysis (RCA) will enable members of the pharmacy team to anticipate potential sources of medication errors prior to an error occurring.
  - a) True
  - b) False
11. A cause and effect (fishbone) diagram is one tool that is often used to enable members of a pharmacy team to visualize a root cause analysis (RCA).
  - a) True
  - b) False
12. Failure mode and effects analysis (FMEA) is considered a proactive quality improvement process because it uses inductive logic.
  - a) True
  - b) False
13. Failure mode and effects analysis (FMEA) enables members of the pharmacy team to visualize the underlying factors contributing to a medication error.
  - a) True
  - b) False
14. FMEA is very useful for evaluating complex systems where human beings are the only component in the system
  - a) True
  - b) False
15. Research has consistently shown that for every \_\_\_\_ process errors, one mistake will get past normal verification processes.
  - a) 2
  - b) 6
  - c) 10
  - d) 30
  - e) 100
16. Report of a medication error to the USP's Medication Error Reporting Program may only be submitted on-line.
  - a) True
  - b) False
17. Which of the following benefits are derived from a national medication error-reporting program?
  - a) Identification of problem-prone and high risk areas
  - b) Adverse drug reaction reporting
  - c) Proactive risk assessment
  - d) Identification of "better practices"
  - e) Choices a, b, and d above
  - f) Choices a, c, and d above
18. Pharmacists practicing in any practice setting may spontaneously report medication errors to USP's Medication Error Reporting Program.
  - a) True
  - b) False
19. Consumers should routinely ask which of the following questions of their health care providers:
  - a) What is the name of my medication and what is it supposed to do?
  - b) What do I do if I forget to take my medication?
  - c) Are there any side effects and what should I do if they occur?
  - d) Is there any written information available about this medication?
  - e) All of the above
20. Records of peer review activities relating to a medication error are protected from discovery and use in a lawsuit in California.
  - a) True
  - b) False
21. Which of the following practices does NOT help prevent medication errors:
  - a) Identifying the person involved and disciplining that person.
  - b) Filling the prescription from the hard copy rather than the label.
  - c) Returning stock bottles of fast movers to the shelf in a timely manner.
  - d) Opening the container and pouring a tablet or capsule in the lid to "show and tell" when counseling a patient.
  - e) All of the above help prevent medication errors.
22. Good customer relations, honest communication, and a timely and caring response are effective strategies for dealing with patients after an error has occurred.
  - a) True
  - b) False
23. Computer order entry systems are one fail-proof way to reduce medication errors.
  - a) True
  - b) False
24. Many effective CQI programs are similar, in that they contain the following components:
  - a) They engage everyone who participates in the work flow process.
  - b) They foster reporting of errors with a non-punitive environment
  - c) They focus on systems-improvements and not individuals.
  - d) Outcomes of process changes are studied and use for further improvements.
  - e) All of the above.

# HEALTH NOTES

# Quality Assurance

## Preventing Medication Errors

This issue of HEALTH NOTES is a collaborative effort of the California State Board of Pharmacy and the School of Pharmacy, University of California, San Francisco

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## Medication Error Reporting: CQI Programs Offer Avenue to Vital Follow-Up

January 24, 2011 9:28 am Topics: [Continuous quality improvement](#)

*Originally published in the January 2011 NABP Newsletter*

Patient safety advocates have long emphasized the importance of documenting medication errors as a crucial tool in preventing future adverse medical events. Even before the Institute of Medicine's landmark 1999 report, "To Err Is Human: Building a Safer Health Care System," brought the issue to the attention of the public, medication error reporting was seen as an integral and vital element of programs designed to lessen the likelihood of dangerous mistakes and increase the quality and safety of patient care. At least 27 states require hospitals and/or other medical facilities to report serious medical errors, and 17 states mandate that pharmacies implement continuous quality improvement (CQI) programs. In varied pharmacy environments, CQI programs and error reporting have proven useful in helping to modify systems and procedures in order to prevent recurring errors and improve patient safety.

### **Data Analysis is Key**

Error reporting forms the backbone of the health care systems' efforts to improve patient safety. "Without reporting, health care systems have no mechanism to analyze, understand, and eliminate medication errors," stated the authors of a 2004 study surveying Vermont community pharmacists' medication error reporting.

Despite the emphasis on reporting, medication error reporting in and of itself is only useful as part of a broader strategy to reduce errors and improve care. As the National Coordinating Council for Medication Error and Reporting and Prevention (NCC MERP) states, "The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication use system and to apply lessons learned to improve the system." To have an impact on patient safety, the information conveyed by the errors must be analyzed and put to use, not merely collected.

Unanalyzed or improperly analyzed error data can be downright misleading, particularly if the general public attempts to, say, compare two hospitals by looking at the number of errors they have reported. A hospital with a larger number of errors could mean an institution that follows poorer safety practices and should be avoided – or could mean a hospital that has fostered an environment that encourages error reporting and subsequent systems improvement, translating to a safer patient experience. "Use of medication error rates to compare health care organizations is of no value," cautions NCC MERP in a position statement. "The goal of every healthcare organization should be to continually improve systems to prevent harm to patients due to medication errors."

### **Appropriate Analysis Through CQI**

With this goal in mind – and at times prodded by regulation and certification or accreditation requirements – health care facilities from large hospitals to the neighborhood pharmacy have in recent years been moving toward instituting programs that provide continuous assessment and improvement of overall quality. Often, these initiatives follow the principles of CQI, a data-driven, process-based management approach that advocates that entities engage in ongoing, continual efforts to improve. While medication error reporting forms only one part of a comprehensive CQI program, as far as eliminating preventable adverse drug events, it allows managers to identify problems, assess best solutions, and measure successes.

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CQI adherents contend that most problems lie with processes rather than people. Rather than seeking to lay blame, a CQI approach would be more likely to make a non-punitive response to an adverse incident and work to change the process or system such that achieving the desired outcome would be easier, and repeating an error would be difficult, if not impossible.

2003 (43)

2002 (37)

2001 (31)

Health care facilities – including pharmacies – may, of course, engage in quality-improvement efforts without specifying them as “CQI,” but basic principles generally remain: examining current practices, noting real or potential errors, and improving systems to ensure better outcomes. Individual pharmacies may develop quality-related programs on their own, or contract outside providers to assist them.

### Boards Support CQI Programs

While CQI or similar quality assurance (QA) programs have been prevalent in hospital settings for more than 10 years, in recent years regulators have increasingly begun to require similar programs in community pharmacies. Currently, implementation of a CQI or similar QA program that aims for ongoing assessment and improvement, is mandated for pharmacies in at least 17 states. “I believe that a majority of Massachusetts community/ambulatory pharmacies maintained some model of a [CQI] and or quality assurance program prior to Board regulations . . . requiring implementation of the same,” states James D. Coffey, director of the Massachusetts Board of Registration in Pharmacy, which has required CQI programs since 2005. “However, the Board’s CQI regulations established uniform program standards and procedures to identify and evaluate quality-related events, improve patient care, and provide for ongoing education at least annually in the area of CQI to pharmacy personnel.”

Unfortunately, the individual and often complex nature of CQI programs can make enforcement – or determination of their efficacy – difficult. To be effective, beyond certain minimum requirements, CQI programs must be site-specific, created by, and tailored to the specific situation of each pharmacy. In its report, the 2007 NABP Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety noted some of the enforcement difficulties. “It was noted that a major obstacle for states is a lack of resources for enforcement,” explains the report. “[S]tates simply do not have a sufficient number of inspectors to ensure that CQI Programs are being correctly and effectively implemented.”

State CQI program requirements vary widely, and therefore evidence for compliance also varies. At present, inspectors must therefore look for the state’s spelled out requirements, and evaluate each pharmacy’s program as they are able. In Massachusetts, for example, compliance officers and the Board’s CQI quality assurance coordinator/surveyor assess CQI program adherence during routine pharmacy inspections and surveys, and also when a quality-related event is reported to the Board; in the latter case, the Board “examines pertinent documentation,” states Coffey, to get a broader understanding of both the error and the corrective actions taken by the pharmacy. “A challenging assessment issue associated with these types of CQI program reviews involves meaningful validation of the implementation of documented pharmacy policies and procedures established to enhance patient safety and pharmacy personnel’s comprehension [of] the same,” notes Coffey.

In Oregon, says Gary Miner, RPh, compliance director for the Oregon State Board of Pharmacy, no language currently specifies what the state-mandated QA programs should look like, or what elements they should contain; the regulations merely state that the pharmacist-in-charge is responsible for “implementing a quality assurance plan for the pharmacy.” Since 2009, Board inspectors have begun monitoring for the plans’ existence, and it is now included on a required self-inspection report. Kansas, which instituted CQI requirements in 2009, mandates that pharmacy CQI meetings must be held quarterly, for example, and must include a review of incident reports and be followed up with a written meeting report. “Kansas compliance officers do look for CQI reports when they inspect,” states Debra Billingsley, JD, executive secretary of the Kansas State Board of Pharmacy; to make this easier, the Board has requested (though not required) that pharmacies do their CQI in the same months. “Most are doing what we have asked,” notes Billingsley. Officers check to make sure CQI reports are fully filled out, and that suggestions to correct a problem seem sufficient. In addition, Billingsley states, “We have been requiring some stores to provide us with their CQI notes whenever we have had a complaint

filed. Sometimes the complaint doesn't warrant a fine or discipline but we want to make sure that the error was discussed . . . We have asked for additional follow-up if we didn't think that they really considered ways to prevent the error in the future."

The process often comes down to education, notes Oregon's Miner. "Most pharmacists are not educated in quality assurance," he says. The Board is considering adding guidance on its Web site to help pharmacies establish QA programs, from suggested actions to medication-error reporting forms. "Suggesting easy QA-type activities can help them get started," says Miner, such as tracking during monthly reconciliation how many expired medications are on the shelves. Along with handing out information during inspections, the Board may also incorporate QA topics into the pharmacist-in-charge training classes it offers on roughly a monthly basis.

Specific compliance issues vary by location. In Kansas, for example, notes Billingsley, "The biggest hurdle has been the small independent stores. They may only have one pharmacist and they don't think it's necessary to have a CQI when they are the only pharmacist . . . [and] shouldn't have to have a meeting with themselves. We have advised them that it is helpful for them to go over the errors with their staff regardless of the size of the store." In Oregon, meanwhile, the Board has had more issues with chain pharmacies that report medication errors to a company-run, centralized database or program that can then analyze issues on a company-wide basis; the Board has had to emphasize that they need to look at QA "at the store level," says Miner, rather than just the corporate level.

### Analyzing Error Data Leads to Solutions

Numerous studies have examined the process of reporting, looking at factors such as what strategies are most effective in encouraging reporting and examining alternative methods for extracting medication error information.

