



PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

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“MEDICATION ERRORS PREVENTION: 2018/2019”

April / May 2018

THIS IS A DOUBLE LESSON (2 MONTHS—APRIL & MAY, 2018). THERE WILL NOT BE A SEPARATE MAY, 2018 LESSON. THE NEXT LESSON WILL BE JUNE, 2018.

WE PRESENT THIS LESSON EVERY YEAR (OR TWO) BECAUSE OF ITS IMPORTANCE, AND BECAUSE A NUMBER OF STATES REQUIRE CPE RELATED TO THIS TOPIC DURING EACH LICENSE PERIOD.

THIS LESSON IS APPROVED IN FLORIDA, AND MAY FULFILL THAT STATE'S MANDATORY REQUIREMENT FOR THE LICENSE PERIOD ENDING SEPTEMBER 30, 2019.

THE LESSON ALSO FULFILLS 3 HOURS OF PATIENT SAFETY CPE IN THOSE STATES WHERE MANDATED.

IN STATES WHERE THERE IS NO REQUIREMENT, THIS LESSON FULFILLS 3.0 HOURS (0.3 CEUs) OF GENERAL PHARMACY CPE.

ALTHOUGH THIS LESSON IS ESSENTIALLY THE SAME AS THAT PRESENTED IN THE PREVIOUS LICENSE PERIOD, IT HAS BEEN REVIEWED (AND UPDATED WHERE NECESSARY) BY OUR FACULTY EDITORIAL BOARD. THE LESSON HAS BEEN ASSIGNED A NEW ACPE PROGRAM ID#, AND MAY BE USED FOR THE CURRENT LICENSE PERIOD IN ALL STATES.



FLORIDA PARTICIPANTS

This lesson has been APPROVED by the Florida Board of Pharmacy & fulfills the mandatory MEDICATION ERRORS PREVENTION requirement for the license period ending September 30, 2019.

Be sure to provide your Florida License Number in the space provided on the quiz sheet. We need this in order to report your information to CE Broker.com

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FOR TECHNICIANS 0798-0000-18-221-H05-T.

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To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required). Should you score less than 70%, you will be asked to retake the quiz. Computerized records are maintained for each participant for 5 years.

When you send in quizzes, always keep a copy. You may mail or fax quiz. Fax # is 843-488-5554. Or send a conventional email with your answers to (info@ce-info.com).

If you have any comments, suggestions or questions, contact us at the above address, or call 1-843-488-5550.

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MEDICATION ERROR PREVENTION IN PHARMACY: UPDATE

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This is our biannual lesson on 'Medication Errors.' Errors cannot be eliminated, but they can be reduced and minimized. The general goal of this lesson is to review the concepts related to medication error reduction. This is a knowledge – based CPE activity. We shall include a situation that resulted in criminal charges and conviction against a pharmacist as a result of an error. Medication error reduction can, hopefully, be achieved with a program of Continuous Quality Improvement (CQI). We shall discuss this also.

ACPE ID # for this lesson is 0798-0000-18-221-H05-P for pharmacists & 0798-0000-18-221-H05-T for technicians

The objectives of this lesson are such that upon completion participants will be able to:

For Pharmacists:

1. Discuss techniques that can be incorporated into a pharmacy's daily operations in order to prevent or minimize medication errors.
2. Describe "root cause analysis" as a means of determining where errors arise, and using that information as a learning tool for minimizing and/or preventing future errors.
3. Comment upon & list ways to reduce & prevent errors.
4. In a "non-blaming" scenario of delineating where errors can & do arise, discuss this ultimate impact upon patient safety.
5. Describe the problems presented by the culture of punishment as a response to medication errors.
6. Discuss the lessons that can be learned from recent cases associated with medication errors in pharmacy.
7. List the requirements of a Continuous Quality Improvement program.
8. Explain steps that can be taken to comply with a board of pharmacy CQI program.

For Technicians:

1. Discuss techniques that can be incorporated into a pharmacy's daily operations in order to prevent or minimize medication errors.
2. Describe "root cause analysis" as a means of determining where errors arise, and using that information as a learning tool for minimizing and/or preventing future errors.
3. Comment upon & list ways to reduce & prevent errors.
4. In a "non-blaming" scenario of delineating where errors can & do arise, discuss this ultimate impact upon patient safety.
5. Describe the problems presented by the culture of punishment as a response to medication errors.
6. Discuss the lessons that can be learned from recent cases associated with medication errors in pharmacy.
7. List the requirements of a Continuous Quality Improvement program.
8. Explain steps that can be taken to comply with a board of pharmacy CQI program.

INTRODUCTION

In this lesson we often refer to the State of Florida because its requirement regarding error prevention and error prevention education are models. A number of other states have mandated similar requirements, or they are considering similar issues. Most of these other states use similar language and include the similar factors as Florida.

Drug therapy is a risky activity. Risks are necessary for there to be benefits for patients. But risks to patients can be minimized through effective medication safety practices. Effective communication and thorough documentation are key elements of a medication safety system. According to the National Coordinating Council for Medication Reporting and Prevention (NCCMEERP) there are several high-risk situations that can lead to medication errors. These situations include:

- Look-alike and sound-alike drug names.
- Indistinctive product packaging.
- Storage of similar drugs without clear separation.
- Non-standard and ambiguous abbreviations.
- Poor training and/or supervision of support personnel.
- Focus on volume rather than quality.
- Distractions; both systemic and personal.
- Lack of integrated communication systems.
- Computer systems that are not user-friendly.

Pharmacists and pharmacy technicians function within practice environments that present daunting challenges caused by these high-risk situations. Using accepted medication safety techniques, it is possible to effectively manage the risk of harm to patients, and to assure that patients receive the care, the pharmaceutical products and services they need.

While it may be tempting to blame the system for risks that cause medication errors, it is important for pharmacy personnel to take ownership of the system in which they practice. When there is a problem that can be addressed, pharmacy personnel must speak up about the problem. As unpleasant as it may seem, pharmacy personnel must assume that they practice in a fish bowl that will be scrutinized by others after a medication error has occurred. Pharmacy personnel should always consider what others may think of their actions, their words, and their writings, if an error occurs. There will be little sympathy with pharmacy personnel who say, "I assumed things would be okay," after an error has occurred. Responsible pharmacy personnel do not assume things will be okay. They take action to protect patients when risks to patient safety are identified.

To Err Is Human

Pharmacists are human beings and human beings make mistakes. There is simply no avoiding this reality. Pharmacists try hard not to make mistakes. But imperfection is a part of the human condition and pharmacists are not perfect. This is the message we were all told many times as we grew up, when a mistake we made was met with the comforting response, "nobody is perfect." Medication errors by pharmacists are inevitable, although they certainly are undesirable, unpleasant and sometimes tragic. Pharmacist errors must be addressed in a systematic way to avoid harm to patients. Simply telling pharmacists to "be more careful" will

not work. Pharmacists are already careful. But they are human and they just can't help making errors, particularly in the contemporary pharmacy practice setting where there is considerable stress, high prescription volume and countless distractions.

Dr. James Reason, and other experts who have studied errors made by health care professionals, has concluded that human error is “normal” in health care. In saying this, they do not mean that error is welcome, or that it is of no real consequence. In concluding that error is “normal,” these experts are saying that the inevitability of human error requires that it be planned for in the sense that systems must be developed to identify, absorb, and prevent error. Human errors can be forgiven, but the failure to implement institutional procedures to prevent foreseeable errors cannot be forgiven. There is a difference between the pharmacist who has erred despite having done everything possible to prevent the error, and the pharmacist who has erred without having implemented any error prevention strategies in that pharmacist's practice.

