



A PHARMACY CONTINUING EDUCATION PROGRAM

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August 2010 Part 2 "2010: Medication Error Prevention" 707-000-10-008-H05-P



*This Month:
Part 2 "Medication
Errors Prevention
Update 2010"*

Licensed in FL or NY? This lesson, along with next month's, fulfills the mandatory "Medication Errors" requirement.

FL Pharmacists. The combination of this lesson & next month's must be turned in for you to receive credit for CE Broker.

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This is Part 2 of the biannual lesson on "Medication Errors." It's been divided into two portions. In this lesson we describe Compliance with CQI Requirements; Value of CQI; and, Committing to CQI & Avoiding Criminal Liability. This lesson provides 1.5 hours (0.15 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-10-008-H05-P. Pharmacists completing this lesson by Aug 31, 2013 may receive full credit.**

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

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

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

1. Describe how boards of pharmacy have undertaken rulemaking that requires quality improvement programs to reduce the incidence of medication errors.
2. List the elements of a successful pharmacy CQI program.
3. Describe the implementation of a pharmacy CQI program.

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IN THIS LESSON

We concluded Part 1 of the Medication Errors Series with a consideration of "State Board of Pharmacy Continuing Quality Improvement (CQI) Programs".

Now we continue with the discussion by first "Interpreting the Boards of Pharmacy CQI Rule." Additional concerns include:

1. Compliance with CQI Requirements
2. Value of CQI
3. Committing to CQI & Avoiding Criminal Liability

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 occurs when one does something incorrectly, while an error of omission 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. 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

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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 Board has 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 has occurred. Following that meeting, the documents may be discarded, and probably should be. To the extent that maintaining documents creates 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 are confidential and are 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 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 the Florida 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 Board of Pharmacy is to enable success by individual pharmacy permittees, not to prescribe the specific keys to succeed 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 to a higher level of success than the meeting before. Given the basic premise that there is no “generic” program of pharmacy CQI, the recommendations are intended to illustrate one possible way to comply with the Florida 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 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 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.

Step 2: Define “Quality-Related Event”

The Florida pharmacy CQI 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. 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 iden-

tification 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 in 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 the Florida CQI rule is technical accuracy in order processing and the identification and management of potential problems with drug therapy. The Florida Board of Pharmacy expects 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 rule, 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 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 the 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 prescription?
- 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:

1. Are the supportive staff hours scheduled properly to efficiently handle peaks in prescription volume?
2. Do the pharmacists' schedules provide for sufficient overlap on peak volume days?
3. 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:

1. Is the primary pharmacy work area or counter organized for accuracy; is it neat and clean?
2. Is the pharmacy following a standard workflow, organized into the designated stations?
3. Are waiting and will call prescriptions appropriately separated?
4. 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:

1. Are key data entry and prescription assembly personnel physically separated from people who might interrupt them

with distracting questions?

2. Are pharmacists evaluating DUR computer edits when a technician detects a significant potential problem?
3. Is the telephone equipment of sufficient quality to enable personnel to hear well the voice of those who call the pharmacy?
4. Is the voice mail equipment of sufficient quality to enable personnel to hear well the messages left for the pharmacist?
5. Are procedures being followed to assure that all medicines going into a bag are intended for that patient?
6. 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:

1. How will we know that our problems with quality have been solved?
2. What are the possible solutions to our problems with quality?
3. Of the suggested possible solutions to our problems, which solution is the best and why?
4. How will we implement our chosen solution?
5. 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 them 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.

THE VALUE OF CQI

Once established, a CQI program will begin producing good results. Effective CQI reduces pharmacy errors and it promotes beneficial therapeutic outcomes for patients. Because it is a mandatory component of any pharmacy business in Florida, CQI is an element of the inspections made of Florida pharmacies by professionals whose job it 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 the 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 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 the Board 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.

COMMITTING TO CQI AND AVOIDING CRIMINAL LIABILITY (CONCLUSION)

The justification for holding a pharmacist criminally liable for an error is that the pharmacist was so reckless that no person could fail to realize that such recklessness would inevitably lead to patient harm. This is the sort of "intent" that the Ohio pharmacist was charged with. The criminal justice authorities were unable to see that the error was unintentional because they could not see serious efforts that were being taken to prevent it. Unintentional error does not expose one to criminal prosecution. A CQI program can demonstrate that any errors that occur in a pharmacy were unintentional and that criminal liability is inapplicable.

FUTURE TOPICS

HIV/AIDS Update

Role of Pharmacist in Pharmacogenetics

Pharmacy's role in Natural Disasters

Barriers to Medication Compliance

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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?

Describe how boards of pharmacy view CQI	Yes	No
List elements of a successful pharmacy CQI program	Yes	No
Describe implementation of a pharmacy CQI program	Yes	No

2. Was the program independent & non-commercial Yes No

	Poor		Average		Excellent		
3. Relevance of topic	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? _____

Please Select the Most Correct Answer

1. Which element is NOT part of any of the state CQI programs?

- A. Intent
- B. Noncompliance
- C. Negligence
- D. All of these

2. Under the Florida CQI rule, a CQI P & P manual may be a chapter within a general P & P manual or a separate CQI manual focusing entirely on that subject.

- A. True
- B. False

3. Members of a CQI committee may include:

- A. Pharmacist
- B. Interns
- C. Technicians
- D. Clerks
- E. Other necessary staff
- F. A & B only

4. CQI committees should meet at least once every:

- A. Year
- B. 2 years
- C. 6 months
- D. 3 months
- E. 18 months

5. A CQI program is:

- A. Systematic
- B. Chaotic
- C. Confusing
- D. Puzzling
- E. B, C, & D

6. What name is given to a situation in which a pharmacist dispenses a medication in variation from the prescriber's order?

- A. Quality-related Event
- B. Mishap
- C. Misadventure
- D. Sentinel Event

7. Under the Florida CQI rule, summarization documents must be maintained for how long?

- A. 1 year
- B. 2 years
- C. 3 years
- D. 5 years

8. QREs may be a result of:

- A. Incorrect drug
- B. Incorrect strength or dosage form
- C. Incorrect patient, packaging, labeling or directions
- D. All of these

9. The Florida CQI rule describes a single "right way" to practice pharmacy.

- A. True
- B. False

10. Under the Florida CQI program, which of the following factors should be discussed as part of a CQI team meeting?

- A. Staffing levels
- B. Workflow
- C. Technological support
- D. All of these

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