The analysis of error data has enabled researchers to identify strategies for reducing medication errors in hospital settings, and studies have shown that certain tools are effective. For example, the use of bar code technology has been shown to reduce medication errors. A Food and Drug Administration (FDA) rule that took effect in 2004 requires that prescription drugs, many biological products, and over-the-counter medications commonly used in hospitals carry a bar code label. According to FDA, a Veterans Affairs medical center in Topeka, KS, cut its medication error rate by 86% over a nine-year period by combining the bar-coded medication with a bar-coded identification wristband worn by each hospital patient. A quick scan at the time of medication administration helps alert the administering nurse if there is not a match between the patient and the medication, or another problem. Similarly, the US Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality in 2010 published the results of a study showing that bar code technology combined with an electronic medication administration record reduced non-timing administration errors by 41% (and thereby a 51% reduction in potential drug-related adverse events) and cut timing errors (when a patient was given a medication an hour or more off schedule) by 27%.

### Nationally Aggregated Error Data

Much medication error collection happens on the local level, by a particular hospital, within a particular hospital program, or at a particular pharmacy. Analysis of this data helps in the creation of situation-specific solutions to identified problems. At the same time, error reporting on a larger or even national scale is helpful, as well. The Institute for Safe Medication Practices, which operates the Medication Errors Reporting Program (MERP), has for well over a decade publicized errors and hazards and recommended error-reduction strategies to health care workers (and sometimes the public) based on MERP information, allowing practitioners or pharmacies to take advantage of it by increasing their awareness of hazards and taking appropriate action. The MEDMARX error reporting system, developed by the United States Pharmacopela (USP) and currently owned and managed by software company Quantros, Inc, contains more than 1.5 million reports of adverse drug events and the data is being analyzed. The National Patient Safety Foundation, for example, is funding research looking at more than 50,000 medication errors reported to MEDMARX and attributed wholly or in part to Computerized Prescriber Order Entry (CPOE), to gain a better understanding of the errors common to CPOE, a technology originally anticipated to do away with prescribing-related medication errors.

## Encouraging Error Reporting

Medication error reporting – and factors that might inhibit it – continue to receive much attention from those entities seeking to increase patient safety. As fear of negative consequences – whether of discipline or lawsuits – has been identified as a large factor inhibiting the reporting of errors, rules governing the inadmissibility of error reporting in lawsuits or discipline have appeared on levels ranging from the workplace to states to the federal government. In particular, the federal Patient Safety and Quality Improvement Act of 2005 makes the “quality reports” associated with the monitoring and quality improvement aspects of a QA program protected against discovery in the event of legal proceedings. According to HHS, the Patient Safety Act “establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs [Patient Safety Organizations, organizations that can work with clinicians and health care organizations to identify, analyze, and reduce the risks and hazards associated with patient care], on a privileged and confidential basis for the aggregation and analysis of patient safety events.” HHS issued a Final Rule to begin implementation of the Patient Safety Act in early 2009.

States may also offer their own protections; when CQI programs were mandated for pharmacies in Kansas starting in 2009, for example, the regulations spelled out confidentiality protections: “Reports, memoranda, proceedings, findings, and other records generated as part of the pharmacy CQI program shall be considered confidential and privileged peer review documents and not subject to discovery, subpoena, or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than an administrative proceeding initiated by the board of pharmacy.”

Board of pharmacy efforts to support and educate pharmacists on QA practices attest to the value of CQI or QA programs in improving patient safety. Whether it be reviewing reports at an independent community pharmacy or analyzing an error that occurred in a pharmacy environment with more complex hierarchies, assessment of error data and other reports can help to determine how policies and procedures should be adjusted. Future trends in CQI will likely involve continued assessment of what data should be collected, how the data should be reported, and how such data can best be analyzed and acted upon to improve patient outcomes.

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## **Report of the Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety**

### **Members Present:**

Kim Caldwell (TX), *chair*; Joseph Adams (LA); Vernon H. Benjamin (IA); Amy Buesing (NM); James T. DeVita (MA); Randall Knutsen (CO); Paul Limberis (CO); Alice Mendoza (TX); Kevin Mitchell (OH); Rebecca Poston (FL).

### **Members Not Present:**

W. Benjamin Fry (TX).

### **Others Present:**

Richard A. “Rich” Palombo, *executive committee liaison*; Chuck Young, *ex-officio member*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Gertrude “Gg” Levine, *NABP staff*.

### **Presenter:**

Donna Horn, *ISMP representative via conference call*

### **Introduction:**

The Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety met December 6-7, 2007, at NABP Headquarters.

This Task Force was established in response to Resolution 103-5-07, Medication Error Reporting, which was approved by NABP membership at the Association’s 103<sup>rd</sup> Annual Meeting in May 2007.

### **Review of the Task Force Charge**

Task Force members reviewed their charge and accepted it as follows:

To review current *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* language addressing continuous quality improvement, peer review, and freedom from discovery and, if necessary, recommend to the Executive Committee amendments to reflect the present practice environment. The Task Force will also evaluate the need for an assessment tool for use by boards of pharmacy to evaluate pharmacies in the area of patient safety.

### **Recommendation 1: Amend the Model Act**

The Task Force recommends the following changes to the *Model Act*, including changes to the *Model Rules for the Practice of Pharmacy*.

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### **Section 104. Practice of Pharmacy.**

The “Practice of Pharmacy” means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Review; the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer,

Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and training.

## Section 105. Definitions.

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- (ii) ~~“Criteria,” when used in the context of a Continuous Quality Improvement Program, means predetermined elements of health care with which aspects of the quality of a health care service may be compared. “Standards,” when used in the context of a Continuous Quality Improvement Program, means acceptable variation from a criterion.~~

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- (aaaa) ~~“Localized Minimum Data Set” means aggregate data from a single pharmacy concerning Quality-Related Events and total number of patients to whom pharmaceutical products and services have been provided at the pharmacy.~~

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- (tttt) “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 which continually improves the quality of care provided to patients.
- Peer review should not be a punitive activity or a performance evaluation.

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- (uuuu) “Peer Review Committee” means:
- (1) a pharmacy peer review, judicial, or grievance committee of a pharmacy society or association 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 pharmacy peer review 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.

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(yyyyy)“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 variations from the specifications of a prescriber’s prescription drug order, such as wrong Drug, wrong strength, wrong directions, and wrong dosage form. 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.

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.

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(zzzzz)“Periodic Quality Self-Audit” means an internal evaluation at a pharmacy to assess the effectiveness of the Continuous Quality Improvement (CQI) Program. of the Localized Minimum Data Set maintained at that pharmacy.

### **Section 105(bb). 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 Pharmacy 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. Pharmacy 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 Pharmacy 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.

## Model Rules for the Practice of Pharmacy

### Section 3. Pharmacy Practice.

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#### J. 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) ~~(1)~~ 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:
  - (a) 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;
  - (b) document QREs as soon as possible, but no more than three days, after determining their occurrence;
  - (c) analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;
  - (d) 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;
  - (e) provide ongoing CQI education at least annually to all pharmacy personnel;
  - (f) for those Persons utilizing a Drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.
- (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 ~~medication errors~~ shall be reported to a nationally-recognized error reporting program designated by the Board. ~~For those Persons utilizing a Drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.~~
- (2) ~~Criteria and Standards~~

~~Each Pharmacy shall adopt Criteria and Standards that reflect the benchmark against which the Pharmacy intends to measure itself over a designated period of time. The adopted Criteria and Standards shall be sufficiently specific to permit comparisons of quality from one period of time to another. The adopted Criteria and Standards shall be sufficiently broad to permit a self assessment of the quality of Pharmacist Care provided by the Pharmacy to the patients served by the Pharmacy.~~
- (3) ~~Localized Minimum Data Set~~

~~Each Pharmacy shall maintain a Localized Minimum Data Set of data related to patients for whom the Pharmacy provides pharmaceutical products and services so as to permit a determination as to whether Criteria and Standards have been met at the Pharmacy over time. The data shall be maintained in such a way that comparisons between actual performance and Criteria and Standards for performance can be routinely done.~~
- (5) Periodic Quality Self-Audit

Each Pharmacy shall conduct a Periodic Quality Self-Audit at least quarterly ~~once every three months~~ to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures. ~~Criteria and Standards have been met over time~~ and to develop a plan for improved adherence with the CQI Program ~~Criteria and Standards~~ in the future. Each pharmacy shall conduct a Periodic Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program. ~~Criteria and Standards.~~

(6) Consumer Survey

As a component of its CQI Program, each Pharmacy ~~may~~ 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 ~~shall~~ should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.

(7) Privilege 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 as necessary to protect the public health and safety. All information, communications, or data furnished to any ~~Professional Performance Evaluation~~ Peer Review Committee, association board, organization board, or other entity and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity, are privileged. The records and proceedings of any ~~Professional Performance Evaluation~~ Peer Review Committee, board, or entity are confidential and shall be used by such committee, board, or entity, and the members thereof, only in the exercise of the proper functions of the committee, board, or entity and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged ~~Professional Performance Evaluation~~ 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 the 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 facility or individual by the appropriate licensing board.

## **Background:**

Members reviewed the *Model Act* and concluded:

1. the definition of the "Practice of Pharmacy" should be updated to include the concept of continuous optimization of patient safety through the use of emerging technologies and training
2. the terms "Peer Review Committee" and "Peer Review" should be added and defined;
3. the definition for "Quality-Related Event" should be amended;
4. the term "Periodic Self-Audit" should be changed to "Quality Self-Audit" and the definition also amended; and

5. the definitions for “Criteria” and “Localized Minimum Data Set” should be deleted.

It was also agreed that the *Model Act* should be amended to provide for a more specific CQI Program implementation section that would:

1. relay a non-punitive approach;
2. provide discovery protection for peer review committees and processes; and
3. allow the state boards of pharmacy access to a pharmacy’s CQI Program records as necessary to protect public health.

### **Recommendation 2: Explore the Development of a Pharmacy Accreditation Program**

The Task Force recommends that NABP explore the possibility of developing and implementing a pharmacy accreditation program, in conjunction with the state boards of pharmacy, that will ensure pharmacies are operating in a manner consistent with CQI standards, decreasing the occurrence of Quality Related Events (QREs) and ultimately increasing patient safety.

#### **Background:**

Task Force members were given an overview of the old and ever present problem of QREs in the practice of pharmacy by ex-officio Task Force member Chuck Young. Mr Young described various QREs and how he became involved in this area over the last thirty years. Task Force members concurred with the findings of Mr Young and agreed that QREs are a significant public health concern of mounting media interest.

Donna Horn, from the Institute for Safe Medication Practices (ISMP), provided a telephonic presentation that detailed a proposal which would use specially trained state inspectors to educate pharmacists in the use of ISMP’s Ten Key Elements of the Medication Use System. The program would involve the state boards of pharmacy, NABP, and ISMP, working together to develop materials for inspectors to identify and evaluate safe practices in the community pharmacy setting and corresponding training workshops, and with input from other pharmacy organizations, such as the National Association of Chain Drug Stores, the development of educational modules for community pharmacies based on the ISMP Ten Key Elements.

After hearing from Mr Young and Ms Horn, Task Force members discussed their respective state CQI programs, noting that such programs attempt to focus on processes rather than on people. Task Force members agreed that CQI Programs should promote a proactive approach rather than respond with reactive discipline. Peer review committees and the need for discovery protection were also discussed as methods to encourage reporting of QREs and increase the effectiveness of CQI Programs.

