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**July 2010 Part 1 "2010: Medication Error Prevention" 707-000-10-007-H05-P**

*This Month:
Part 1 "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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**CE Provider Registered # with CE Broker 50-3170.
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This is our biannual lesson on "Medication Errors." It's been divided into two portions. In this lesson we describe an incident where an Ohio pharmacist was imprisoned as the result of a medication error. Additionally, we discuss CQI policies. In Part 2, we will interpret CQI rules; discuss compliance; comment upon value of CQI; and, finally, describe the significance of committing to CQI. 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 707-000-10-007-H05-P. Pharmacists completing this lesson by July 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. Compare civil & criminal liability for medication errors by pharmacists.
2. Discuss steps to reduce exposure to criminal liability for inadvertent errors.
3. Describe Boards of Pharmacy rulemaking regarding quality improvement programs

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## INTRODUCTION

It is well accepted in pharmacy that those who make errors in practice must accept responsibility for the consequences of their actions. Pharmacists who fill a prescription with the wrong drug, wrong strength, wrong directions, or wrong dosage form understand that their error is a serious matter and that malpractice insurance may be required to compensate the patient for harm, or that they may be required to account to the licensing agency for the error. Pharmacists are humans; humans make mistakes, and it is important to address the consequences of an error that has been made. This is not entirely unlike the child who throws a hard snowball at a friend and who unfortunately breaks a neighbor's window due to poor aim. Although the child certainly did not intend to break the neighbor's window, the error will result in the withholding of allowance until the window has been paid for. There will almost certainly be restrictions on the child's activities for a period of time. It is human to err, but it is equally human to accept the consequences of one's own error.

On the other hand, it is unusual for a pharmacist to be held criminally liable for an inadvertent error in pharmacy practice. Because all pharmacists are human, all pharmacists make inadvertent errors. Likewise, it is unusual for a pharmacist to be held criminally liable for failing to detect the inadvertent error of a pharmacy technician. A pharmacist's final check of a technician's assembly of medication cannot be perfect, because pharmacists may not have all necessary information when a final check is performed, or they may inadvertently overlook an important piece of information. Pharmacists cannot visualize the final product of a technician's work and know from that visualization whether the product is what it is intended to be. Errors are inevitable even if a pharmacist is conscientious and caring. Yet, a recent case from Ohio has the potential to change the traditional view of pharmacy error. In this instance, the pharmacist was held criminally responsible for the harm done to the patient. It is a wakeup call to pharmacists that the legal community may be expecting more than can reasonably be provided by humans who practice within the pharmacy profession.

In this lesson we attempt to accomplish two major things:

1. To describe the now well known incident in which an Ohio pharmacist was imprisoned as the result of having failed to detect an error made inadvertently by a pharmacy technician. Intent is a major premise related to criminal accusations. Pharmacy errors do not incorporate intent.
2. Additionally, we describe how state boards of pharmacy are accepting responsibility to proactively reduce medication errors, not just reactively punish those who make them. To this end, we discuss at length Continuous Quality Improvement (CQI). We especially look at the example of the requirements in Florida in order to visualize how these may be extrapolated to all states. The overall premise is to learn from "Quality Related Events." Tied to the overall concept is **"repair the processes in order to reduce errors"**.

## THE OHIO CASE

There is a requirement under the law that criminal liability be associated with intent to commit a crime. It is not enough to cause harm. The person causing the harm must have intended to cause it for there to be criminal liability. Civil malpractice liability serves to compensate victims of one's negligent conduct. Administrative licensure liability serves to assure that a person providing professional services is adequately qualified to perform the services. Criminal liability serves to punish the perpetrator of intention harm caused to another person. As a caveat to the intent component of a criminal liability, one who is reckless toward another person can be held to have intended harm in the sense that some sort of harm was inevitable and foreseeable, even though the specific harm that occurred was not.