The Outdated Culture of Punishment

Pharmacists are responsible health care professionals. When a responsible person makes an error, traditional thinking has been that the appropriate reaction is to punish the erring person. This can be done through action taken against a pharmacist's license, by discipline within the pharmacist's workplace, or via malpractice litigation. The culture of punishment in pharmacy is gradually being replaced with a culture of forgiveness and improvement, yet this is a slow process. Pharmacists who have been associated with an error are often still confronted by those who want to single out this pharmacist as the sole culprit, based on the outdated notion that “the buck stops here” and that a responsible pharmacist should be chastened into doing better in the future. In many ways, the oft-repeated saying attributed to a king of old, “the floggings will continue until morale improves,” can be applied to punishment meted out after a pharmacy error.

To be responsible connotes that one is in a position to respond when goods or services are provided to another person in a way that indicates the possibility for harm occurring to the person (a patient, for example) who receives the goods or services. A pharmacist is in a position to respond when the final check of a prescription by the pharmacist indicates that the patient is about to receive the wrong drug, or the right drug in the wrong strength, or the right drug in the wrong dosage form, or that the directions for use are incorrect. A pharmacist is also in a position to respond when the accurate processing of a prescription, exactly as the prescriber has issued it, could cause harm to the patient through a drug-drug interaction, the emergence of a common and severe side effect, or any other adverse effect that can be foreseen by the pharmacist. This is what responsibility of the pharmacist means.

When a bad outcome like an adverse drug event occurs after the provision of products or services by a responsible pharmacist, the pharmacist will be held accountable. To be held accountable means that a pharmacist must provide a description by way of explanation. This accounting will be evaluated by pharmacy management, a group of peers, an administrative agency, or a jury. The accounting may be judged completely acceptable, and the conclusion will be reached that the pharmacist met her or his responsibility despite the occurrence of an unfortunate, but unpreventable, bad outcome. Simply because something did not work out well does not mean the pharmacist failed to meet a responsibility. Alternatively, the accounting may be judged unacceptable based on the conclusion of the evaluators, and had the pharmacist acted appropriately the bad outcome would not have occurred. This is the process through which accountability is developed after responsibility has been established. The principle of

accountability assures that pharmacists will be given the opportunity to provide an explanation after there is harm to a patient that may, but also may not, be the result of a failed responsibility.

The next step in the outdated culture of punishment is to ascribe culpability to a responsible person whose explanation by way of accounting is not judged acceptable. Culpability designates as blameworthy the responsible person whose explanation has failed to justify exoneration. Blame carries with it connotations of unworthiness and carelessness. Sometimes referred to as the “blame and shame” approach, the outdated culture of punishment usually singles out a specific person, the person closest to the error, and designates that person as the sole culprit in the production of the bad outcome. To borrow a sports metaphor, it is similar to the scorer in a baseball game who identifies the shortstop as the erring player after a muffed play. The coach may have instructed the shortstop to play the position too deeply or too shallow, the catcher may have called the wrong pitch, the pitcher may have thrown a poor pitch, or the hit ball may just have spun in a completely unpredictable way. Regardless of whether the shortstop did everything that humanly could have been done to prevent the error, or that any other competent shortstop could have made the same error, the scorer will blame the shortstop. It is a rule of the game. Fortunately for the shortstop, baseball is only a game. No such luck for the erring pharmacist. When a pharmacist muffs a prescription, the patient may die.

The last step in the culture of punishment is liability. A culpable pharmacist may be liable for discipline by a licensing agency, for professional malpractice, and under very rare circumstances may be criminally liable. Liability is a step that is essentially a determination of causality. A responsible pharmacist, whose accounting is unacceptable, and who is determined to be culpable, will be liable only if the patient's harm would not have occurred in the absence of the pharmacist's inappropriate conduct. If the patient's harm was the result of other factors, such as the patient's underlying disease, or the failure by the patient to use medications as instructed, then the pharmacist will usually not be held liable.

There are several advantages of punishment as an approach to addressing error. Punishment is quick and easy. It appears to be responsive to societal requirements that wrongs be righted, and it may mollify the vengeful patient or the patient's family. In theory, punishment can serve as a deterrent to careless pharmacists who become more careful for fear that their errors may lead them to liability. On the other hand, punishment has its disadvantages. It really does not work because pharmacists do not need an additional incentive to avoid errors—they already try their best to avoid errors. Non-volitional (unintentional) errors cannot be deterred through threats of punishment, because threats require that a volitional (by your will) choice be made to effectively deter errors. Since pharmacists do not choose to make mistakes, the threat of punishment is not an effective deterrent. Punishment has the disadvantage of deterring risky but beneficial therapies (like anticoagulation or pain management, for example) that are necessary to promote good outcomes for patients but may lead to problems if done erroneously. Finally, punishment leads to the cover-up of errors and the loss of opportunities to develop error reduction techniques.

A famous story is told of a tragic airline crash that could have been avoided had federal airline authorities not supported a culture of punishment at the time the crash occurred. According to the story, a flight was approaching Washington Dulles Airport, and had followed directions to navigate to a particular place in preparation for landing. The directions given by air traffic control were confusing and the captain went to the wrong place. As the airplane descended through clouds, the sky cleared and it became obvious that an error had occurred because

the airplane was about to crash into a hill. The pilot corrected the error and the airplane landed safely. Shortly thereafter, the captain posted a notecard in the crew break room in St. Louis, advising his colleagues of the potential confusion in that approach to Dulles Airport, and instructing them on the appropriate way to make the approach safely.

Several months after this near-miss, a captain of another flight made the same mistake, going to the wrong place in the sky, but this time the cloud cover was lower and the mistake was not recognized in time. The airplane crashed into the hill and all on-board died. In their investigation, federal agents learned of the notecard posted in St. Louis. They located the captain who had posted it and asked him why he had not brought this problem to their attention. The agents accused the captain of causing the crash by not reporting his near-miss and pointed out to him that federal law required reporting of all flight errors. The captain explained to them that their policy was to punish those who made mistakes, even if the mistake had led to a near-miss rather than a crash, so out of self-preservation he had decided not to report it. The federal authorities learned from this experience. They abandoned the culture of punishment and encouraged flight crews to report errors so the system could be fixed and future errors prevented. As a result, reports of piloting errors have risen dramatically and the system has been improved, with a significant reduction in lives lost due to pilot errors. The health care regulatory system, and more specifically the pharmacy regulatory system, has followed the model of aviation. It has adopted continuous quality improvement rules that mimic the lesson learned in aviation.

Defining the Problem

In a study of pharmacist liability conducted by the CNA insurance company over a ten-year period, the types of medication errors leading to claims against pharmacists were identified. The table below summarizes those findings.

Mechanical Error	Percent
Wrong Drug	43.8%
Wrong Dose	31.5%
Compounding Miscalculation	3.7%
Wrong Dosage Form	2.5%
Improper Substitution	1.9%
Drug Contamination	0.6%
Wrong Strength	0.6%
Intellectual Error	Percent
Failure to Contact Prescriber	4.9%
Overdosage	3.1%
Wrong Patient	3.1%
Drug Allergy	1.9%
Failure to Counsel Patient	1.2%
Drug-Drug Interaction	0.6%
No Child-Resistant Closure	0.6%

As distressing as these results may seem, because even one pharmacy error is too many, the path to improvement is relatively obvious from this claims analysis. The results show that the pharmacy medication errors that are so serious that they lead to claims of legal liability are fixable. Wrong drug and wrong dose comprise almost 75% of the errors. Better systems can be developed to prevent mechanical errors of this type. As is sometimes said, "This is not rocket science."