Some Task Force members expressed concern with states that have simply written regulations that mandate pharmacies implement CQI Programs, stating that such efforts are insufficient. It was noted that a major obstacle for states is a lack of resources for enforcement...that states simply do not have a sufficient number of inspectors to ensure that CQI Programs are being correctly and effectively implemented. In response to Ms Horn’s discussion, Task Force members noted that inspectors currently are and should continue to be used as educators.

As a solution, members proposed that an accreditation program be implemented by NABP in the community setting similar in some regards to accreditation programs for hospitals. It was agreed

that NABP was the optimal entity to explore the possibility of developing and implementing such an accreditation program for the following reasons:

- NABP's proven expertise in accreditation based on the success of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program, VAWD and VIPPS;
- NABP has the ability and experience to address the nuances and intricacies of chain and independent pharmacy practice;
- NABP has the appropriate resources;
- NABP will likely be recognized by entities, such the Centers for Medicare and Medicaid Services and pharmacy benefit management organizations, that may soon require accreditation; and
- NABP is seen by the public as an independent, trustworthy, safety-oriented organization.

All Task Force members gave their full support to NABP in the development of a nationwide pharmacy accreditation program that will incorporate a standardized CQI Program. This type of program will hopefully ensure that QREs will be minimized and patient safety will be greatly improved.

### **Recommendation 3: Utilize Medication Safety Organizations such as ISMP to Assist in the Development of the Accreditation Process**

The Task Force recommends that NABP seek additional input from patient safety organizations like ISMP to assist in the development of its accreditation program.

#### **Background:**

Task Force members agreed that ISMP's efforts to evaluate safe practices in the community pharmacy setting could be used to assist NABP in the development of a pharmacy accreditation program.

### **Recommendation 4: Develop and Endorse a CQI Program Inspection Form and Pharmacy Quality Self-Audit Form**

The Task Force recommends that NABP develop a CQI Program inspection form and pharmacy quality self-audit form for incorporation in the *Model Act*. NABP will draft these documents, which will then be discussed with members of the Task Force on a future conference call. The members further recommend that these documents be used proactively and solely for educational purposes.

#### **Background:**

Task Force members agreed that NABP should develop a CQI Program inspection form and pharmacy quality self-audit form as an initial step in a pharmacy accreditation program. By including these forms in the *Model Act*, they will be readily available for boards to use until an accreditation program is established. It was recommended that NABP review the Massachusetts CQI Program Survey as background in the development of the checklist and self-survey. Task Force members, concerned that these documents may at some point be used as a method by which to punish, rather than educate, licensees, emphasized the need to use these forms only for proactive and educational purposes to ensure continued success of CQI Programs.

## Appendix F

### I. Quality-Related Event (QRE) Data Collection Sheet

### II. Continuous Quality Improvement (CQI) Program Inspection Form

### III. Pharmacy Quality Self-Audit

#### I. Quality-Related Event (QRE) Data Collection Sheet

##### I. QRE Prescription Data

Attach copy of: prescription <input type="checkbox"/> label <input type="checkbox"/> photo copy of vial <input type="checkbox"/> (mark all available)	
Prescription No.:	
Original Rx date:	Refill date:

##### II. QRE Data

<p>QRE Type: (select all that apply)</p> <p>A. Prescription processing error:</p> <p>(1) Incorrect drug <input type="checkbox"/></p> <p>(2) Incorrect strength <input type="checkbox"/></p> <p>(3) Incorrect dosage form <input type="checkbox"/></p> <p>(4) Incorrect patient <input type="checkbox"/></p> <p>(5) Inaccurate or incorrect packaging, labeling, or directions <input type="checkbox"/></p> <p>(6) Other: _____</p>	<p>B. A failure to identify and manage:</p> <p>(1) Over/under-utilization <input type="checkbox"/></p> <p>(2) Therapeutic duplication <input type="checkbox"/></p> <p>(3) Drug-disease contraindication <input type="checkbox"/></p> <p>(4) Drug-drug interactions <input type="checkbox"/></p> <p>(5) Incorrect duration of treatment <input type="checkbox"/></p> <p>(6) Incorrect dosage <input type="checkbox"/></p> <p>(7) Drug-allergy interaction <input type="checkbox"/></p> <p>(8) Clinical abuse/misuse <input type="checkbox"/></p>
Prescription was received by the pharmacy via: <input type="checkbox"/> telephone <input type="checkbox"/> written <input type="checkbox"/> computer <input type="checkbox"/> fax	Prescription was: <input type="checkbox"/> new <input type="checkbox"/> refill

##### III. QRE Contributing Factors

Day of the week and time of QRE:		
# of new prescriptions:	# of refill prescriptions:	RPh to tech ratio:
RPh staff status: <input type="checkbox"/> regular staff <input type="checkbox"/> occasional/substitute staff		
# of hours RPh on duty:	Average # of prescriptions filled per hour:	
# of other RPh's on duty:	# of support staff on duty:	
Describe preliminary root contributors:		

**IV. Pharmacist Information**

<u>Name of verifying pharmacist:</u>
<u>Name(s) of other person(s) and title(s) involved in processing the prescription:</u>
<u>Name of individual(s) responsible for CQI program:</u>
<u>Describe remedial action taken:</u>

**If patient received medication, complete Sections V, VI, and VII. If patient did not receive medication, complete only Section VIII.**

**V. Patient Information**

<u>Patient's name:</u>	<u>Prescription was dispensed to:</u>
<u>If minor, name of parent(s)/guardian(s):</u>	<u>Patient DOB:</u> <u>Sex: M or F</u>
<u>Address:</u>	<u>Telephone No.:</u>
<u>Reporter's name and relationship to patient:</u>	<u>Date reported:</u>
<u>Did patient ingest medication?</u> <input type="checkbox"/> yes <input type="checkbox"/> no <u>If yes, how many doses?</u>	
<u>Describe patient outcome if ingestion occurred:</u>	
<u>Who has custody of medication?</u>	

**VI. Prescriber Information**

<u>Was the Prescriber informed:</u> Yes <input type="checkbox"/> No <input type="checkbox"/> <u>If yes, on what date?</u>
<u>Prescriber's comments/instructions:</u>
<u>Prescriber's Name:</u> <u>Telephone No.:</u>
<u>Prescriber's Address:</u>

**VII. Additional Contributing Factors**

Counseling was offered:  yes  no      Counseling was given:  yes  no

If counseling was given please check all applicable below:

Discuss name and description of the Drug  yes  no

Discussed dosage form, dose, route of Administration, and therapy duration  yes  no

Discussed intended use of the Drug and expected action  yes  no

Discussed special directions/precautions for preparation/Administration/use  yes  no

Discussed common severe side or adverse effects  yes  no

Discussed interactions/therapeutic contradictions avoidance/required actions  yes  no

Discussed techniques for self-monitoring Drug therapy  yes  no

Discussed proper storage  yes  no

Discussed prescription refill information  yes  no

Discussed action to be taken if dose missed  yes  no

Other information discussed:

Documentation of offer:  yes  no      Documentation of counseling:  yes  no

**VIII. Report Affirmation**

Additional Comments:

Name and title of preparer of this report:

Signature:

Date:

Date \_\_\_\_\_

Name of Pharmacist \_\_\_\_\_

Pharmacist License No. \_\_\_\_\_

Pharmacy Name \_\_\_\_\_

Pharmacy Permit \_\_\_\_\_

Pharmacy Manager Name \_\_\_\_\_

Day of the week and time of the incident \_\_\_\_\_

1. What type of Dispensing occurred?

Wrong Drug \_\_\_\_\_ Wrong Strength \_\_\_\_\_ Wrong Directions \_\_\_\_\_

Wrong Dosage Form \_\_\_\_\_ Wrong Patient \_\_\_\_\_

Other (explain) \_\_\_\_\_

2. Was the prescription telephoned to the pharmacy or was it transmitted in writing paper, fax, or computer?

Telephoned \_\_\_\_\_ Written \_\_\_\_\_ Computer \_\_\_\_\_ Fax \_\_\_\_\_

3. Was the prescription a new prescription or a refill prescription?

New \_\_\_\_\_ Refill \_\_\_\_\_

4. Was the prescription prepared for a person who chose to wait for it, or was it prepared for the "will call" or delivery area?

Waited \_\_\_\_\_ Will Call or Delivery \_\_\_\_\_ Unknown \_\_\_\_\_ Mail \_\_\_\_\_

5. How many hours was the pharmacist on duty when the prescription was filled?

Up to 8 hours \_\_\_\_\_ More than 8 hours \_\_\_\_\_

6. Take the number of prescriptions filled on the day of the error by the pharmacist who made the error and divide it by the number of hours worked by that pharmacist to calculate an average of prescriptions filled per hour on that day by that pharmacist.

The average number of prescriptions filled per hour was \_\_\_\_\_

7. How many other pharmacists were working at the time the Dispensing error occurred?

1 \_\_\_\_\_ 2 \_\_\_\_\_ 3 \_\_\_\_\_ 4 \_\_\_\_\_ 5 \_\_\_\_\_

8. How many support staff members were working at the time the Dispensing error occurred?

1 \_\_\_\_\_ 2 \_\_\_\_\_ 3 \_\_\_\_\_ 4 \_\_\_\_\_ 5 \_\_\_\_\_

9. Was the pharmacist involved with the Dispensing error a regular staff member at the pharmacy, or was the pharmacist an occasional staff member (for example, a floater or relief pharmacist)?

Regular staff member \_\_\_\_\_ Occasional staff member \_\_\_\_\_

10. Does the pharmacy have a written policy regarding the addition of staff based on an increase in prescription volume?

Yes \_\_\_\_\_ No \_\_\_\_\_

11. Does the pharmacy have a written policy requiring that all Dispensing errors be documented permanently, either on paper or in a computer system?

Yes \_\_\_\_\_ No \_\_\_\_\_

12. Does the pharmacy have a written policy requiring that all prescription errors be evaluated so that system improvements can be made to prevent similar errors in the future?

Yes \_\_\_\_\_ No \_\_\_\_\_

13. Was the prescription dispensed to the patient or to another person acting for the patient?

The Patient \_\_\_\_\_ Another Person \_\_\_\_\_ Unknown \_\_\_\_\_

14. Is it documented in writing that the person to whom the medication was given received an offer to be counseled by the pharmacist?