In the Ohio case, the defendant pharmacist pled guilty to criminal charges, despite the fact that the error he made was unintentional. Here is how the Cleveland Plain Dealer reported the results on August 15, 2009:

> *"Two-year-old Emily Jerry was supposed to leave the hospital with her family, cancer-free after her last dose of chemotherapy in February 2006. But her little body was delivered to the morgue instead — killed by a lethal dose of sodium chloride mistakenly mixed in her chemotherapy bag.*
>
> *For that, the pharmacist who approved the solution will spend the next six months behind bars.*
>
> *Eric Cropp of Bay Village was sentenced Friday for involuntary manslaughter in connection with Emily's death. His time in the County Jail will be followed by six months of house arrest and three years of probation. Cuyahoga County Common Pleas Judge Brian Corrigan also ordered Cropp to pay a $5,000 fine and complete 400 hours of community service, during which he must seek out pharmacological organizations and tell them his story, in the hopes it would prevent others from making his deadly mistake.*

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*Cropp was the supervising pharmacist at Rainbow Babies & Children's Hospital on Feb. 26, 2006, when a pharmacy technician prepared a chemotherapy treatment for Emily.*

*The solution was 23 percent salt when the formula called for a saline base of 1 percent. Emily slipped into a coma after receiving the treatment and died on March 1.*

*As supervising pharmacist, Cropp had the duty to inspect and approve all work prepared by technicians before the drugs were administered to patients.*

*Cropp initially was charged with reckless homicide but agreed to plead no-contest in May to involuntary manslaughter. The State Pharmacy Board revoked his pharmacist license in April 2007.*

*Court records showed that a problem with the hospital's computer system on the day Emily received the deadly solution left the pharmacy with a backlog of drug orders. Records also suggested that Katherine Dudash, the technician who mixed the solution, was preoccupied with planning her upcoming wedding, the judge said.*

*Prosecutors charged Dudash with negligent homicide, Assistant County Prosecutor James Gutierrez said. But a grand jury did not indict her.*

*During a media conference after the hearing, Gutierrez emphasized that the case was not meant to criminalize medical malpractice. The law specifically states that misbranding a pharmaceutical drug is a crime, and Cropp's conduct was outrageously negligent, Gutierrez said.*

*Before Cropp was sentenced Friday, Emily's mother, Kelly Jerry, clutched a photo of the little girl and described in agonizing detail her daughter's last days.*

*Emily had just celebrated her second birthday with cupcakes and an endless stream of friends and family who visited her in the hospital. The little girl had been declared cancer-free, and her family couldn't wait to take her home after one last round of chemotherapy.*

*Three days into the treatment, Emily received the lethal solution. She awoke from an afternoon nap listless and complaining of a severe headache, Kelly Jerry said. The pain grew, until Emily began vomiting and lost consciousness. She was rushed to the hospital's Intensive Care Unit, where doctors struggled to determine what caused the complication.*

*She remained on life support for several days. Emily's brain had swollen so badly that her eyes bulged. Jerry gave her tiny daughter one last sponge bath before she was removed from life support. Emily's body was rigid and cold when nurses finally pulled the little girl from Kelly Jerry's arms.*

*"It was a senseless and preventable death," Jerry said, addressing Cropp in her prepared statement. "You were the only person who could have prevented this from happening, and you didn't do it. You killed my baby."*

*Cropp asked the judge for mercy and said no prison sentence could be more punishing than the weight of his conscience and the loss of his career.*

*He addressed the Jerry family but frequently referred to his written statement to find the words to apologize, which Kelly Jerry later said in a news conference left her dissatisfied.*

*"It will never be over for me and my family," Jerry said. "Mr. Cropp received six months. But six months of his life doesn't compare to what we have to endure for a lifetime."*

For those who are interested in viewing a news report of this tragic occurrence, and the unprecedented response to it, go to:
http://www.cnn.com/video/#/video/crime/2010/02/15/mattingly.oh.pharmacist.jailed.cnn?iref=allsearch

## REACTION TO THE OHIO CASE

The response from the pharmacy community to this reaction to a human error has been fully supportive of the pharmacist whose unintentional error has made a criminal of him. Realizing that all pharmacists make unintentional errors, all pharmacists see themselves as potential criminals if the Ohio case is viewed as any sort of precedent.