There are several system-based solutions proposed by the authors of the CNA report. These

solutions include:

- Make error-prone drugs conspicuous (use a sleeve on the bottle).
- Challenge expectations (rotate product location periodically).
- Don't over-rely on technology (if something seems wrong, speak up).
- Recognize individual capabilities (provide for breaks and have realistic expectations).
- Remove impediments to attention.
 - Systemic (distractions, disorder, lack of management support)
 - Personal (illness, fatigue, outdated skills)

Unfortunately, there is no "generic" solution to problems that cause errors in every pharmacy. Rather, it is up to each pharmacy to discover its own problems and to develop effective solutions for that pharmacy. This can be done in many ways, one of which is through a process called root cause analysis

ROOT CAUSE ANALYSIS

A system is a combination of parts incorporated into a unitary whole, with coordination of inputs and outputs to achieve established goals. Traditionally there has been no comprehensive system of pharmacy practice. Each practice site has either developed its own system or has muddled through without a system. Many factors with which pharmacists must deal present significant challenges to a systematic practice of pharmacy. Orders from physicians to pharmacists are often unclear. Physicians are often unavailable to clarify these orders. The names of drugs ordered are similar and are easily confused with each other. The packaging of stock bottles of very different drugs is very similar, and the traditional way to organize stock is to place look-alike, sound-alike drug containers right next to each other. There are no clear standards for the management of potential problems such as drug-drug interactions or drug-disease contraindications, and computer systems over warn pharmacists about potential problems of a trivial nature. In many states, there are no standards for pharmacy technician training. Patients believe that the best pharmacy is the fastest and cheapest pharmacy. Third party payers constantly seek ways to compensate pharmacies at lower and lower levels, while they establish administrative barriers for pharmacists who want to do the right thing for their patients. Given the many system problems, it is a true wonder that pharmacists make so few errors.

Despite a strong record of success in practice and empirical evidence that pharmacy errors are quite low, the public expectation of pharmacists is one of perfection, and the profession strives to achieve that unreachable goal. No pharmacy is satisfied that it makes only very few errors or that only a tiny percent of its patients is harmed by pharmacy errors. Pharmacies take a systems view and look for ways to eliminate errors that can be controlled through system improvements. Within this activity, management works on the system to provide tools, training, equipment and materials. Pharmacists and other pharmacy personnel work within the system to follow established procedures and evaluate how the procedures work and when they should be changed. It is teamwork that makes the systems approach effective. Management cannot rely on pharmacy personnel to solve all of their own problems, and pharmacy personnel cannot wait for management to bring them solutions on a silver platter. Together they can achieve at a level that would be impossible to reach separately.

Case Studies in Pharmacy Error and Quality Improvement

Case studies drawn from actual litigation against pharmacies and pharmacists provide an opportunity to learn how errors may occur in a pharmacy, and what can perhaps be done to improve systems to avoid similar errors in the future. Two of these case studies are reviewed below, not to cast aspersions on the pharmacists involved, but to promote a better understanding of how pharmacy errors occur and how they can be prevented through system improvements.

Case No. 1: *Bookman v. Ciolino* (Louisiana, 1994)

The patient in this case had been prescribed two drugs, Restoril and Prozac. The pharmacy filled both prescriptions, and allegedly placed the intended contents of each prescription in the vial of the other. Thus, the patient took Restoril according to directions for Prozac, and vice-versa. After being hospitalized and recovering, the patient sued the pharmacy contending that the pharmacists were overworked and that the error occurred due to the stress caused by their being overworked. The court noted as follows:

"In 1990, three full-time pharmacists were employed at C's, with Steven Ciolino filling in part of the time. The drugstore filled about 800 prescriptions per day. Based on the average eight-hour day, counsel for the plaintiff figured, and Skinner agreed, that the average number of prescriptions filled per hour was 28.5, or one prescription every 2.1 minutes. This took a great deal of concentration, and if interrupted during the process, he would have to start over again. He was often interrupted to answer questions or to answer the telephone."

The court ruled in favor of the pharmacy in this case, based on confusing testimony from the patient that suggested she was the one who had switched the medications and not the dispensing pharmacist. Nevertheless, the case stands for the important lesson that distractions can cause errors and pharmacy practice sites should be designed to avoid unnecessary distractions. Fortunately, the intervening two decades have produced technological innovations that make it less likely that interruptions will adversely affect the quality of a pharmacist's practice.

Nevertheless, the problems created by distractions continue to be a challenge for pharmacists who develop error-reduction strategies.

The court also made an observation about the manner in which prescriptions were processed at the pharmacy:

"When filling a prescription, Skinner would first receive a computer-generated, three-part label; he would then read the prescription to check for accuracy of the information. The first portion of the label is attached to the prescription; the second part of the label contains refill information and the pharmacist's name along with the name of the medication, directions, etc. Skinner would then get the medicine, bring it to the counter and check it against the prescription, check it against the computer-generated document, count the pills, and put them in the bottles. After stamping his (pharmacist's) name on the bottle, the contents are again checked to make sure that the medication has been correctly dispensed. When filling more than one prescription for the same patient, both medications are pulled at the same time; each one is filled separately, as outlined above. After so doing, the bottles are again opened and checked before handing the prescriptions down. Each pharmacist is responsible for checking his own work."

Lessons to learn from this description of workflow suggest opportunities to improve both at the front end and the back end of the dispensing process. First, the pharmacist usually should not retrieve both stock bottles at the same time. In doing so, the pharmacist has both medications and both labels available concurrently, and the chance of a switched label medication error

is increased. If the pharmacist instead fills one prescription completely, returns the first stock bottle to the shelf, and then fills the second prescription completely, the chances of a switch are reduced considerably. Second, self-checking is notoriously ineffective. One tends not to notice one's own mistakes. Having another person check the accuracy of what has been done by the person actually filling a prescription can dramatically reduce errors.

Case No. 2: Harco v. Holloway (Alabama, 1995)

In the case that first recognized the responsibility of pharmacies to initiate sufficient institutional controls over the manner in which medications are dispensed, the court was critical of both the pharmacy that had created a challenging work environment and the pharmacist whose error led to litigation. Here is what the court said:

“There was evidence that: (1) the prescription was illegible; (2) the pharmacist knew that the prescribing physician was an oncologist (a cancer specialist); (3) the pharmacist gave the patient Tambocor, an antiarrhythmic drug used by cardiologists to treat arrhythmias and other serious heart ailments, although it is undisputed that the prescription actually called for Tamoxifen, a cancer-fighting drug; (4) the pharmacist admitted that she realized at the time that she was giving the plaintiff Tambocor, a heart medication; (5) the pharmacist did not attempt to call the physician to verify the accuracy of her reading of the prescription and did not even try to question Ms. Holloway about why her oncologist was supposedly prescribing a heart medication for her; (6) the pharmacist did not re-read the prescription to verify the accuracy of her reading of it.”

The court suggests in this passage that misfilled prescriptions can frequently be prevented if the pharmacist talks with the patient or requests clarification from the prescriber. Any time a prescription is illegible, the pharmacist should first ask the patient what the physician has explained about the medication. Sometimes things become crystal clear with the addition of a tiny piece of new information from the patient. Should the patient's information still not be adequate to clarify what drug has been prescribed, then the pharmacist must contact the prescriber. To guess what the medication probably must be is to invite disaster. Accuracy in pharmacy requires pharmacists to make certain of what they do, and not take chances with patients' medications.

ERROR REDUCTION & PREVENTION

State Board of Pharmacy Continuous Quality Improvement Programs

To protect the public and to assist pharmacists in the reduction of errors, approximately two-thirds of the states have now implemented some sort of requirement for a program that will monitor system failures, promote system improvements, reduce the occurrence of errors, and demonstrate that pharmacists who make a mistake were trying hard to prevent errors. The Florida Board of Pharmacy was the first state to adopt such a program, and its program serves as an example (and model) of how most programs are conducted. Boards of Pharmacy are authorized by the State Legislatures to promulgate administrative rules that establish standards of practice for the profession of pharmacy. This is a compliment to the pharmacy profession on its ability to self-regulate in the public interest, and it is an opportunity for the profession to solve its own problems without well-intentioned but uninformed outside intervention. Pursuant to this legislative authority, Boards of Pharmacy responded to the problem of errors in pharmacy, through the development of CQI. The enabling language from the Florida Pharmacy Act, as an example, reads as follows:

465.0155 Standards of practice.--

Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.