Yes \_\_\_\_\_ No \_\_\_\_\_

15. Is it documented in writing that the person to whom the medication was given received counseling by a pharmacist?

Yes \_\_\_\_\_ No \_\_\_\_\_

16. What was the consequence of this incident?

- Patient did not use medication \_\_\_\_\_
- Patient used medication but was not harmed \_\_\_\_\_
- Patient used medication and was harmed \_\_\_\_\_
- Comments:

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## II. Continuous Quality Improvement Program Inspection Form

**Pharmacy Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **License No.** \_\_\_\_\_

**Pharmacist-In-Charge:** \_\_\_\_\_

**Pharmacists:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Support Staff:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Practice Setting:**

- Community Chain \_\_\_\_\_
- Community Independent \_\_\_\_\_
- HMO/Clinic
- Hospital
- Long Term Care
- Other \_\_\_\_\_

<b><u>Continuous Quality Improvement Program</u></b>	
<b><u>Policy and Procedures</u></b>	<b><u>Yes/No/Answer</u></b>
<u>Pharmacy has a policy and procedure manual</u>	
<u>Policy and procedure manual is readily retrievable</u>	
<u>Employees must verify review of policy and procedure manual</u>	
<u>A CQI program is currently in place</u>	
<u>Written CQI program policy has been developed</u>	
<u>Policy is in place addressing the return to stock of unclaimed prescriptions</u>	
<u>Policy is in place to assure outdated medication is segregated</u>	
<u>Policy is in place allowing pharmacists at least a thirty minute break when working six or more hours/day</u>	
<u>Policy is in place to periodically update patient profiles for drug allergies, adverse reactions, and alternative medication/herbal remedy/OTC usage</u>	

<b><u>Periodic Continuous Quality Improvement Meetings</u></b>	<b><u>Yes/No/Answer</u></b>
<u>Pharmacy holds CQI meetings (if “yes” indicate frequency)</u>	
<u>Average length of CQI meetings in minutes</u>	
<u>Staff attending CQI meetings</u>	
<u>    Pharmacists        Technicians        Manager</u>	
<u>    Pharmacy Supervisor        Owner        Other</u>	
<b><u>Quality Related Event (QRE)</u></b>	
<u>Written QRE protocol exists</u>	
<u>Written QRE reports exist?</u>	
<u>Physician is notified of the QRE</u>	
<u>    Always        Sometimes        Rarely        Depends</u>	
<u>Person responsible for handling QREs:</u>	
<u>QRE report requires action plan for each QRE</u>	
<u>Pharmacist knows how to conduct a “root cause analysis”</u>	
<b><u>Staffing</u></b>	
<u>Number of pharmacists hours allocated per week</u>	
<u>Number of pharmacy intern hours allocated per week</u>	
<u>Number of pharmacy technician hours allocated per week</u>	
<u>Number of other pharmacy support staff hours allocated per week</u>	
<b><u>Workload</u></b>	
<u>Number of hours pharmacy department is opened during the week</u>	
<u>Average number of prescriptions filled per week</u>	
<u>Usual ratio of pharmacists to technicians</u>	<u>        /</u>
<u>Policy is in place that requires increased staffing if workload increases</u>	
<b><u>Pharmacy Technicians</u></b>	
<u>Areas of training</u>	
<u>    Cash register</u>	
<u>    Pharmaceutical calculations</u>	
<u>    Computer data entry</u>	
<u>    Inventory</u>	
<u>    Pharmaceutical and medical terminology</u>	
<u>    Prescription intake</u>	
<u>    Clean room</u>	
<u>    Counting medications</u>	
<u>    Identifying drugs, doses, routes of administration, dosage forms, etc.</u>	
<u>    Knowledge of practice setting</u>	
<u>    Returning stock bottles to shelf</u>	
<u>    Knowledge and ability to perform compounding, packaging, and labeling</u>	
<u>    Other</u>	
<u>Written protocol for technician training exists</u>	
<u>Technicians are encouraged to become certified</u>	

<u>Technicians play role in helping to avert “near miss” QREs</u>	
<b><u>Technology</u></b>	
<u>Types of technology employed in the pharmacy department</u>	
<u>Automatic counters</u>	
<u>Automatic dispensing</u>	
<u>Automatic phone system</u>	
<u>Baker Cells®</u>	
<u>Bar scanning</u>	
<u>Computer imaging</u>	
<u>Computer scanning of prescription hardcopy</u>	
<u>Internet refill</u>	
<u>Other</u>	
<u>Computer records are linked to other company pharmacy locations</u>	
<u>Frequency that automated counters are cleaned</u>	
<u>Frequency that DUR information is updated</u>	
<u>System contains “High Dose Warning” feature</u>	
<u>System tracks weight/age and uses to verify dose</u>	
<u>Inventory maintenance</u>	
<u>Automatic reorder</u>	
<u>Manual order entry</u>	
<u>Personnel responsible for inventory maintenance</u>	
<u>Frequency of inventory replenishment</u>	
<u>Daily</u>	
<u>Weekly</u>	
<u>Bi-weekly</u>	
<u>Other</u>	
<u>Prescriptions can be received via electronic method(s)</u>	
<u>Typical methods of prescribing medications</u>	
<u>Computer</u>	
<u>Facsimile</u>	
<u>Patient presents hardcopy</u>	
<u>Phoned in</u>	
<u>Other</u>	
<b><u>Initiatives to Enhance Pharmacist Care</u></b>	
<u>Pharmacist Care Services Offered</u>	
<u>Anticoagulation</u>	
<u>Asthma</u>	
<u>Blood pressure screening</u>	
<u>Diabetes</u>	
<u>Lipid monitoring</u>	
<u>Other</u>	

<u>Types of community involvement</u>	
<u>Brown bag</u>	
<u>Drug use prevention</u>	
<u>Education to other health care professionals</u>	
<u>Poison control</u>	
<u>Other</u>	
<u>Methods used to document pharmacy interaction in relation to CQI programs</u>	
<u>Computer data base</u>	
<u>Custom made form</u>	
<u>On prescription</u>	
<u>Standard form</u>	
<u>First time refills are checked against the hardcopy</u>	
<u>Method used to verify drug product with prescription label</u>	
<u>Bar code</u>	
<u>NDC code</u>	
<u>Name of product</u>	
<u>Other</u>	

<b><u>Consumer Surveys</u></b>	<b><u>Yes/No/Answer</u></b>
<u>Consumer survey policy in place</u>	
<u>Other technique in place to evaluate performance (if “yes”, describe)</u>	
<u>Frequency of consumer survey</u>	
<u>Method of conducting consumer survey</u>	
<u>Distributed at time of dispensing medication</u>	
<u>Mail</u>	
<u>Telephone</u>	
<u>Consumer survey feedback utilized to improve delivery of pharmacy services</u>	

<b><u>Professional Performance Evaluation</u></b>	<b><u>Yes/No/Answer</u></b>
<u>Professional Performance Evaluation policy in place</u>	
<u>Annually</u>	
<u>Bi-annually</u>	
<u>Quarterly</u>	
<u>Other</u>	
<u>Policy to insure pharmacists’ licenses are renewed and satisfy requirements</u>	
<u>Staff required to have professional performance evaluations</u>	
<u>All employees (both full and part-time)</u>	
<u>Full time pharmacists</u>	

Part-time pharmacists

<b><u>Quality Self-Audit</u></b>	<b><u>Yes/No/Answer</u></b>
<u>Pharmacy conducts self-audit</u>	
<u>Self-audit conducted</u>	
<u>Annually</u>	
<u>Monthly</u>	
<u>Quarterly</u>	
<u>Other</u>	
<u>Self-audit includes</u>	
<u>Number of overridden drug-drug interaction warnings</u>	
<u>Number of patients that received duplicative drug therapy</u>	
<u>Number of patients that received extensive counseling</u>	
<u>Number of QREs tracked over time</u>	

Comments:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Survey participant(s)  
Name and title: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature(s): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Surveyor(s)  
Name and title: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature(s): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Best Practice Recommendation, COI Compliance Survey

	<u>Yes</u>	<u>No</u>	<u>Comment</u>
1. <u>Develop policies and procedures providing that incident reports will be completed and submitted to a national database.</u>			
2. <u>Institute a system to quarterly review incident reports.</u>			
3. <u>Develop and implement an effective workflow pattern.</u>			
4. <u>Routinely poll customers regarding quality of care and satisfaction with service.</u>			
5. <u>Develop and implement a comprehensive technician training program.</u>			
6. <u>Implement a policy requiring that counseling be offered to every Patient receiving a prescription.</u>			
7. <u>Develop policies and procedures that insure patient profiles are periodically updated.</u>			
8. <u>Adopt written policies and procedures for the return of unsold prescriptions to stock.</u>			
9. <u>Utilize available age and weight adjusted dosing guidelines when appropriate.</u>			
10. <u>Provide adequate and easy access to appropriate reference materials.</u>			
11. <u>Monitor adherence to prescriber directions by monitoring early and late refills.</u>			
12. <u>Develop written policies and procedures to remove outdated stock.</u>			
13. <u>Adopt written policies and procedures for the handling of filled prescription orders for pickup by patient or patient representative.</u>			
14. <u>Develop procedures for timely action of drug recalls.</u>			
15. <u>Explore reasons for out of stock items.</u>			
16. <u>Adopt a policy allowing for continuation of therapy for out of stock or unavailable items.</u>			
17. <u>Adopt a policy allowing pharmacists up to a thirty-minute lunch break when working six or more hours per shift.</u>			
18. <u>Develop policies and procedures regarding proper staffing.</u>			
19. <u>Utilize interpreters as necessary.</u>			
20. <u>Develop policies and procedures that continually improve the practice of pharmacy by incorporating strategies to optimize therapeutic outcomes.</u>			
21. <u>Develop policies and procedures which continually ensure the integrity of biologicals and pharmaceuticals.</u>			
22. <u>Develop policies and procedures regarding the receipt, storage and security of controlled substances.</u>			
23. <u>Develop written policies and procedures for medication identification.</u>			

### III. Pharmacy Quality Self-Audit

Each pharmacy shall conduct a quality self-audit at least quarterly and upon change of pharmacist-in-charge. The goals of the quality self-audit are to monitor changes in the number of quality-related events (QRE) over time, to evaluate compliance with CQI procedures, and to develop a plan for improved adherence with the CQI Program.

**Date:** \_\_\_\_\_ **Quarterly**  **Change of pharmacist-in-charge**

**Pharmacy Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **License No.** \_\_\_\_\_

**Pharmacist-In-Charge:** \_\_\_\_\_

**Pharmacists:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Support Staff:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Staffing/Workload Data**

<b><u>Staffing</u></b>	<b><u>Yes/Answer</u></b>
<u>Number of pharmacist hours allocated per week</u>	
<u>Number of pharmacy technician hours allocated per week</u>	
<u>Number of other pharmacy support staff hours allocated per week</u>	
<u>Number of certified technicians</u>	
<u>Number of non-certified technicians</u>	
<u>All staff has reviewed CQI policy and procedures</u>	
<b><u>Workload</u></b>	
<u>Number of hours pharmacy department is open during the week</u>	
<u>Average number of prescriptions filled per week</u>	
<u>Usual ratio of pharmacists to technicians</u>	____ / ____
<u>Policy is in place that requires increased staffing if workload increases</u>	

**QRE Incidents**

Utilizing QRE Data Collection Sheets, compile the data below.

<u>Date</u>								
<u>QRE type (ie, A(1) = incorrect drug dispensed)</u>								
<u>Rx received via:</u>								
<u>New or refill</u>								
<u>Day of week/time</u>								
<u># new rx's filled at time of QRE</u>								
<u># refill rx's filled at time of QRE</u>								
<u>RPh to tech ratio</u>								
<u>RPh staff status</u>								
<u># hrs RPh on duty</u>								
<u># other RPh on duty</u>								
<u># other support staff</u>								
<u>Average # rx/hour</u>								
<u>Responsible RPh name</u>								
<u>Responsible support staff name(s)</u>								
<u>Patient received medication</u>								
<u>Prescriber notified</u>								



<u>Other information</u>								
<u>Documentation of counseling</u>								

Number of overridden drug-drug interactions since last self-audit: \_\_\_\_\_

Last staff professional performance evaluation conducted on: \_\_\_\_\_

**Consumer Survey**

Compile information gained from consumer surveys.