The response by Dr. Michael Cohen, President of the Institute for Safe Medication Practices, has been particularly forceful. Excerpts from that response posted to the ISMP website on August 21, 2009, are reproduced below:

*"Since Friday's sentencing of Eric Cropp, an Ohio hospital pharmacist involved in a tragic medication error, staff at the Institute for Safe Medication Practices (ISMP) have been deeply saddened and greatly troubled to learn that he received 6 months in jail, 6 months home confinement with an electronic sensor locked to his ankle after his release, 3 years probation, 400 hours of community service, a fine of $5,000, and payment of court costs. Eric made a human error that could have been made by others in healthcare given the inherent weaknesses in our manual checking systems: he failed to recognize that a pharmacy technician he was supervising had made a chemotherapy solution with far too much sodium chloride in it. The final solution was supposed to contain 0.9% sodium chloride but it was over 20%.*

*As learned from the sources above, the details of this tragic error are as follows. When Eric Cropp came to work on the day of the event, he learned that the pharmacy computer system was down and his assistant in the preparation area for intravenous (IV) solutions was a pharmacy technician who, according to press reports, was also planning her wedding on the day of the event and, thus, distracted while working (see link to press account below). With the pharmacy computer system down, a backlog of physician orders had developed, creating incredible time pressures for Eric. A nurse had also called requesting the chemotherapy solution (for the young child who died) immediately, which ultimately may not have been warranted. This added more time pressures to Eric's workload. According to a witness at the state board hearing, the chemotherapy was not needed until much later that afternoon. Testimony at the board hearing also uncovered that Eric was working short-staffed that day and had no time for normal work breaks.*

*The technician started to prepare the chemotherapy. We do not have complete knowledge of exactly what caused the sodium chloride overdose in this case. However, when preparing IV chemotherapy, some pharmacies remove fluid from a bag when they have to add a large volume of medication to infuse, and then add additional fluid to the bag and titrate with 23.4% sodium chloride injection to bring the final concentration of the infusion to whatever was prescribed (usually not more than 0.9%). Or, they start with an empty bag and follow a similar process. But compounding the solution from scratch is error-prone and such exactness of base solutions is most often unnecessary from a clinical standpoint. According to one press report, the solution was greater than 20 times more concentrated than it should have been.*

*Eric did not make the error himself. Still, he did not notice that the technician made the error when he checked her work. Such an error is crucial, but we have no knowledge regarding how Eric missed the technician's preparation error other than the fact that he is human and thus prone to human fallibility. I have no doubt that the work pressures and working conditions mentioned above played a significant role. But the price of that error was ever so costly: a little girl named Emily Jerry received an incredibly high amount of sodium chloride. After receiving the chemotherapy later that day, she suffered a terrible headache and thirst, and she soon lapsed into a coma and died.*

*As expected, the child's family was devastated, as was Eric, his colleagues at the hospital, and everyone in healthcare who was made aware of the tragic event. A February 2008* **USA Today** *article told the story publicly. The Ohio Board of Pharmacy became involved and Emily's mother, Kelly Jerry, participated in the board hearing as a witness for the state. She also appeared later in court. As an articulate but anguished parent, Ms. Jerry was compelling in her quest to have Eric's license revoked, and as of last week, even to have him imprisoned. Her emotional testimony has been truly heart wrenching as she holds up a picture of Emily.*

*In the past, ISMP has, at no cost, helped to defend healthcare practitioners who have been unjustly targeted for criminal indictment after a medication error, as happened with Eric. At times, our knowledge of the events has been gained from direct on-site investigation, similar to the role the National Transportation Safety Board plays when an airline crash occurs. We have published our findings for a few of these events, including a fatal medication error in an otherwise healthy newborn that led to criminally negligent homicide charges against three Denver nurses. An ISMP article about a fatal medication error during labor and delivery that resulted in the death of a young mother and criminal negligence charges for a Wisconsin nurse will appear in a November or December issue of* **The Joint Commission Journal on Quality and Patient Safety.**