The specific language of the Florida Board of Pharmacy CQI rule (and the model for other states) is as follows:

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, registered pharmacy interns, registered 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.

(5) 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 the subsection below.

(6) 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.

Interpreting the Board of Pharmacy CQI Rule

This language is relatively straightforward, but it is also sufficiently complex to warrant detailed explanation. The explanation that follows includes a description both of what is explicitly stated, and of what is implied but unstated within the rule.

The first paragraph sets the stage for the entire rule by defining CQI as a “system.” Within a system, activities are coordinated, so that outputs are associated with inputs. In other words, one knows in a system that if one behaves in a particular way, then the result will be of a particular kind. A system is a better organized alternative to the hit-or-miss approach that is taken in non-systems where new ideas are “given a try” without concern for whether they will be proven effective or ineffective. CQI is a continuous system. In theory, if there were no new patients, no new drugs, no new pharmacists, and no new diseases, then the CQI system could operate for a finite period of time and stop, having achieved as close to perfection as can be achieved. But since new factors are constantly introduced into the pharmacy practice system, there is always room for improvement and CQI activities will never end. A system that has not improved patient care is not a CQI system. To show that one has operated a CQI system, one must show that there have been improvements in patient care. These improvements may be reflected in many ways, including (for example) fewer complaints of error, and/or in surveys that demonstrate increased consumer satisfaction with pharmacy services.

The second paragraph of the rule defines the concept of “Quality-Related Event.” This phrase is usually shortened to just “QRE.” The examples of QREs given in the rule are illustrative, they are not inclusive. Section (2)(a) describes problems that traditionally have been referred to as mechanical errors, or errors of commission, while Section 2(b) describes problems that traditionally have been referred to as intellectual errors, or errors of omission. An error of commission (mechanical) occurs when one does something incorrectly, while an error of omission (intellectual) occurs when one fails to do something that is required under the standard of care. Use of this terminology avoids the blame and shame that have accompanied discussions of pharmacist error in the past. The phrase QRE is not simply meaningless, feel-good, new speak. A QRE is more comprehensive than an error, because it may be interpreted to include “almost-errors.” When a problem

occurs within a pharmacy, and an incorrect dosage form is almost dispensed to the patient, or a serious drug-drug interaction almost goes undetected, there is a great deal to learn from what could have occurred but did not. While the language of the Florida CQI rule does not explicitly require that "almost-errors" be incorporated into the definition of QRE, it leaves open the possibility that pharmacies may choose to make this inclusion in their program. Ignoring one "almost-error" after another, until eventually an actual error slips through, is certainly not the best way to address quality concerns. It is far better to learn about system failures from the error that did not reach the patient than from the error that did reach the patient. Limiting the definition of QRE to those problems with quality that have produced adverse consequences for a patient, even if the patient never ingested an incorrect medication but is simply concerned about having received an incorrect medication, limit the ability of a pharmacy to improve its system and realize its full potential.

The third paragraph describes a policy and procedures manual that must be maintained within each pharmacy. This manual may be a general P&P manual, with a chapter devoted to the CQI program, or it may be a separate CQI manual focusing entirely on that subject. The manual must describe how the pharmacy staff will cooperate as a team in CQI activities, and how the prescription department manager or the consultant of record will accept responsibility for conducting a meeting of the team at least once each three months. Meetings may be more frequent than that if there is a need for more frequent meetings. The manual must describe how it is that QREs will be recorded, and what process will be undertaken to review documented QREs to decide how patient care can be improved. Section (3)(b) specifies that any consequences for a patient of a QRE must be appropriately managed. If, for example, a patient ingests an incorrectly dispensed medication, this section would require that a pharmacist determine the potential consequences for the patient from the ingestion and notify the prescriber of the need to treat the patient to avoid any foreseeable adverse effects. Section (3)(c) states that the matters to be considered in reviewing past QREs include, but are not limited to, staffing levels, workflow, and technological support. There certainly may be many other factors that could contribute to a QRE, depending on the circumstances of a particular pharmacy on a particular day. Those factors should be considered in addition to the three factors listed by the Board in its rule. The prescription department manager or the consultant of record will decide which factors need to be included in a discussion of the causes of QREs.

The fourth paragraph operationalizes the information that is contained within the P&P manual. The Florida Board (and many other Boards) have imposed a QRE documentation requirement. The documentation of QREs may be either in a written record or in a computer database. No mention is made of whether the computer database must be on-site, so it may be off-site as long as the information is readily retrievable at the pharmacy. A QRE must be documented by the pharmacist to whom it is reported, on the date of its having been reported. The pharmacist who documents a QRE may not be the same person as the pharmacist who was initially involved in the occurrence of the QRE. Documentation of a QRE is a pharmacist-only activity. Technicians and clerks may not document QREs. The level of detail required in the documentation of a QRE must be sufficient to permit the committee to understand the QRE. Committee members will need to be able to figure out what likely caused the QRE and how the QRE represents a system failure that can be corrected by modifications in the system. The documents generated through initial QRE reports need be maintained only until the meeting to consider them. Following that meeting, the documents may be discarded, and probably should be. To the extent that maintaining documents create the impression that individuals will be blamed for error, and that

evidence of the error will be maintained to facilitate blame, getting rid of the documents can go a long way toward establishing a non-threatening culture of quality in a pharmacy.

Compliance with CQI Requirements

All records generated as part of the CQI process must be confidential and protected from discovery by an opposing party in either an administrative or civil action. Once a meeting has been held to consider the effects on quality of factors such as staffing levels, workflow and technological support, the pharmacy must create a summarization document that contains an analysis of remedial measures undertaken following documented QREs. The rule (in Florida and other States) specifies that no patient or employee name shall appear in this summarization document. The purpose of the document is **NOT** to learn who is at fault and whom to blame. The focus is entirely away from people and their errors. **The summarization document focuses on the system and on what is being done to improve the system to prevent QREs in the future.** Some knowledge of the past is necessary to improve in the future. But past QREs are used as information to guide a choice of what to do to improve, not as evidence of whom to punish. Contents of the summarization document may vary considerably from one pharmacy to another. But each pharmacy should use this document to provide strong evidence that an effective CQI program is in place and that it is being used consistently to prevent harm to patients. The summarization document, including the recommendations for future improvements, must be maintained in the pharmacy for two years.

Compliance with a pharmacy CQI rule is not onerous. Any pharmacist who has 20 hours to review the literature and study her or his practice site can develop a plan that works well for any site. The goal of the Florida model was to enable success by individual pharmacy permittees, not to prescribe the specific keys to success for every permittee.

All pharmacy CQI programs should be different, because all pharmacy practices differ to some degree. There is no single “right way” to practice pharmacy, so there is no single “right way” to conduct a pharmacy CQI program. Every pharmacy's P&P manual should be unique; every CQI program should function differently; and every CQI meeting should be conducted in a new and different way so it can lead it to a higher level of success than the meeting before it. Given the basic premise that there is no “generic” program of pharmacy CQI, the recommendations in this lesson are intended to illustrate one possible way to comply with a pharmacy CQI rule. Even within this general template there is room for considerable individual variation based on the unique characteristics of each pharmacy practice site.