<u>Survey Date</u>					
<u>Results summary</u>					
<u>Summary of improvements made pursuant to consumer feedback</u>					



## NABP MODEL LANGUAGE:

- (j) 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;
    - (vi) for those Persons utilizing a Drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.
  - (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.

State of Arizona  
House of Representatives  
Forty-eighth Legislature  
First Regular Session  
2007

# HOUSE BILL 2255

AN ACT

AMENDING TITLE 32, CHAPTER 18, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTION 32-1973; RELATING TO THE STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Title 32, chapter 18, article 3, Arizona Revised Statutes,  
3 is amended by adding section 32-1973, to read:

4 32-1973. Pharmacies; quality assurance

5 A. AS PRESCRIBED BY THE BOARD BY RULE, EACH PHARMACY SHALL IMPLEMENT  
6 OR PARTICIPATE IN A CONTINUOUS QUALITY ASSURANCE PROGRAM TO REVIEW PHARMACY  
7 PROCEDURES IN ORDER TO IDENTIFY METHODS FOR ADDRESSING PHARMACY MEDICATION  
8 ERRORS. THE RULES SHALL PRESCRIBE REQUIREMENTS TO DOCUMENT COMPLIANCE AND  
9 ANY OTHER PROVISIONS NECESSARY FOR THE ADMINISTRATION OF THE PROGRAM.

10 B. RECORDS THAT ARE GENERATED AS A COMPONENT OF A PHARMACY'S ONGOING  
11 QUALITY ASSURANCE PROGRAM AND THAT ARE MAINTAINED FOR THAT PROGRAM ARE PEER  
12 REVIEW DOCUMENTS AND ARE NOT SUBJECT TO SUBPOENA OR DISCOVERY IN AN  
13 ARBITRATION OR CIVIL PROCEEDING. THIS SUBSECTION DOES NOT PROHIBIT A PATIENT  
14 FROM ACCESSING THE PATIENT'S PRESCRIPTION RECORDS OR AFFECT THE  
15 DISCOVERABILITY OF ANY RECORDS THAT ARE NOT GENERATED ONLY AS A COMPONENT OF  
16 A PHARMACY'S ONGOING QUALITY ASSURANCE PROGRAM AND MAINTAINED ONLY FOR THAT  
17 PROGRAM.

18 C. A PHARMACY MEETS THE REQUIREMENTS OF THIS SECTION IF IT HOLDS A  
19 CURRENT GENERAL, SPECIAL OR RURAL GENERAL HOSPITAL LICENSE FROM THE  
20 DEPARTMENT OF HEALTH SERVICES AND IS ANY OF THE FOLLOWING:

21 1. CERTIFIED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES TO  
22 PARTICIPATE IN THE MEDICARE OR MEDICAID PROGRAMS.

23 2. ACCREDITED BY THE JOINT COMMISSION ON THE ACCREDITATION OF HEALTH  
24 CARE ORGANIZATIONS.

25 3. ACCREDITED BY THE AMERICAN OSTEOPATHIC ASSOCIATION.

26 Sec. 2. Pharmacies; quality assurance program; initial rules

27 Before the Arizona state board of pharmacy adopts initial rules  
28 pursuant to section 32-1973, Arizona Revised Statutes, as added by this act,  
29 the Arizona state board of pharmacy shall appoint an advisory committee to  
30 advise the board regarding the proposed rules. The advisory committee shall  
31 include representatives from the following:

32 1. An association that represents pharmacists.

33 2. An association that represents pharmacies.

34 3. A health services administration.

35 4. A hospital association.

36 5. A health care association.

37 6. A health system that represents hospital pharmacists.

## ARTICLE 1. ADMINISTRATION

### R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Continuous quality assurance program" or "CQA program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.

"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.

## ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

### R4-23-620. ~~Reserved~~ Continuous Quality Assurance Program

- A.** Each pharmacy permittee shall implement or participate in a continuous quality assurance (CQA) program. A pharmacy permittee meets the requirements of this Section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:
1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
  2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
  3. Accredited by the American Osteopathic Association.
- B.** A pharmacy permittee or the pharmacist-in-charge shall ensure that:
1. The pharmacy develops, implements, and utilizes a CQA program consistent with the requirements of this Section and A.R.S. § 32-1973;
  2. The medication error data generated by the CQA program is utilized and reviewed on a regular basis, as required by subsection (D); and
  3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.
- C.** A pharmacy permittee or pharmacist-in-charge shall:
1. Ensure that policies and procedures for the operation and management of the pharmacy's CQA program are prepared, implemented, and complied with;
  2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
  3. Document the review required under subsection (C)(2);
  4. Assemble the policies and procedures as a written or electronic manual; and
  5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.
- D.** The policies and procedures shall address a planned process to:
1. Train all pharmacy personnel in relevant phases of the CQA program;
  2. Identify and document medication errors;
  3. Record, measure, and analyze data collected to:
    - a. Assess the causes and any contributing factors relating to medication errors, and
    - b. Improve the quality of patient care;

4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and
  5. Communicate periodically, and at least annually, with pharmacy personnel to review CQA program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQA program findings.
- E.** The Board's regulatory oversight activities regarding a pharmacy's CQA program are limited to inspection of the pharmacy's CQA policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.
- F.** A pharmacy's compliance with this Section shall be considered by the Board as a mitigating factor in the investigation and evaluation of a medication error.

# CALIFORNIA

## **4125. Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents**

(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.

**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.

*Specific Authority 465.0155 FS. Law Implemented 465.0155 FS. History—New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07.*

## INDIANA

### **856 IAC 1-28.1-1 Definitions**

Authority: IC 25-26-13-4

Affected: IC 16-42-19-5; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:

*(8) "Performance improvement program" means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.*

### **856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation**

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:

- (1) monitor the stability of existing medication use processes;
- (2) identify opportunities for improvement; and
- (3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:

- (1) an intensive analysis of causal factors involved in the event; and
- (2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:

- (1) Staffing levels of both professional and technical personnel.
- (2) Workflow.
- (3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:

(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.

(2) The quality related or sentinel event shall be:

- (A) initially documented by the pharmacist to whom it is first described; and
- (B) recorded on the same day of its having been so described to the pharmacist.

(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.

(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.

(5) No patient names or employee names shall be included in this summary report.

(6) This report shall be maintained for a period of not less than two (2) years.

(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).

*(Indiana Board of Pharmacy; 856 IAC 1-28.1-11; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)*

**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.

**65-1695 Continuous quality improvement program; purpose; confidential peer review documents; rules and regulations.**

(a) No later than July 1, 2009, each pharmacy shall establish a continuous quality improvement (CQI) program. The purpose of the CQI program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy shall take appropriate action to prevent a recurrence.

(b) Reports, memoranda, proceedings, findings, and other records generated as part of the pharmacy CQI program shall be considered confidential and privileged peer review documents and not subject to discovery, subpoena, or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than an administrative proceeding initiated by the board of pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing such patient's own prescription records. Nothing in this section shall effect the discoverability of any record not solely generated for or maintained as part of the pharmacy's CQI program.

(c) No person in attendance at any meeting conducted as part of the CQI program shall be compelled to testify in any civil, criminal or administrative action other than an administrative proceeding initiated by the board of pharmacy as to any discussions or decisions which occurred as part of the CQI program.

(d) All reports and records generated as part of the pharmacy's CQI program shall be available for inspection by the board of pharmacy within a time period established by the board in rules and regulations.

(e) In conducting a disciplinary proceeding in which omission of any matters that are confidential and privileged under subsection (b) are proposed, the board of pharmacy shall hold a hearing in closed session when any report, record or testimony is disclosed. Unless otherwise provided by law, the board of pharmacy in conducting a disciplinary proceeding may close only that portion of the hearing in which disclosure of such privileged matters are proposed. In closing a portion of a hearing as provided in this subsection, the presiding officer may exclude any person from the hearing except members of the board, the licensee, the licensee's attorney, the agency's attorney, the witness, the court reporter and appropriate staff support for either counsel.

The Board of pharmacy shall make the portions of the administrative record in which such privileged matters are disclosed subject to a protective order prohibiting further disclosure. Such privileged matters shall not be subject to discovery, subpoena, or other means of legal compulsion for their release to any person or entity. No person in attendance at a closed portion of a disciplinary proceeding shall be required to testify at a subsequent, civil, criminal, or administrative hearing regarding the privileged matters, nor shall such testimony be admitted into evidence in any subsequent civil, criminal, or administrative hearing.

The board of pharmacy may review any matters that are confidential and privileged under subsection (b) in conducting a disciplinary proceeding but must prove its findings with independently obtained testimony or records which shall be presented as part of the disciplinary proceeding in an open meeting of the board of pharmacy. Offering such testimony or records in an open public hearing shall not be deemed a waiver of the peer review privilege relating to any peer review testimony, record, or report.

(f) The board may establish by rules and regulations requirements regarding the function and record keeping of a pharmacy CQI program.

(g) This section shall be part of and supplemental to the Pharmacy Act of the state of Kansas.

**History:** L. 2008, ch. 104, § 16; July 1.

**68-19-1. Minimum program requirements.** Each pharmacy's continuous quality improvement program shall meet the following minimum requirements:

- (a) Meet at least once each quarter of each calendar year;
- (b) have the pharmacy's pharmacist in charge in attendance at each meeting; and
- (c) perform the following during each meeting:
  - (a) Review all incident reports generated for each reportable event associated with that pharmacy since the last quarterly meeting;
  - (2) for each incident report reviewed, establish the steps taken or to be taken to prevent a recurrence of the incident; and
  - (3) create a report of the meeting, including at least the following information:
    - (A) A list of persons in attendance;
    - (B) a list of the incident reports reviewed; and
    - (C) a description of the steps taken or to be taken to prevent recurrence of each incident reviewed. (Authorized by and implementing L. 2008, ch. 104, §16; effective April 10, 2009.)

## **Massachusetts**

### **Rules and Regulations**

#### **15.00: Continuous Quality Improvement Program**

- 15.01: [Definitions](#)
- 15.02: [Continuous Quality Improvement Program](#)
- 15.03: [Quality Related Event Discovery, Notification and Documentation](#)
- 15.04: [Records](#)

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#### **15.01: Definitions**

**Continuous Quality Improvement Program** or **CQI Program** means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

**Quality-Related Event** or **QRE** means the incorrect dispensing of a prescribed medication that is received by a patient, including:

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

1. dispensing an incorrect drug;
2. dispensing an incorrect drug strength;
3. dispensing an incorrect dosage form;
4. dispensing the drug to the wrong patient; or
5. providing inadequate or incorrect packaging, labeling, or directions; or

(b) a failure to identify and manage:

1. over-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.