*ISMP has also supported patients and family members after tragic medical errors have harmed them or their loved ones. Quite regularly, we hear from patients and family members who have been victims of medication errors, and help them through the healing process by anonymously publishing the events to maximize widespread learning from the error and encourage prevention strategies. On occasion, our work with patients and families has led to a public health advisory issued by the FDA.*

*I wasn't invited but wish I could have been given the opportunity to speak on Eric's behalf at the board hearing and at Eric's sentencing. All who work in healthcare can understand how the Jerry family must feel about Eric and the health system that let their little Emily down. I can't say that I wouldn't feel the same way if I lost a loved one to a medical error. But I fail to see how the Court's action on Friday will be effective at anything other than serving a desire to see Eric go to jail as punishment for making an error that led to Emily's death. It has been my observation that many who have been harmed from medical errors find it possible, even healing, to recognize and forgive human fallibility, especially since human error is not a behavioral choice, and many of the system issues that contributed to the error were beyond Eric's control.*

*I expected more from the Ohio State Board of Pharmacy and the Honorable Judge Brian J. Corrigan. I had hoped they would be able to rise above the emotionally charged atmosphere in this case to give Eric Cropp a more just resolution to this event. Based on my knowledge of the error and my expe-*

*rience in analyzing the causes of medication errors and human failures, I believe with certainty that Eric was not treated justly by either the Ohio Board of Pharmacy or by the Honorable Judge Corrigan’s court. What good can come from imprisoning Eric and destroying a man, who, up until the tragic event, had an excellent professional record?*

*In fact, I believe the undeserved harsh treatment of Eric will have a potentially disastrous effect in healthcare. Some will ask, “Why disclose errors and risk going to jail?” That, in itself, is a tragic testimony to the impact of this case and one that could cause a horrible backlash against the patient safety movement. In time, if we continue to see the legal system issuing criminal indictments when medical errors occur, we could see how young college students may not be drawn to legally “risky” professions or tasks within professions like pharmacy, such as preparing IV medications using high-alert drugs.*

*In fact, most healthcare professionals unwittingly put themselves at risk for criminal indictments when they enter the profession. They are fallible human beings destined to make mistakes along the way, as well as to drift away from safe behaviors as perceptions of risk fade when trying to do more in resource strapped professions. Many healthcare professionals already fear making that one error that could result in the harm or death of a patient. Escalating application of criminal error laws also serves as a reminder that a harmful error—often similar in form to minor mistakes we all make on a daily basis—could also strip away a hard-earned and cherished livelihood, the ability to help others, and personal freedoms perhaps once taken for granted, as has happened to Mr. Cropp.*

*While the law clearly allows for the criminal indictment of healthcare professionals who make harmful errors, despite no intent to cause harm, it will long be debated whether this course of action is fair, required, or even beneficial. The fact remains that the greater good is better served by fixing the medication-use system issues that allow tragedies like this to happen. By focusing instead on the healthcare professionals involved in the error—the easy targets—one can easily avoid addressing inherent system problems.*

*The focus on the easy target in this case makes my colleagues and I wonder whether any regulatory or accreditation agency in Ohio, or anywhere else for that matter, has taken any steps to ensure that all hospitals learn from this event and adjust their systems to prevent the same type of error. I am unaware of any Ohio state action to bring the system failures in the Emily Jerry case to the attention of Ohio hospitals. I also do not know of any visits undertaken by state surveyors to detail what the expectations are for implementing prevention strategies, at least those that have probably been put in place at the hospital where Emily died. If nothing has in fact happened, the death of this little girl is a heartbreaking commentary on healthcare’s inability to truly learn from mistakes so they are not destined to be repeated.”*