Step 1: Select a Quality Team Leader

Every pharmacy should have one person who steps forward and proudly claims to be the single person who is ultimately responsible for the quality of pharmacy practice at that pharmacy. The buck stops with that person. On a day-to-day basis, everyone is responsible for what is done on that day, but the overall responsibility for system design and operation must reside with a single person. Pharmacists, pharmacy technicians, and clerical support staff all must do the best job they can under the circumstances. However, in a pharmacy that has no central person who organizes quality activities, the good efforts of many suffer due to the less-than-good efforts of a few. The quality team leader is responsible for assuring that the system is as good as it can be and that the system is adhered to by pharmacy personnel.

The most logical choice for quality team leader is the prescription department manager or the consultant of record. This is the person who ultimately will be responsible to the Board of Pharmacy for compliance by the pharmacy with the CQI rule requirements. Yet, just as the

prescription department manager or the consultant of record may delegate the responsibility to perform other necessary activities within the pharmacy, so may that person delegate the responsibility to oversee the CQI program. There may be a person in the pharmacy who is far better qualified in CQI than the prescription department manager or the consultant of record. It may be that a hospital chain or a community pharmacy chain has a specialist in pharmacy CQI who is the logical choice to take responsibility for meeting the CQI rule requirements, or for exceeding those requirements. Or, perhaps, an outside consultant best fits this role for a single hospital or pharmacy.

The quality team leader should either have training in CQI or be prepared to undertake self-training in CQI. This is not a burdensome project. There are many excellent live and correspondence continuing education programs that can bring even the novice at CQI up to speed quickly. The role of the quality team leader is not to have all the right answers, but to ask all the right questions. Sometimes the most important question to ask is "Why are we doing it this way?" This is not a technically complex question, but it can result in a series of complex answers that help identify problems and solutions. Learning how to ask good questions and to lead a discussion of the responses to these questions is really only a matter of taking the time to read two or three critical books that describe the basic processes of error detection and prevention.

The level of participation by management in CQI programs is an open question that should be resolved by each individual pharmacy. In pharmacies that have already established a culture of trust and respect, personnel will have no problems with active management participation in CQI. In other pharmacies, where the blame and shame tradition must be overcome, it might be wise to have minimal management participation at first, with the goal of growth toward full integration of all personnel, including management, into the CQI activities. The responsibility for conduct of CQI is a management responsibility, but the Florida CQI model rule does not require that management do CQI for pharmacy personnel. In fact, the spirit of the rule contradicts CQI being done for pharmacy personnel by management and supports this activity as a shared exercise, done by management with pharmacy personnel. (This is also the procedure in many other States).

Step 2: Define "Quality-Related Event"

The Florida CQI model rule describes what "Quality-Related Event" must include, but it also specifies that a pharmacy need not limit itself to that definition of QRE. Each pharmacy should decide what definition makes sense based on its own individual needs. For example, a busy pharmacy may receive a telephoned prescription for a patient and then "lose" that prescription. Perhaps this is not the type of problem that is traditionally viewed as an error, but the consequences of this problem adversely affect the quality of drug therapy nonetheless. The patient who requests this prescribed medication will not be able to receive it and use it if the prescriber cannot be located to provide information about the prescription that was previously telephoned to the pharmacy but cannot be found. One pharmacy may prefer to classify this event as a QRE, while another pharmacy would prefer not to. Neither pharmacy would be right or wrong. It is simply a matter of individual preference.

Examples of other "optional" QREs would be the failure to counsel the patient when appropriate, the misspelling of the patient's name, the unauthorized disclosure of confidential information or the refusal to dispense a seemingly suspicious prescription that turned out to be unquestionably valid. This is not a complete list, but it is illustrative of the types of problems that a pharmacy might wish to identify and solve. Each of these problems has the potential to adversely affect

the quality of drug therapy. Each of them can lead to embarrassment and time-consuming discussions. The best approach is to avoid such problems. The way to do that is to incorporate them into the CQI process.

Step 3: Describe the Practice Process

Every pharmacy uses a process to dispense medications and provide professional services. Some processes are better defined and better organized than others, but every pharmacy has an identifiable process. It is impossible to improve a pharmacy practice process without knowing what one's practice process is. Defining a practice process makes it possible to standardize some of the more critical elements of pharmacy practice so that all personnel are on the same page as to what is being done. New and temporary pharmacists and pharmacy technicians can understand what is done and how by examining a written description (preferably a diagram or flow chart) of the way pharmacy is practiced at a specific location.

Most pharmacies have "stations" or physical places where professional activities are done. These stations often correspond with a link in the chain of pharmacy practice. At each station, there are many tasks performed by a pharmacist or technician prior to the order being transferred to the next station. Each of these tasks presents an opportunity to succeed or fail. In evaluating a pharmacy practice system, it is absolutely necessary to know each task performed at each station, and to identify which task was performed at a suboptimal level, to know why the system did not function as it should. The worst thing that could happen would be the development of a CQI program that identified non-problems and introduced non-solutions into the practice system.

The exercise of describing the practice process is going to be done in as many different ways as there are pharmacies. Pharmacy personnel who sit down to begin drawing a picture of what they do and when, may be surprised to discover that not everyone agrees on who does what and where. This is a helpful exercise, because it can lead to the identification of problems that may have been unnoticed for a long period of time. In many pharmacies, the stations are identified as follows:

- Receiving the Prescription.
- Data Entry.
- Prospective Drug Use Review.
- Prescription Assembly.
- Final Check.
- Patient Counseling.
- Medication Delivery.

Within each of these stations (and the many others that pharmacies will identify within their practice process), there are specific tasks to perform. The activity of describing the practice process is not complete until consensus is achieved regarding the stations and tasks that comprise the practice of pharmacy at a practice site.

Step 4: Develop a QRE Recording System

It is impossible to know whether things are going well or poorly within a system unless the results of activities within the system are recorded consistently. Pharmacists pride themselves on the high rate of their success. One of the problems pharmacists have had is that they have been too

reluctant to "beat their own drum" and show off the high quality of what they do. Pharmacists save lives as a matter of routine, when they correct inaccurately prescribed drug doses, and when they inform a patient's physician of the potentially interacting drug therapy being already prescribed by another physician. These are but two examples of the many, many successes in pharmacy practice that go unrecorded. As part of a CQI program, it might be a good thing to record the patient morbidity averted by alert pharmacists who consult with physicians before filling harmful prescriptions.

The primary measure of success in a pharmacy that complies with a CQI rule is technical accuracy in order processing and the identification and management of potential problems with drug therapy. Boards of Pharmacy expect a very high level of success from pharmacies. The public expects a high level of success also. In fact, the public expects 100% success all of the time. When a rare error occurs in pharmacy, there is no point in referencing the many prescriptions that were filled correctly on that day. Nobody who receives an erroneous prescription from a pharmacist cares that everyone else received the correct medication, or that others had potentially catastrophic prescribing errors corrected by the pharmacist. Any error by a pharmacist is a Quality-Related Event, and all QREs must be documented so they can be prevented from happening again.

The data generated through documentation should be maintained in the pharmacy, available to the quality team leader, for use in CQI committee meetings. Either a written record or a computer database may be used for this purpose. Development of a spreadsheet, using one of any number of available off-the-shelf programs is strongly advised. Electronic spreadsheets facilitate the presentation of information to observers in an organized fashion. Under the Florida Board of Pharmacy model (and used in many States), these data need not be retained after they have been used for CQI purposes and a summarization document has been created.

Step 5: Train Pharmacy Staff in CQI

Pharmacy CQI is not "just common sense." It is a methodic approach to addressing and resolving potential problems. Many American industries have succeeded with CQI or have failed without it. Some staff may resist the implementation of a CQI program saying something like "We're too busy misfilling prescriptions to take the time needed to get it right." These initial resisters will often become the most enthusiastic advocates of the program once they understand it. But understanding may come only with concerted effort.