**Pharmacy**, as referenced in 247 CMR 15.00, means a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.

**Pharmacy Personnel** means pharmacist, pharmacy intern, pharmacy technician and pharmacy support personnel.

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#### 15.02: **Continuous Quality Improvement Program**

(1) **Continuous Quality Improvement Program Requirements.** Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs). At a minimum, a CQI program shall include provisions to:

- (a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;
- (b) identify and document QREs;
- (c) minimize impact of QREs on patients;
- (d) analyze data collected in response to QREs to assess causes and any contributing factors;
- (e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
- (f) provide ongoing education at least annually in the area of CQI to pharmacy personnel.

(2) **Implementation Date.** The CQI Program requirements of 247 CMR 15.00 shall be implemented by each pharmacy by December 31, 2005.

### 15.03: **Quality Related Event Discovery, Notification and Documentation**

(1) **QRE Discovery and Notification.** All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

- (a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;
- (b) directions for correcting the error; and
- (c) instructions for minimizing the negative impact on the patient.

(2) **QRE Documentation.**

(a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.

(b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:

1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
3. a description of the QRE reviewed; and
4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.

(3) **QRE Analysis and Response.**

(a) **QRE Analysis.** The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and

assessment shall include:

1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
2. any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and
3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.

(b) **Response.** Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

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#### 15.04: **Records**

- (1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.
- (2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.
- (3) QRE records shall be maintained in an orderly manner and filed by date.
- (4) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

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REGULATORY AUTHORITY  
247 CMR 15.00: M.G.L. c. 112, §§ 37 through 39 and 42A.

Back to [247 CMR](#) or [Board Home Page](#)

[Privacy Policy](#)

# PHARMACY QUALITY ASSURANCE REPORT NOTICE

DHHS  
 DIVISION OF PUBLIC HEALTH  
 LICENSURE UNIT  
 TELEPHONE # (402) 471-2118

Your Pharmacy Quality Assurance Report (PQAR) is due on the same date annually. The Department will accept your PQAR THIRTY (30) days before the due date. Once completed, please send the PQAR to your pharmacy inspector listed on page 3. You will be notified by the Department whether your PQAR is determined to be in full compliance with the Health Care Facilities Licensure Act and 175 NAC 8 Nebraska Regulations Governing Licensure of Pharmacies.

Pharmacy Name: \_\_\_\_\_  
 Pharmacy License Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
 Pharmacy Street Address: \_\_\_\_\_  
 Pharmacy City, State, Zip Code: \_\_\_\_\_  
 DEA registration Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
 Pharmacy Telephone #: \_\_\_\_\_ Pharmacy Fax #: \_\_\_\_\_  
 Owner's Name: \_\_\_\_\_  
 Pharmacy Web Page/E-mail: \_\_\_\_\_  
 Pharmacy Hours: \_\_\_\_\_

**List Pharmacy Personnel:**

Name of PIC: \_\_\_\_\_ License #: \_\_\_\_\_

Staff Pharmacists Name & NE License #	Pharmacist Interns Name & NE Registration #	Pharmacy Technicians Name & NE Registration #

SOFTWARE: \_\_\_\_\_ RX'S PER DAY: \_\_\_\_\_

I, the pharmacist in charge, state that all of the statements herein contained are each and strictly true in every respect. I have read the applicable Nebraska State Statutes and Rules and Regulations concerning the practice of pharmacy, am familiar with its provisions, and agree to abide by all said provisions. I understand that false or forged statements made in connection with this Quality Assurance Report may be grounds for action against my pharmacist license and/or the pharmacy license.

\_\_\_\_\_  
 (Signature of Pharmacist-in-Charge) (Date)

Pharmacy Name: \_\_\_\_\_ Pharmacy License #: \_\_\_\_\_ PQAR Date \_\_\_\_\_

**C = In Compliance**

**NC = Not in Compliance**

**NA = Not Applicable**

Section cited	Requirement	C	NC	NA
175 NAC 8-003.01A	1. All information provided on the application for a pharmacy license is accurate and correct.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02C	2. Adequate security is maintained for the prescription inventory and prescription records.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02A	3. Drugs, devices and biologicals are stored at the proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.02	4. The pharmacy is maintained in a clean, orderly, and sanitary manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.03	5. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.01	6. The pharmacy provides the pharmacist access to all utilities/equipment needed to practice pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04H	7. Patient counseling is being provided as required.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04H2	8. The pharmacy maintains documentation of a patient's refusal of counseling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04H	9. Patient counseling is being done by only a pharmacist or pharmacist intern.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 38-2869	10. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist is conducting a prospective drug utilization review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 CFR Ch. II 1304, 1306	11. All computer or electronic record keeping requirements are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-005.03A5	12. The poison control phone number is posted in the pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 CFR Ch. II 1305.05	13. Power of Attorney forms are complete and appropriately filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.03A Neb. Rev. Stat.- 28-411(4)	14. The pharmacy maintains complete and accurate records of all controlled substances received and added to the inventory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 CFR Ch. II 1307.21	15. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02D	16. The pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04C, .04D, .04E	17. The pharmacy assures that all requirements pertaining to unit dose packaging and labeling are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04G	18. The pharmacy assures that all requirements pertaining to multi-drug containers are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.05B, .05C	19. All requirements pertaining to the inventory of controlled substances are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 CFR Ch. II 1305.11	20. CII acquisitions are properly documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.05A	21. All controlled substances are properly stored.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04B 21 CFR Ch. II- 1306.05(a)	22. All prescriptions contain the required information prior to being filled.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04B.9a, 172 NAC- 128-014.01(9a), 21 CFR Ch. II 1306.22	23. All refill requirements for prescriptions are in compliance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 CFR Ch. II 1306.13, 1306.23, Neb. Rev. Stat. 28-414	24. Partial fillings of controlled substances are recorded and dispensed appropriately.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat.- 28-414 (3b)	25. Prescriptions filled for a Schedule II controlled substance are signed and dated on the front of the prescription.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 28-414 175 NAC 8-006.05D 21 CFR Ch. II- 1306.11(d)(1,2,3,4)	26. All emergency Schedule II prescriptions are properly filled and recorded.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pharmacy Name: \_\_\_\_\_ Pharmacy License #: \_\_\_\_\_ PQAR Date \_\_\_\_\_

Neb. Rev. Stat.- 28-414, 28-1437, 38-2870	27. All requirements for filling electromagnetic transmission prescriptions are followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 38-2055	28. All prescriptions are properly labeled. All prescriptions and the prescription container labels shall bear the name of the prescribing practitioner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 28-414, 175 NAC 8-006.03A1, 21 CFR Ch. II 1306.11	29. Hardcopy requirements for Schedule II prescriptions are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 71-5401 to 71-5409	30. The pharmacy is in compliance with the Drug Product Selection Act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.03A1, Neb. Rev. Stat.- 28-414(3a)(3c)	31. A three-file system for prescriptions is used and maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neb. Rev. Stat. 71-2413	32. Proper records are maintained for Emergency Drug Boxes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.01D	33. All requirements and documentation are met for the utilization of Pharmacy Technicians.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-005.03A(13)	34. No outdated inventory is mixed with saleable stock.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Please forward your completed Pharmacy Quality Assurance Report (PQAR) to your Pharmacy Inspector at the address provided below. Keep a copy for your records:**

<b>Tony Kopf, RP</b> <b>9353 Corby</b> <b>Omaha NE 68134</b>	<b>Mike Rueb</b> <b>3104 N. 160th Ave</b> <b>Omaha NE 68116-2442</b>	<b>Mike Swanda, RP</b> <b>1521 Newell</b> <b>Cozad NE 69130</b>
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## Continuous Quality Assurance

### Quality Assurance (QA) Plans

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### Examples of monitoring

- [Step by Step Power Point](#)
- [Example forms](#)

### QA Forms

- [Blank QA Tracking Form](#)
- [Blank QA Action Plan Form](#)

### Ready-to-implement QA Projects

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# Oregon

John A. Kitzhaber, MD, Governor

Oregon Board of Pharmacy  
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Web: [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us)

## Quality Assurance (QA) Requirements

The Oregon Board of Pharmacy is dedicated to the quality of care and safety of patients. QA is the process of demonstrating a commitment to the ongoing improvement of customer outcomes through the systematic review and enhancement of the pharmacy quality of care standards and their continuous improvement over time<sup>1</sup>. Quality Assurance programs are being required for accreditation but, as professionals, pharmacists should be able to take on this directive themselves.

Each pharmacy must develop and implement a QA program as stated in [OAR 855-019-0300\(5\)\(g\)](#). The program should be tailored to the individual pharmacy's needs. Any variance from the appropriate dispensing of a prescribed medication not corrected prior to the delivery of medication, also known as a quality-related event, should be documented. In addition, the pharmacy should choose one or two areas of improvement to monitor. Goals should be set and a system devised to regularly (at least quarterly) assess progress. When goals are achieved, the pharmacy should choose other/additional areas for improvement. Over time, the plan should address the entire prescription process as well as isolated events when they occur.

In order to be successful, it is essential that QA efforts be communicated among pharmacy staff. Appropriate efforts should be taken to ensure that all employees are familiar with the QA plan as well as the policy and procedure changes that the plan brings about.

The QA program should be continually updated to allow for new improvement tracking as well as new best practices. It is intended that pharmacies will start simply and then develop a plan that will meet their needs and the needs of their patients. The program can be maintained by a pharmacist or certified pharmacy technician as long as there is professional oversight and communication within the staff. The Board currently will not be inspecting the QA programs. However, they will expect to see that procedures are in place, monitoring in progress, and initiatives being taken to improve care.

This website includes examples of quality-related events, areas to monitor and QA procedures, as well as blank forms and a number of ready-to-implement quality assurance initiatives. There is no requirement to use the materials provided by the Board, but they are intended to help you get started. It is understood that many pharmacies have organizational quality assurance plans. These will be acceptable if you are able to show your active participation in the plan to the inspectors.

1. Quality Care Pharmacy Program. Continuous Quality Improvement. Australia  
[[http://www.qcpp.com/continuous\\_quality\\_improvement.htm](http://www.qcpp.com/continuous_quality_improvement.htm)]

## **Quality-Related Events**

. The term quality-related event includes (but is not limited to):

- Incorrect drug
- Incorrect drug strength
- Incorrect patient
- Inadequate or incorrect packaging, labeling, or directions
- Over-utilization or under-utilization
- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage or duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse

## **Examples of Areas to Monitor**

- Is a date of birth or some identifying piece of information obtained for every new prescription dropped-off?
- Are complete demographics, allergies and health conditions obtained for each patient?
- Are patient profiles being accessed and verified using date of birth or some identifying piece of information other than the patient's name?
- Is there a double-check of prescription data prior to submitting information and obtaining a label?
- Is the counting technician checking the prescription prior to sending it off for final verification?
- Are expiration dates checked and adjusted if necessary when filling prescriptions?
- Are out-dates being pulled?
- Is freight being put away and rotated properly?
- Is there a set process of verification all pharmacists use?
- Are DURs done by a pharmacist or intern on all prescriptions?
- Is the pharmacist or intern actively consulting with patients?
- Is counseling and refusal of counseling being properly documented by pharmacist or intern?
- Is the pharmacist verifying phoned-in prescriptions by repeating information back to the prescriber?
- Is the pharmacist requesting identifying patient information on all phoned-in prescriptions?
- Is an open-ended question used to verify the patient is receiving the right prescription?