**LEGAL PRECEDENT FOR CRIMINAL PROSECUTION OF PHARMACISTS WHO HAVE ERRED**

As Dr. Cohen suggests, pharmacists are “sitting ducks” if criminal justice authorities pursue prosecutions, and resulting incarceration, of human beings who, while trying to perform at the best of their abilities, occasionally do less than their best, due to workload, distractions, understaffing, or a myriad of other challenges that pharmacists face on a day-to-day basis. Under the law, early pharmacists were held criminally liable for human errors. In 1828, in an English case known as Tessymond’s Case, a pharmacist was prosecuted for having dispensed tincture of opium when camphorated tincture of opium had been prescribed. The patient died, and the court said, “If a party is guilty of negligence, and death results, the party guilty of that negligence is also guilty of manslaughter.” Within a modern context, it has traditionally been held under the law that a pharmacist’s inadvertent error does not expose the pharmacist to criminal liability, although civil liability for malpractice is likely. One of the first cases to consider this principle was the case of *People v. Greenwald*, decided by the New York Court of Appeals in 1974. In that case, the pharmacist misread a written prescription and dispensed 147 grains of sulfathiazole in tablet form when 21 grains in powder form had been ordered. An eight month old infant died after having been injected six times with 21 grains of drug rather than 3 grains. The pharmacist was convicted of manslaughter, which was reversed on appeal. The court said “The record established that the defendant made a mistake in reading the prescription, but failed to include evidence of culpable negligence within the contemplation of the manslaughter statute.” This principle, that intent or reckless disregard is necessary for a criminal conviction has, until recently, shielded modern pharmacists from criminal prosecution.

In 1995, a Baltimore pharmacist was charged with manslaughter after she filled syringes with morphine instead of heparin. The syringes were used to flush the IV lines of young children. The children experienced respiratory depression but had no permanent damage. The local prosecutor apparently sought approval from the community by making an example of the pharmacist. Initially the prosecutor was supported for filing criminal charges against the pharmacist. The local newspaper said in its first editorial to address the subject, “No matter how bad we feel for the hospital and its dedicated employees, there is no way to put a positive spin on an incident that can only be classified as rank carelessness.” One month later, the same newspaper said, “Upon further reflection, it’s our opinion that [the pharmacist], however careless,

should not be criminally charged.” Eventually, the charges were dropped against the pharmacist, and the newspaper opined that the prosecutor’s decision to press charges for carelessness was itself careless. The paper queried, “So why were these charges filed? States’ Attorney Frank R. Weathersbee was coming off an election in which he had been lambasted as passive, and had also been attacked, unjustly, for not immediately intruding into the hospital investigation. So, with the community upset, the temptation to make [the pharmacist] a scapegoat seems to have overpowered the prosecutor’s best judgment.”

Unfortunately, the Ohio pharmacist did not benefit from second thoughts about the appropriateness of criminalizing inadvertent pharmacy error. Unlike the pharmacist in Baltimore, the Ohio pharmacist was made the scapegoat for a system failure and he was held criminally liable. The possibility that this counterproductive step could occur more frequently warrants action being taken both by the profession of pharmacy and through its state boards of pharmacy. The profession does not seek to avoid responsibility for error. Those pharmacists who err in their practice should be held accountable for the consequences of their errors through malpractice liability. Their insurance companies, or they themselves, should correct the injustice that has been done to a patient through an error, by financially compensating the victim of an error that has occurred. On the other hand, criminal liability for inadvertent error can lead to overly conservative pharmacy practice that does not meet the needs of patients. Pharmacists who face criminal liability may decline to dispense particularly dangerous medications such as anticoagulants, or decline to dispense medications to high risk patients such as the elderly. To protect patients from these decisions that pharmacists exposed to criminal liability might make, state boards of pharmacy have developed continuous quality improvement programs that are designed to improve systems and reduce pharmacy errors.

## RATIONALE & SIGNIFICANCE OF CQI

Throughout the remainder of this lesson, we will discuss the significance of Continuous Quality Improvement (CQI). Perhaps, if it had been emphasized during the Ohio Case, criminal charges would have been avoided for Pharmacist Cropp.