The Quality Team Leader will have to set aside some time to explain the basics of CQI, the specific process that has been selected for the pharmacy, and the steps necessary for compliance with the process. Homework is a necessary component of this educational exercise. Pharmacy personnel must be asked to "read up" on the program prior to their attendance at an initial educational session. Alternatively, there are Internet websites that include very valuable information about pharmacy CQI, and these may be useful to pharmacy personnel who handle a computer with ease.

To assure success of training, an assessment should be administered to personnel to evaluate the level of understanding of the program. Deficiencies in understanding can be addressed by additional one-on-one advice or counseling.

CQI training never ends. Some of the best CQI training is done on-the-job by the Quality Team Leader who stops by to give a hand and shows just how to do a particularly problematic task. Many pharmacists and technicians learn by doing, and they will particularly value being shown

how a task is done in a way that is sensitive to quality improvement factors.

Step 6: Conduct Continuous Quality Improvement Meetings as Needed

CQI meetings need not be long, but they must be conducted at least once every three months. This meeting is the most important, and the most difficult of all the challenges to be faced by the Quality Team Leader. It should be done with great care and concern. The following sample meeting agenda may be helpful in the conduct of a CQI meeting, although there are many good ways for such a meeting to be run.

Setting the Tone

The very first thing the Quality Team Leader should do is to take control of the situation and establish the serious nature of it. This is not the time for jokes or sarcasm. People who feel that quality is a joke should be invited to explain this feeling to management. These are salient features of the meeting:

- This is a professional meeting to improve outcomes for patients.
- The focus of this meeting is on the future, and not on the past.
- Everything said at this meeting is to be held in the strictest confidence; there should be no fear of management reprisal as the result of any comments.
- My job is to help you and not punish you. I don't have all of the answers, but I can probably ask some pretty good questions.

Reviewing Facts about Events

Until it is established precisely what happened regarding an error, it is impossible to diagnose what systematic problem may have led to the error. The Quality Team Leader should ask:

- Was the prescription telephoned to the pharmacy, or was it transmitted in writing (paper, fax, or computer)?
- Was the prescription a new prescription or a refill?
- Was the prescription prepared for a person who chose to wait for it, or was it prepared for the "will call" or delivery area?
- Was the prescription prepared for the patient or for the caregiver of the patient?

Reviewing Facts about Environment

The event itself may not be the most relevant factor in determining the cause of an error. It may be that environmental factors significantly contributed to a failure of quality, and only by asking the right questions about the environment will the background problems be identified. The following questions are relevant:

- How many prescriptions were filled on the day the incident occurred?
- How many pharmacists/techs/clerks were working on that day?
- Is it documented that DUR was being done consistently on that day?
- Is it documented that patient counseling was being done consistently on that day?
- Was there anything "special" or unusual about that day?

Staffing Issues

General impressions of the staffing at a pharmacy can lead to conclusions about personnel issues and their possible contribution to error. Important questions to ask include:

- Are the supportive staff hours scheduled properly to efficiently handle peaks in prescription volume?
- Do the pharmacists' schedules provide for sufficient overlap on peak volume days?
- Are all personnel properly trained, especially with regard to pharmacy safety program guidelines?

Workflow Issues

A pharmacy may be able to trace its problems not to workload but to workflow. Pharmacy safety programs are designed to promote a smooth workflow, with defined responsibilities and cooperation between pharmacists, pharmacy technicians and clerical support staff. In evaluating the workflow, ask the following questions:

- Is the primary pharmacy work area or counter organized for accuracy; is it neat and clean?
- Is the pharmacy following a standard workflow, organized into the designated stations?
- Are waiting and will call prescriptions appropriately separated?
- Are stock bottles shelved neatly, with look-alike and sound-alike drugs placed in separate places on the shelves to avoid confusion?

Communication Issues

Most failures of quality in pharmacy are attributable at least in part to problems with communication. In evaluating the cause of errors, pay particular attention to those factors that threaten accuracy in communication. Consider asking these questions:

- Are key data entry and prescription assembly personnel physically separated from people who might interrupt them with distracting questions?
- Are pharmacists evaluating DUR computer edits when a technician detects a significant potential problem?
- Is the telephone equipment of sufficient quality to enable personnel to hear well the voice of those who call the pharmacy?
- Is the IVR (interactive voice response) equipment of sufficient quality to enable personnel to hear well the messages left for the pharmacist?
- Are procedures being followed to assure that all medicines going into a bag or other container intended for that patient?
- Are personnel repeating the name of the patient and the name of the physician to the person who picks up prescriptions at the will-call area?

Toward Solutions

Identifying threats to quality based on a record of past errors is half the battle in a pharmacy safety program. Discerning those changes that can be made to reduce the incidence of problems is the follow-through piece that brings it all together. To look forward toward a future pharmacy practice that has eliminated as many problems of the past as is possible, the following questions are useful:

- How will we know that our problems with quality have been solved?
- What are the possible solutions to our problems with quality?
- Of the suggested possible solutions to our problems, which solution is the best and why?
- How will we implement our chosen solution?

- Whose responsibility is it to determine whether our chosen solution has been successful?

Step 7: Implement Changes and Evaluate Results

Sometimes a CQI meeting will conclude that no changes need to be made. This would be an unusual conclusion. In a busy pharmacy, there is always room for improvement. A pharmacy that has had no documented QREs in three months' time is not taking the program seriously. As counterintuitive as it may initially seem, the healthy pharmacy is the pharmacy that has a lot of documented QREs. Each QRE report is an opportunity to learn. The pharmacy that does not document QREs has lost the opportunity to learn and has seriously impaired the ability to improve the quality of pharmacy practice.

A likely conclusion of a CQI meeting is that system changes are unnecessary, and that existing policies are adequate, but that personnel need to recommit to existing policies. There is always a tendency to backslide on even the most sensible and valuable policies. For example, pharmacists and technicians may find it challenging to organize their practices into stations, or to repeat the orders verbally given by physicians, or to call out to patients the names of their physicians when they pick up medication. The value of these measures, having been established through consensus of the group, may need to be repeated on a regular basis.

Sometimes a CQI committee will conclude that fundamental changes in the system must be made. These changes may reflect a specific QRE or cluster of similar QREs. Alternatively, the changes may be the result of concerns that a weak link in the practice process has been identified and must be strengthened. While well-intentioned people working together to improve the quality of pharmacy practice usually develop productive suggestions for change, this is not always the case. Some changes may be non-productive, and some may actually be counter-productive. **To determine whether a change has been effective, without having unintended adverse consequences, the Quality Team Leader will have to conduct periodic audits.**

The purpose of audits is to create a longitudinal record of success or failure over time. Auditing the accuracy of prescriptions in the will-call area is one way to do this. Conducting a partner audit at the end of each shift is another way. In partner audit, a technician or pharmacist reviews the front and back of each new prescription to make sure that the computer information matches what has been prescribed.

Pharmacist final check audits are another way to discern whether changes are effective. Simply recording the discrepancies when a pharmacist checks an order can lead to a significant conclusion about the effectiveness of a newly implemented program.

PATIENT SAFETY

The Value of CQI

Once established, a CQI program will begin producing good results for pharmacies and patients. Effective CQI reduces pharmacy errors and it promotes beneficial therapeutic outcomes for patients. Because it is often a mandatory component of any pharmacy business, CQI is an element of the inspections made of pharmacies by professionals whose job is to assure that the public is being adequately protected. Trial lawyers will also be interested in knowing whether a CQI program existed and was being meaningfully operated, following a tragic dispensing error that has led to patient harm. The point of these oversight activities by both Board of Pharmacy and the trial lawyers is to try to determine whether a pharmacy where an error occurred was doing its best to prevent errors, or whether the pharmacy was making no real effort to prevent errors. A pharmacy that has tried hard to prevent errors but has experienced

an unfortunate and inevitable failure of quality, will be relatively forgiven for the regrettable, but unpreventable, consequences. Another pharmacy that has not tried to prevent errors will be less likely to be forgiven for its similar errors that will be viewed as preventable. It is the effort that counts, not the result.