[CQI Program Power Point](#)

[Quality Related Event Form](#)

## How to Design and Implement a Basic Quality Assurance Plan

A quality assurance plan should generally include two basic areas: how to address errors (quality-related events), and how to improve practice before an error occurs (continuous quality improvement). This document outlines steps to take in establishing a QA plan plan.

- I. Design a means to effectively document quality-related events (QREs) and educate staff appropriately
  1. Collect all relevant details of the event, identify the root cause(s), and make a plan to avoid the same error in the future (consider the example provided on the Board of Pharmacy's website)
  2. Always educate staff on documented QREs and their resulting plans.
  3. Many errors reported to the Board are due to poor customer service in resolving the issue- consider including training on how to handle an error as part of your plan
- II. Identify one or two quality related parameters you would like to measure and improve. You might consider two categories of parameters:
  1. Areas known to require improvement.
    - a. These areas may be identified through a previous dispensing or procedural error, a deficiency notice from the Board, or observations of pharmacy staff.
    - b. Monitoring will be with the intent to track successful improvement.
  2. Areas expected to be satisfactory
    - a. These areas may be identified as perceived strengths in your pharmacy.
    - b. The intent of monitoring may be to verify that processes are done correctly and to identify unsuspected weaknesses.
- III. Design a method to measure the identified areas. Here are some tips:
  1. Focus on quantitative measures that can show clear results
  2. Utilize your computer system's capabilities where appropriate
  3. Use random samples where appropriate (e.g. you don't necessarily have to go through the entire prescription log book to quantify counseling documentation)
  4. Consider a method that can be accomplished in a reasonable amount of time by appropriate staff. Keep it simple.
  5. Consider a method that can be done consistently as part of normal procedures.
  6. Determine how often the measurement will be repeated and make plans to ensure it is not forgotten.
- IV. Set appropriate goals
  1. Perfection is not always a realistic goal. Determine what is acceptable for your practice.
  2. Set an attainable goal and be prepared to update the goal when it is achieved.
  3. Include instructions on what the person taking the measurement should do if the goal is not met (e.g. who to contact)
- V. Be prepared to make new plans when goals are not met
  1. Set a deadline for when unmet goals will be addressed
  2. Be prepared to change policies or procedures in order to improve areas of deficiency
- VI. Educate your staff on the Quality Assurance Plan, both at inception and at regular intervals. Include:
  1. Why it is being done
  2. What is being tracked
  3. How to perform measurements
  4. Progress in areas being monitored, including improvements implemented as a result thereof
  5. Updates on any QREs, including the plan to avoid those errors in the future
- VII. Quality assurance never ends
  1. Continue to update your plan as necessary. Over time, the entire prescription process can be monitored and improved.



## Quality-Related Event Documentation

**I. QRE Prescription Data** Prescription No.: 123456

Attach copy of: prescription  label  photo copy of vial  (mark all available)

### II. QRE Data

QRE Type: (select all that apply)

#### A. Prescription processing error:

- (1) Incorrect drug
- (2) Incorrect strength
- (3) Incorrect dosage form
- (4) Incorrect patient
- (5) Inaccurate or incorrect packaging, labeling, or directions
- (6) Other: \_\_\_\_\_

#### B. A failure to identify and manage:

- (1) Over/under-utilization
- (2) Therapeutic duplication
- (3) Drug-disease contraindication
- (4) Drug-drug interactions
- (5) Incorrect duration of treatment
- (6) Incorrect dosage
- (7) Drug-allergy interaction
- (8) Clinical abuse/misuse

Prescription was received by the pharmacy via:  telephone  written  computer  fax

Prescription was:  new  refill

### III. QRE Contributing Factors

Day of the week and time of QRE: Friday @ 6:00pm

# of new prescriptions: 100 # of refill prescriptions: 260 RPh to tech ratio: 1:2

RPh staff status:  regular staff  occasional/substitute staff

# of hours RPh on duty: 8 Average # of prescriptions filled per hour: 40

# of other RPh's on duty: 0 # of support staff on duty: 2

Describe preliminary root contributors: We have not been consistently requesting a second patient identifier in addition to the patient name. This is the suspected root cause of this error in which two similar patient names were confused and the drug was dispensed to the wrong patient.

Describe remedial action taken: First, James Doe was contacted to ensure that he had not been provided incorrect drugs. Training was developed to educate pharmacy staff on the importance of obtaining at least two patient identifiers when dispensing a prescription. By default, we will always ask for name and date of birth. The patient is to state these identifiers, not confirm them when stated by the employee. Training was provided verbally and all staff acknowledged by signature their understanding of the policy.

Name and title of preparer of this report: Billy Johnson, RPh

Date: 28 June

EXAMPLE

Quality Assurance Tracking Form  
Year: **2010**

Quality Related Parameter to be Monitored: **Outdated drugs in inventory**

Measurement Method: **We will perform monthly random checks of seven drug storage shelves and determine the percentage based on these.**

Plan to Assess Progress: **Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will then be addressed by creating and documenting an action plan.**

	GOAL	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Results	<5%	<b>3%</b>	<b>0%</b>	<b>0%</b>	<b>4%</b>	<b>12%</b>							
Date	--	<b>1/6</b>	<b>2/3</b>	<b>3/9</b>	<b>4/2</b>	<b>5/5</b>							
Employee Performing Measurement	--	<b>JB</b>	<b>GR</b>	<b>GR</b>	<b>SC</b>	<b>SC</b>							
Supervising Pharmacist	--	<b>AR</b>	<b>AR</b>	<b>GH</b>	<b>AR</b>	<b>GH</b>							

# Example #1-Outdated stock

- **GOAL:** Less than 5% of drugs in stock will be outdated at any one time.
- **Measurement method:** A random inspection of seven drug storage shelves will be completed once per month. Percentage of outdated drugs will be determined based on these selections. If findings are at goal, no further action is necessary but random inspections will continue. If findings are not at goal, an improvement plan will be developed.

*Assume now that at one of the random inspections it was found that 12% of drugs were outdated . . .*

	GOAL	J	F	M	A	M	J	J	A	S	O	N	D
<b>Outdated drugs in inventory</b>	<5 %	3 %	0 %	0 %	4 %	12 %							

•**Action Plan:** In an effort to decrease outdated drugs in inventory we will implement a quarterly inventory inspection by technicians to remove outdated products. Random inspections will continue on a monthly basis to determine if this plan has resolved the situation.

*Assume now that after 3 months all random inspections have been at goal . . .*

	GOAL	J	F	M	A	M	J	J	A	S	O	N	D
<b>Outdated drugs in inventory</b>	<5%	3 %	0 %	0 %	4 %	12 %	2 %	0 %	1 %				

**Assessment:** Implementation of plan was successful. Monthly review of all drugs will continue as standard practice.

*But if after 3 months random inspections had continued to yield results >5% . . .*

	GOAL	J	F	M	A	M	J	J	A	S	O	N	D
<b>Outdated drugs in inventory</b>	<5%	3 %	0 %	0%	4 %	12 %	7 %	8 %	10 %				

**Assessment:** Plan was not successful. Further investigation will be necessary to ensure that plan was properly implemented and to address deficiencies. Once deficiencies are noted, a new plan will be tested to address them

## Example #2- Counseling Documentation

- **GOAL:** 98% of appropriate prescriptions will be offered counseling.
- **Measurement method:** Offer to counsel will be documented by initials of pharmacist/intern in appropriate area of prescription log book. Logs of 75 new prescriptions will be randomly checked every two weeks. If findings are at goal, no further action is necessary but random inspections will continue. If findings are not at goal, an improvement plan will be developed.

*Assume now that one of the bimonthly inspections revealed only 92% were offered counseling . . .*

	GOAL	J1	J2	F1	F2	M1	M2	A1	A2	M1	M2	J1	J2
<b>Counseling Offered</b>	98%	92%											

**Action Plan:** In an effort to improve counseling, the checking pharmacist will attach a pink bow to all prescriptions requiring pharmacist consultation as a reminder to other employees of the need for counseling.

*Assume now that 4 consecutive bimonthly checks have been at goal . . .*

	GOAL	J1	J2	F1	F2	M1	M2	A1	A2	M1	M2	J1	J2
<b>Counseling Offered</b>	98%	92%	100%	99%	99%	100%							

**Assessment:** Plan was successful. Pink bows will become standard of practice.

*But if the 4 consecutive bimonthly checks had not been consistent . . .*

	GOAL	J1	J2	F1	F2	M1	M2	A1	A2	M1	M2	J1	J2
<b>Counseling Offered</b>	98%	92%	97%	99%	96%	94%							

**Assessment:** Plan was not successful. We will stop attaching pink bows and investigate other options to reach our goal.

## Example #3- Quality Related Single Event

- On June 15, John Doe returns to the pharmacy with a bottle of glipizide that was dispensed to him in error. The bottle is actually labeled for James Doe. He suggests that he won't complain to the Board of Pharmacy if you can show him evidence that you will take steps to prevent this error in the future.
- You immediately begin assessing the situation using the Quality Related Event Documentation form.

# Quality Related Event Documentation

- Any variance from the appropriate dispensing of a prescribed medication not corrected prior to the delivery of medication, also known as a quality-related event, should be documented.
- The manner of this documentation is left up to each particular pharmacy.
- The following is an example of proper documentation using the sample form provided on the Board of Pharmacy website.

• **Quality-Related Event Documentation**

• **I. QRE Prescription Data** Prescription No.: \_\_\_\_\_

• Attach copy of: prescription  label  photo copy of vial  (mark all available)

• **II. QRE Data**

• QRE Type: (select all that apply)

• A. Prescription processing error: B. A failure to identify and manage:

• (1) Incorrect drug  (1) Over/under-utilization

• (2) Incorrect strength  (2) Therapeutic duplication

• (3) Incorrect dosage form  (3) Drug-disease contraindication

• (4) Incorrect patient  (4) Drug-drug interactions

• (5) Inaccurate or incorrect packaging, labeling, or directions  (5) Incorrect duration of treatment

• (6) Other: \_\_\_\_\_ (6) Incorrect dosage

• (7) Drug-allergy interaction

• (8) Clinical abuse/misuse

• Prescription was received by the pharmacy via:  telephone  written  computer  fax

• Prescription was:  new  refill

• **III. QRE Contributing Factors**

• Day of the week and time of QRE: \_\_\_\_\_

• # of new prescriptions: \_\_\_\_\_ # of refill prescriptions: \_\_\_\_\_ RPh to tech ratio: \_\_\_\_\_

• RPh staff status:  regular staff  occasional/substitute staff

• # of hours RPh on duty: \_\_\_\_\_ Average # of prescriptions filled per hour: \_\_\_\_\_

• # of other RPh's on duty: \_\_\_\_\_ # of support staff on duty: \_\_\_\_\_

• Describe preliminary root contributors: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

• Describe remedial action taken: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

• Name and title of preparer of this report: \_\_\_\_\_

Quality Assurance Tracking Form  
Year: 2010

Quality Related Parameter to be Monitored: Outdated drugs in inventory

Measurement Method: We will perform monthly random checks of seven drug storage shelves and determine the percentage based on these.