A number of states have implemented CQI. We continually refer to Florida’s situation because:

1. They were the first.
2. Their requirements are inclusive but flexible.
3. Their requirements incorporate full input by all pharmacy staff.

CQI is a system. It differentiates between mechanical errors (errors of commission) and intellectual errors (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.

Development of a CQI System is a positive illustration that demonstrates a pharmacy’s plan to improve and minimize errors. It allows us to analyze measures.

Without a focus on “fixing a system,” then errors become, in a sense, “blame oriented.” We need to focus away from blame. Otherwise, the profession will “sweep errors under the rug” and avoid discussion. The premise of “Forgive & Remember” is essential to “improve & reduce errors.”

Finally, as we will discuss in detail, a viable CQI program will include and outline:

1. Selecting a Quality Team Leader.
2. Define “Quality-Related Event.”
3. Describe the Practice Process.
4. Develop a QRE Recording System.
5. Train Pharmacy Staff in CQI.
6. Conduct Continuous Quality Improvement Meetings as Needed.
7. Implement Changes and Evaluate Results.

## STATE BOARD OF PHARMACY CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAMS

Approximately half 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 committed no crime because their efforts to prevent errors show a lack of intent to commit them. The intent element is missing from any error committed in a pharmacy that uses a CQI program. The Florida Board of Pharmacy was the first state to adopt such a program, and its program serves as an example of how most programs are conducted. The Florida Board of Pharmacy is authorized by the State’s Legislature 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-reg-

ulate 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, the Board of Pharmacy has responded to the problem of error in pharmacy, through the development of its CQI rule. The enabling language from the Florida Pharmacy Act 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 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.*

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

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

**This concludes Part 1. In Part 2, we shall interpret the Pharmacy CQI Rule; discuss compliance with CQI requirements; discuss value of CQI; and, finally, describe the significance of committing to CQI.**

## 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?

| | | |
|---|---|---|
| Compare civil & criminal liability for medication errors by pharmacists | Yes | No |
| Discuss steps to reduce exposure to criminal liability for inadvertent errors | Yes | No |
| Describe Boards of Pharmacy rulemaking regarding quality improvement programs | 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 of the following serves to punish the perpetrator of intentional harm caused to another person?
   A. Ministerial liability
   B. Administrative liability
   C. Criminal liability
   D. Civil liability
2. Typically, criminal liability is associated with:
   A. Negligence
   B. Intent
   C. Recklessness
   D. Abject noncompliance
3. CQI programs usually include:
   A. Selecting a team leader
   B. Develop a QRE record system
   C. Train staff in CQI
   D. Conduct CQI meetings
   E. All of these
4. Which of these acts may result in civil malpractice liability?
   A. Negligence
   B. Intent
   C. Recklessness
   D. Abject noncompliance
5. For what crime was the pharmacy technician indicted based on the error in preparing medication for Emily Jerry?
   A. Negligent homicide
   B. Manslaughter
   C. Reckless disregard
   D. Technician was not indicted
6. Errors of commission occur when someone does something incorrectly.
   A. True B. False
7. Within a modern context, it has traditionally been held under the law that a pharmacist’s inadvertent error does not expose the pharmacist to criminal liability.
   A. True B. False
8. How many months in prison must former pharmacist Eric Cropp spend as punishment for his failing to detect the error made by a pharmacy technician in the preparation of medication for Emily Jerry?
   A. 3
   B. 6
   C. 9
   D. 12
9. In 1995, a Baltimore pharmacist was initially charged with a crime for an error she made. What drug did this pharmacist dispense in error?
   A. Warfarin
   B. Theophylline
   C. Morphine
   D. Oxycodone
10. In the Tessymond Case, a pharmacist dispensed an incorrect prescription, and the court held that the pharmacist was guilty of:
    A. Negligence
    B. Manslaughter
    C. Abject noncompliance
    D. A & B

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**CORRECT**
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