Pharmacy is a pervasively regulated profession, because patients place their lives in the hands of pharmacists and pharmacy owners. Pharmacy regulation is an important component of the profession, because without it there could be a “race to the bottom” led by unscrupulous people whose goal is to generate huge profits without providing sufficient value for what is being paid. Patients would have no choice but to accept such an erosion in practice standards, because they can only go to pharmacies to receive pharmaceutical products and services. In exchange for the monopoly over pharmacy practice that is granted to pharmacists by the public, pharmacists agree to be inspected on a regular basis to assure that practice standards are being met. Most pharmacists and pharmacy owners recognize the important role of inspection and regulation, because the oversight provided by inspectors and regulators assures an even playing field among competitors.

A pharmacy’s best evidence of compliance with a pharmacy CQI rule will be a policy and procedures manual that shows an individualized CQI program for that pharmacy. A generic book that is the same or similar to the book being used by hundreds or thousands of other pharmacies, really is not a policy and procedures manual. It may be a very valuable resource on how to construct a CQI program, and it may contain useful information for inclusion within a policy and procedures manual, but unless the book incorporates the unique characteristics of the individual pharmacy, it is not a policy and procedures manual.

Showing compliance will also require evidence that the established CQI program is actually in operation. The best evidence to show serious operation of a program is the Summarization of Quality-Related Events document mandated by most Boards of Pharmacy. A standard form should be created, based on each individual pharmacy’s unique needs, to analyze remedial measures undertaken following QREs. These forms must be retained for at least two years at the pharmacy. Along with an individualized and carefully crafted policy and procedures manual, complete and seriously executed summarization documents provide convincing evidence that the pharmacy is not making a game of CQI but instead is trying hard to reflect on the past and improve in the future. Evaluators cannot reasonably ask that pharmacies prevent all errors, but they can reasonably ask that pharmacies try their hardest to prevent errors.

Individual Participation in Quality Improvement

Dr. Tony Grasha, who studied pharmacy error extensively, was fond of saying “you can put a good pharmacist into a bad pharmacy system, and the system will win every time.” His point was to emphasize the role of systems in error creation and in error prevention, as well as the futility of aspirations for success by pharmacists who are encumbered by formidable system barriers. Yet he did not mean that pharmacists are powerless victims of systems that create impossible expectations. In fact, he stressed that the pharmacist is a critical component of the pharmacy system, and that each individual pharmacist must play a productive role within the system. A system cannot function effectively to recognize and prevent errors unless the pharmacists in the system are doing their part to promote error recognition and prevention.

To fully participate in the quality improvement activities of a pharmacy practice site, it may be appropriate for pharmacists arriving on duty to conduct a brief check of systems, similar to what is done by flight crews in commercial aviation. The questions to ask will vary from pharmacist

to pharmacist and from practice site to practice site. Here are some examples of the types of checks that could be productive for a pharmacist whose goal is to maximize quality during a pharmacy practice shift.

Personal Checks

- Am I feeling physically and mentally well today?
- Do I possess sufficient knowledge of the drug therapies used at this practice site?
- Do I have the skills necessary to perform the tasks required at this practice site?
- Am I able to free myself of personal distractions today?
- Do I have available the reference materials I need?

System Checks

- Are the policies and procedures for this practice site clearly established?
- Does this practice site have the necessary equipment for pharmacy practice?
- Are the drugs and supplies at this practice site sufficient to meet patient needs?
- Is the physical layout of the practice site uncluttered and organized in a logical flow?
- Is the practice site free of unnecessary distractions?

Communication Checks

- Is there adequate technology to communicate effectively with prescribers and patients?
- Will the counseling area allow for complete and private patient education?
- Are there adequate written materials to use in patient education?
- Am I able to contact trusted colleagues if I need assistance or advice?

Personnel Checks

- Do I have sufficient supportive personnel to assist me?
- Are the pharmacy technicians well-trained and experienced?
- Do the support personnel have a sense of responsibility for their actions?
- Can support personnel appreciate the limits of their role?
- Is there a professional environment that stresses the importance of teamwork?
- Will support personnel ask questions without worrying about looking “stupid”?

Management Checks

- Has management created a culture of quality at this practice site?
- Is there a clear understanding of who is in charge of the pharmacy?
- Do I know to whom I answer in the chain of command today?
- Is management available to me if I have questions or comments today?
- Do I feel that I have the necessary support of management to succeed today?

This is not intended as an exhaustive, or even exemplary, list of what any individual pharmacist should or may include in a checklist. The idea is that no pharmacist should practice at a time when the pharmacist is not fully up to the challenge of patient care, and no pharmacy practice site should fail to provide the pharmacist with the support necessary to prevent errors. Whether to use a checklist, what questions to ask in the checklist, how to evaluate the answers to the questions in the checklist, and when to decide that the day, time, place, and person do not check out as adequate for success in the pharmacy, are issues to be addressed individually by each pharmacist. Just as the captain of a commercial airliner may determine that a scheduled flight cannot safely operate, much to the inconvenience and even anger of passengers, a pharmacist may decide that a pharmacy practice site cannot function safely until specifically identified deficiencies have been corrected.

CONCLUSION

Patient safety is a shared responsibility. Those who build, equip, and manage pharmacy practice sites, those who work within them, those who regulate them, and those who educate pharmacists and other pharmacy staff, all must rise to the occasion and do their best to reduce the occurrence of errors. This can be done within the framework of continuous quality improvement. While pharmacy practice cannot be free of error, because humans are imperfect, pharmacy can constantly enhance its performance by learning from the past and improving in the future.

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QUIZ & EVALUATION

APRIL & May 2018 COMBINED LESSON---“MEDICATION ERRORS PREVENTION”

Fill in the information below, answer questions and return with all information for certification of participation to:
CE-PRN

PharmCon, Inc.
341 Wellness Drive
Myrtle Beach, SC 29579.

You may send quiz back:

1. By conventional mail,
2. Fax back to 1-843-488-5554,
3. Or, send answers via a conventional email to info@ce-prn.com

EMAIL Address (WE NEED THIS; PLEASE PRINT CLEARLY) _____

NAME _____

ADDRESS _____ CITY _____ STATE _____ ZIP _____

WE MUST HAVE THE FOLLOWING INFORMATION.

I am a Pharmacist **I am a Technician** **CHECK IF NEW ADDRESS**

ARE YOU LICENSED IN FLORIDA? IF YES, FL LIC # _____

CPE Monitor ID (NABP eProfile) _____ **Birthdate (MM/DD)** _____

LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Discuss techniques to prevent pharmacy medication errors	YES NO
Describe root cause analysis to determine where errors arise	YES NO
List ways to reduce & prevent errors	YES NO
Discuss impact of a “non-blaming” scenario on patient safety	YES NO
Describe culture of punishment as response to medication errors	YES NO
Discuss lessons from recent medication errors cases	YES NO
List requirements of a CQI program	YES NO
Explain steps to comply with a Board of Pharmacy CQI program	YES NO
2. Was the program independent & non-commercial? YES NO

3. Relevance of topic

Low Relevance	Very Relevant
1 2 3 4 5 6 7	

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

6. How would you improve or change this program? _____

PLEASE MARK CORRECT ANSWER(S) BELOW

APRIL & MAY 2018 COMBINED LESSON—“MEDICATION ERRORS PREVENTION”

1. In what manner must pharmacist errors be addressed in order to facilitate & increase patient safety?
 - A. Casual
 - B. Radical
 - C. Systematical
 - D. Disciplinary
2. A pharmacist has made a prescription error by dispensing the weaker strength of a medication. Before the patient picks up her order, the pharmacist’s partner discovers & corrects the error. What should be done?
 - A. The 2nd pharmacist should correct the error, and forget about it.
 - B. The event should be brought to attention of the 1st pharmacist.
 - C. The event should be discussed with the patient.
 - D. The event should be discussed during the next CQI meeting.
 - E. B & D