Plan to Assess Progress: Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will then be addressed by creating and documenting an action plan.

	GOAL	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Results	<5%	3%	0%	0%	4%	12%							
Date	--	1/6	2/3	3/9	4/2	5/5							
Employee Performing Measurement	--	JB	GR	GR	SC	SC							
Supervising Pharmacist	--	AR	AR	GH	AR	GH							





## Quality-Related Event Documentation

**I. QRE Prescription Data** Prescription No.: 123456

Attach copy of: prescription  label  photo copy of vial  (mark all available)

### II. QRE Data

QRE Type: (select all that apply)

#### A. Prescription processing error:

- (1) Incorrect drug
- (2) Incorrect strength
- (3) Incorrect dosage form
- (4) Incorrect patient
- (5) Inaccurate or incorrect packaging, labeling, or directions
- (6) Other: \_\_\_\_\_

#### B. A failure to identify and manage:

- (1) Over/under-utilization
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Prescription was received by the pharmacy via:  telephone  written  computer  fax

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Day of the week and time of QRE: Friday @ 6:00pm

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# of hours RPh on duty: 8 Average # of prescriptions filled per hour: 40

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Describe remedial action taken: First, James Doe was contacted to ensure that he had not been provided incorrect drugs. Training was developed to educate pharmacy staff on the importance of obtaining at least two patient identifiers when dispensing a prescription. By default, we will always ask for name and date of birth. The patient is to state these identifiers, not confirm them when stated by the employee. Training was provided verbally and all staff acknowledged by signature their understanding of the policy.

Name and title of preparer of this report: Billy Johnson, RPh

Date: 28 June

EXAMPLE

Quality Assurance Tracking Form  
Year: **2010**

Quality Related Parameter to be Monitored: **Outdated drugs in inventory**

Measurement Method: **We will perform monthly random checks of seven drug storage shelves and determine the percentage based on these.**

Plan to Assess Progress: **Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will then be addressed by creating and documenting an action plan.**

	GOAL	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Results	<5%	<b>3%</b>	<b>0%</b>	<b>0%</b>	<b>4%</b>	<b>12%</b>							
Date	--	<b>1/6</b>	<b>2/3</b>	<b>3/9</b>	<b>4/2</b>	<b>5/5</b>							
Employee Performing Measurement	--	<b>JB</b>	<b>GR</b>	<b>GR</b>	<b>SC</b>	<b>SC</b>							
Supervising Pharmacist	--	<b>AR</b>	<b>AR</b>	<b>GH</b>	<b>AR</b>	<b>GH</b>							





## Quality Assurance Tracking Form

Year: \_\_\_\_\_

Quality Related Parameter to be Monitored: Proper Expiration Dates on Dispensed Medications

Measurement Method: Pharmacists responsible for final verification will keep a running tally of expiration dates on prescription bottles that extend beyond expiration on stock bottles. Weekly totals will be compared to total # of weekly prescriptions to determine percentage.

Plan to Assess Progress: Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will be addressed by creating and documenting an action plan which will be acknowledged by all employees.

	GOAL	January				February				March			
		Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4
Results	<5%												
Date	--												
Employee Performing Measurement	--												
Supervising Pharmacist	--												



Quality Assurance Tracking Form  
Year: 2010

Quality Related Parameter to be Monitored: Documentation of Counseling Efforts

Measurement Method: Prescription log book will be inspected at the end of each week for any eligible prescriptions that do not show documentation of counseling or refusal of counseling. Percentage will be based off of total number of prescriptions that should have received an offer of counseling.

Plan to Assess Progress: Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will be addressed by creating and documenting an action plan which will be acknowledged by all employees.

	GOAL	January				February				March			
		Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4
Results	98%												
Date	--												
Employee Performing Measurement	--												
Supervising Pharmacist	--												



## Quality Assurance Tracking Form

Year: 2011

Quality Related Parameter to be Monitored: Reconciliation of CII Log Book with Other Pharmacy Records

Measurement Method: Prescription numbers recorded in the CII log book will be reconciled weekly. Ten entries from that week will be randomly selected. The prescription record will be checked to ensure it corresponds to the log book entry.

Plan to Assess Progress: Any findings below goal will be immediately reported to the Pharmacist-in-Charge. Deficiencies will be addressed by creating and documenting an action plan which will be acknowledged by all employees.

	GOAL	January				February				March			
		Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4
Results	100%												
Date	--												
Employee Performing Measurement	--												
Supervising Pharmacist	--												

# **BOARD OF PHARMACY**

## **DIVISION 19**

### **LICENSING OF PHARMACISTS**

#### **855-019-0100**

##### **Application**

- (1) These rules apply to any pharmacist who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon.
- (2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.
- (3) Any pharmacist who engages in the practice of pharmacy in Oregon must be licensed by the Board in accordance with the following rules.
- (4) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).
- (5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.255

##### **Pharmacist Practice**

#### **855-019-0200**

##### **General Responsibilities of a Pharmacist**

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.

(2) A pharmacist shall perform the duties of a pharmacist that include, but are not limited to, DUR, counseling, and final verification of the work performed by those under their supervision.

(3) A pharmacist may not delegate any task that requires the professional judgment of a pharmacist. Such tasks include but are not limited to:

(a) Counseling to a patient or patient's agent, or other healthcare provider;

(b) Verification;

(c) Performing DUR;

(d) Providing a CDTM, DRR, or MTM service;

(e) Ordering, interpreting and monitoring of a laboratory test; and

(f) Oral receipt or transfer of a prescription; except that

(g) An intern under the supervision of a pharmacist may perform all the duties of a technician and the following:

(A) Counseling;

(B) Performing DUR;

(C) Oral receipt or transfer of a prescription,

(D) Immunizations if appropriately trained, and supervised by an immunization qualified pharmacist;

(E) Other activities approved in writing by the Board.

(4) A pharmacist who is supervising an intern is responsible for the actions of that intern, however, this does not absolve the intern from responsibility for their own actions.

(5) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.

(6) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.

(7) A pharmacist while on duty is responsible for the security of the pharmacy area including:

(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;

(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;

(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.025, 689.151, 689.155

## **855-019-0205**

### **Duty to Report**

(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.

(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(3) A pharmacist must report to the Board within 10 days if they:

(a) Are convicted of a misdemeanor or a felony; or

(b) If they are arrested for a felony.

(4) A pharmacist who has reasonable cause to believe that another licensee (of the Board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in

the conduct. The reporting pharmacist shall report the conduct without undue delay, but in no event later than 10 working days after the pharmacist learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

(5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.

(6) A pharmacist who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the Board within 10 days.

(7) A pharmacist must notify the Board in writing, within 15 days, of any change in employment location or residence address.

Stat. Auth.: ORS 689.205

Stats. Implemented: 689.151, 689.155, OL 2009, Ch. 536

## **855-019-0240**

### **Consulting Pharmacist Practice**

(1) Subject to the provisions of OAR 855-019-0100(4), a consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist.

(2) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(3) A consulting pharmacist must maintain appropriate records of their consulting activities for three years, and make them available to the Board for inspection.

(4) A consulting pharmacist is responsible for the safe custody and security of all their records and must comply with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

(5) A consulting pharmacist for a facility that is required by the Board to have a consultant pharmacist but which does not have additional consulting requirements under the terms of its licensure with any other state agency, shall provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

- (b) Provide guidance on the proper documentation of drug administration or dispensing;
- (c) Provide educational materials or programs as requested.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155

## **855-019-0250**

### **Medication Therapy Management**

(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provide by a pharmacist or can be in conjunction with the provision of a medication product with the objectives of:

- (a) Enhancing appropriate medication use;
- (b) Improving medication adherence;
- (c) Increasing detection of adverse drug events;
- (d) Improving collaboration between practitioner and pharmacist; and
- (e) Improving outcomes.

(2) A pharmacist that provides MTM services shall ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:

- (a) Performing or otherwise obtaining the patient's health status assessment;
- (b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;
- (c) Monitoring the safety and effectiveness of the medication therapy;
- (d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;
- (e) Performing a medication review to identify, prevent or resolve medication related problems;
- (f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication;

(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records shall:

(A) Provide accountability and an audit trail; and

(B) Be preserved for at least three years and be made available to the Board upon request except that when records are maintained by an outside contractor, the contract must specify that the records be retained by the contractor and made available to the Board for at least three years.

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen;

(j) Integrating the medication therapy management services within the overall health management plan for the patient; and

(k) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155

### **Pharmacist-in-Charge**

**855-019-0300**

#### **Duties of a Pharmacist-in-Charge**

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a Board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the Board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;

(f) If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

- (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;
  - (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.
  - (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;
  - (g) Implementing a quality assurance plan for the pharmacy.
  - (h) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.
- (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155

## **Discipline**

### **855-019-0310**

#### **Grounds for Discipline**

The State Board of Pharmacy may suspend, revoke, or restrict the license of a pharmacist or intern or may impose a civil penalty upon the pharmacist or intern upon the following grounds:

- (1) Unprofessional conduct as defined in OAR 855-006-0005;
- (2) Repeated or gross negligence;
- (3) Impairment, which means an inability to practice with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;
- (4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;
- (5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;

(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;

(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a license to practice pharmacy or a drug outlet registration;

(8) Permitting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;

(9) Aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;

(10) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto; or

(11) Failure to perform appropriately the duties of a pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.405, OL 2009, Ch. 756

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§ 54.1-3434.03. Continuous quality improvement program.

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

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

(2011, c. [124](#).)

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**Emergency regulation – Effective October 1, 2012 to September 30, 2013**

**BOARD OF PHARMACY**

**Continuous quality improvement programs**

Part I

General Provisions

**18VAC110-20-10. Definitions.**

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

“Dispensing error” means one or more of the following discovered after the final verification

by the pharmacist:

1. Variation from the prescriber’s prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Therapeutic duplication;

b. Drug-disease contraindications, if known;

c. Drug-drug interactions, if known;

d. Incorrect drug dosage or duration of drug treatment;

e. Drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual or potential problem with a patient’s drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited

to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign

Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use

properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).
2. "Room temperature" means the temperature prevailing in a working area.
3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.
4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).
5. "Excessive heat" means any temperature above 40°C (104°F).
6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

**18VAC110-20-418. Continuous quality improvement programs.**

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors;  
and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

## **VERMONT**

**19.21 Quality Assurance** The coordinating pharmacist manager must:

(a) conduct an inspection of the remote pharmacy of the remote pharmacy at weekly intervals or more frequently if necessary. Inspection must be documented and kept on file at the remote pharmacy and available upon request by the Board;

*(b) implement and conduct a quality assurance plan that provides for on-going review of dispensing errors, with appropriate action taken, if necessary, to assure patient safety;*

(c) verify the accuracy and legitimacy of controlled substance prescriptions during weekly inspections;

(d) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be available for Board inspection;

(e) conduct an inventory of all controlled substances at least monthly to verify accuracy; and

*(f) maintain a record of medication errors.*