3. **Pharmacist responsibility includes:**
 - A. Accurate processing of prescriptions.
 - B. Responding to potential prescription drug – drug interactions.
 - C. Providing input regarding common drug side effects.
 - D. All of these.
4. **In the world of “punishment,” a pharmacist might have liability for:**
 - A. Professional malpractice
 - B. Criminal liability
 - C. Discipline from board of pharmacy
 - D. All of these
5. **What was the “bottom line” result of the *Harco v. Holloway* Case?**
 - A. Defined the concept of “duty to warn.”
 - B. Established new guidelines for physician responsibilities.
 - C. Recognized pharmacies' responsibilities to incorporate error control programs & systems.
 - D. Created awareness of patient's responsibility for their own care (the “self-caregiver concept”).
6. **Dr. James Reason & other experts have concluded that in health care, human error is “normal.” What do the experts mean by “normal” error?**
 - A. Errors must be planned for.
 - B. Errors are welcome.
 - C. Errors are no big deal.
 - D. Errors have no real consequences.
7. **What had traditional thinking been regarding the appropriate reaction to an error by a pharmacist?**
 - A. Ignore the error & proceed.
 - B. Punish the erring pharmacist.
 - C. Forgive the error immediately.
 - D. Humiliate the pharmacist.
8. **What does it mean for a pharmacist to be held “accountable?”**
 - A. The pharmacist must respond to a potential problem with drug therapy.
 - B. The pharmacist must provide an accounting by way of explanation, when an adverse event occurs.
 - C. The pharmacist will be punished regardless of who is at fault.
 - D. The pharmacist has been held liable for malpractice.
9. **Which of the following is a disadvantage of punishment as an approach to addressing error?**
 - A. It really does not work as a deterrent of non-volitional error.
 - B. It deters risky but beneficial & necessary behaviors.
 - C. It leads to coverups.
 - D. All of these.
10. **What is the purpose of reviewing case studies of past errors by pharmacists?**
 - A. To cast aspersions on the pharmacists who made the errors.
 - B. To assure that the erring pharmacists are never again hired in another pharmacy.
 - C. To promote a better understanding of how pharmacy errors occur & can be prevented.
 - D. To identify pharmacies where no patient should ever have a prescription filled.
11. **Based on the *Bookman v. Ciolino* Case (*Restoril & Prozac* confused for each other), what conclusion can be reached about a potential cause of pharmacy errors?**
 - A. Pharmacy practice sites should be designed to avoid unnecessary distractions.
 - B. Pharmacists should be required to complete 100 contact hours of continuing education annually.
 - C. Generic substitution should be abolished.
 - D. Extemporaneous compounding should be restricted.
12. **Self-checking of a prescription that a pharmacist has filled by himself or by herself is less effective than having another person check the prescription.**
 - A. True.
 - B. False.
13. **A pharmacist receives a prescription that has been issued with confusing directions for uses that are not clear to the pharmacist. After talking with the patient, the pharmacist still is not sure how the prescribed medication is to be used. This is a potential prescribing error. What should the pharmacist do at this point?**
 - A. Contact the prescriber to clarify the order, and not fill the prescription until the order is clarified.
 - B. Tell the patient that the prescriber has committed malpractice and that the prescription cannot be filled.
 - C. Fill the prescription based on the most likely interpretation and instruct the patient to contact the prescriber for further instructions.
 - D. Fill the prescription based on the most likely interpretation and record the potential error for discussion at a later time.

- 14. Approximately how many states have now implemented some sort of requirement for a continuous quality improvement program that monitors system failures and promotes system improvements?**
- A. Florida is the only such state.
 - B. Florida and California are the only two states to do this.
 - C. About ten states.
 - D. About two-thirds of the states.
- 15. According to the CQI rule in many States, how is a Continuous Quality Improvement Program described?**
- A. As an unfunded mandate.
 - B. As a bureaucratic burden.
 - C. As a system of standards and procedures.
 - D. As a guaranteed means to eliminate all pharmacy errors.
- 16. What is a Quality Team Leader?**
- A. Person who is responsible for morale & goodwill in the pharmacy.
 - B. Person who is responsible for ordering controlled substances.
 - C. Person who provides patient counseling.
 - D. Person who is responsible for the quality of pharmacy care & practice.
- 17. The Quality Team Leader's primary job is to:**
- A. Report CQEs to the board of pharmacy.
 - B. Have all the correct answers.
 - C. Punish pharmacy staff who makes errors.
 - D. Ask the correct questions.
- 18. The "Practice Process" document:**
- A. Describes how pharmacy is practiced in your location.
 - B. Specifically describes how controlled substances are maintained in your pharmacy.
 - C. Provides language regarding punitive approaches to errors made in your pharmacy.
 - D. All of these.
- 19. What is true regarding CQI?**
- A. It's all common sense.
 - B. Training is responsibility of Quality Team Leader.
 - C. Success of CQI is directly proportional to training.
 - D. Assessments of personnel are necessary.
 - E. B, C & D
- 20. Which of the following are workflow issues?**
- A. Is work area neat & clean?
 - B. Is "will call" area separated from other prescription waiting places?
 - C. Is the inventory organized?
 - D. Are "sound alike" medications separated in the pharmacy?
 - E. All of these.
- 21. Under the Florida CQI law (and in many other States), how frequently must the CQI Committee review QREs at each pharmacy?**
- A. At least once a week.
 - B. At least once a month.
 - C. At least once every 3 months.
 - D. At least once every 6 months.
- 22. Which of the following is considered to be a "Quality-Related Event?"**
- A. Dispensing a trade-name product when a generic has been requested.
 - B. Shorting a patient's prescription by dispensing 55 dosage units when 60 were prescribed and billed.
 - C. Incorrect packaging.
 - D. Inadvertently deleting a patient's electronically transmitted prescription from the computer.
- 23. Where shall a Quality-Related Event be documented?**
- A. In either a written record or a computer database.
 - B. In a written record, but not in a computer database.
 - C. In a computer database, but not in a written record.
 - D. In neither a written record nor a computer database.
- 24. Records maintained as a component of a pharmacy CQI program should be considered confidential.**
- A. True.
 - B. False.
- 25. A Summarization of Quality-Related Events should be maintained for what period of time?**
- A. One year.
 - B. Two years.
 - C. Three years.
 - D. Five years.

- 26. What is considered a good first step in the development of a CQI program?**
- A. Request that all personnel suggest solutions to problems they have identified.
 - B. Select a quality team leader.
 - C. Ask all personnel to list the negative qualities of other pharmacy personnel.
 - D. Send a report to the board of pharmacy listing all errors from the previous year.
- 27. One step that should be taken to comply with CQI rules is to describe the practice process at a pharmacy. What is a good way for this to be done?**
- A. List the stations at which actions are taken by a technician or pharmacist.
 - B. Draft a policy stating that practice will be conducted at a high level of quality.
 - C. Draft a policy stating that practice will be conducted at the very highest level of quality.
 - D. Post a sign that states "Quality First" in the pharmacy.
- 28. Pharmacy CQI is "just common sense."**
- A. True.
 - B. False.
- 29. What should be the stated purpose of the CQI team meeting?**
- A. To blame prescribers for their errors.
 - B. To blame pharmacists for their errors.
 - C. To blame pharmacy technicians for their errors.
 - D. To improve patient care.
- 30. What checks might a pharmacist want to conduct if the pharmacist's goal is to maximize quality during a pharmacy practice shift?**
- A. Personal Checks.
 - B. Process Checks.
 - C. Communication Checks
 - D. All of the above.