Reducing Medication Errors Through the Implementation of Continuous Quality Improvement Programs

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Learning Goals

Upon completion of this activity pharmacists will be able to.

- ❑ Review quality improvement regulations for Florida pharmacies;
- ❑ Define elements of a Continuous Quality Improvement (CQI) Program.
- ❑ Discuss how to use Root Cause Analysis (RCA) to prevent errors.
- ❑ Restructure pharmacy practice to address quality related events.
- ❑ Implement an action plan to address quality of care in pharmacies with a goal towards error reduction and prevention.
- ❑ Integrate changes within pharmacy health care systems to improve patient safety

Upon completion of this activity, technicians will be able to:

- ❑ Define Continuous Quality Improvement and Root Cause Analysis; Recognize the most common medication errors.
- ❑ Use techniques to reduce and prevent medication errors using CQI.
- ❑ Recognize the role of the technician in patient safety efforts within pharmacy health care systems

DISCLOSURE
Pharmacy Quality Commitment Program

- FPA has available a continuous quality improvement program
- System is web based for documenting and reporting purposes
- Visit **www.FloridaPharmacy.org** for more information
- FPA also has a relationship with (PMG) Pharmacist Mutual
- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant money for this continuing education program, or any affiliation with an organization whose philosophy could potentially bias my presentation

Assessment Questions

- What are steps that a pharmacist can do to resolve negative quality related events?
- Should the prescriber be contacted if a prescription error had been discovered?
- Would dispensing an expired drug be considered a quality related event?
- What are examples of high alert medications?
- (T or F) DOH inspectors are entitled to view comprehensive CQI pharmacy reports
- (T or F) Checklists have no place in health care

"Incompetent people are, at most 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it's the processes that set them up to make these mistakes."

Dr. Lucien Leape
Harvard School of Public Health

The Problem (Root Cause)

Error Factors	Example
•Institutional •Regulatory	Patient on anticoagulants receive IM pneumococcal vaccine. Health system under pressure to improve vaccination rates
•Organizational •Management	Nurse detected a medication error but was discouraged by the physician from reporting it
•Work environment	Pharmacy team continues to provide medication management services even though the patient record system was offline for maintenance
•Staffing	Overworked nurse mistakenly administers insulin instead of antinausea medication resulting in hypoglycemia coma
•Team environment	Surgeon completed operation despite being informed that a suction catheter tip was missing
•Task-related	Influenza vaccine administered to a patient where the historical records were not reviewed. Patient was previously dosed 3 months ago
•Patient characteristics	Parents of a young boy misread the instructions on a bottle of APAP resulting in liver damage

https://psnet.ahrq.gov/primers/primer/10/root-cause-analysis

How big is the problem?

- Medical errors are the 3rd leading cause of death (May 3, 2016 NPR Report)
- One research study suggested that errors occurred more frequently at the beginning of each month

How big is the problem?

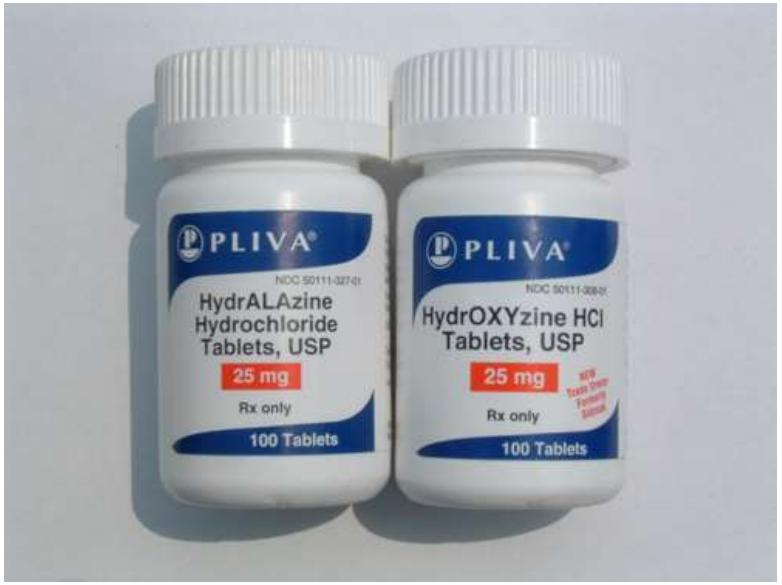
- Each year, adverse drug events account for nearly 700,000 ER visits and 100,000 hospitalizations*
- Patients generally fail to ask questions about how to use their medications

*https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events

Reports From the FDA

- Dog received the drug Sinequan instead of Zeniquin
- One patient died because 20 units of insulin was abbreviated as "20 U," but the "U" was mistaken for a "zero." As a result, a dose of 200 units of insulin was accidentally injected.

Look-Alike Examples



Quality Improvement in health care services is not a one-person operation!

- Organizational system wide support
- Staff commitment
- Management or owner
- Patients and patient caregiver

Nurse Criminally Prosecuted for Fatal Drug Error

- Patient was admitted to a Tennessee hospital for a brain injury
- Patient was prescribed Midazolam for administration prior to an MRI
- The nurse retrieved a paralyzer drug vecuronium from a computerized medication system and administered the drug
- Prosecutors portrayed the nurse as irresponsible and uncaring and ignored her training
- Claims were made that warning signs were ignored
  - Midazolam is a liquid
  - Vecuronium is a powder

Is the criminalizing of mistakes the right way to correct errors?

- Yes
- No

Case Study

Ohio Pharmacist Imprisoned from Rx Error

- Pharmacist signed off on improperly prepared chemotherapy treatment.
- 23.4% saline solution used in compound rather than 0.9%
- Resulted in patient's death
- View video

Case Study

Ohio Pharmacist Imprisoned from Rx Error

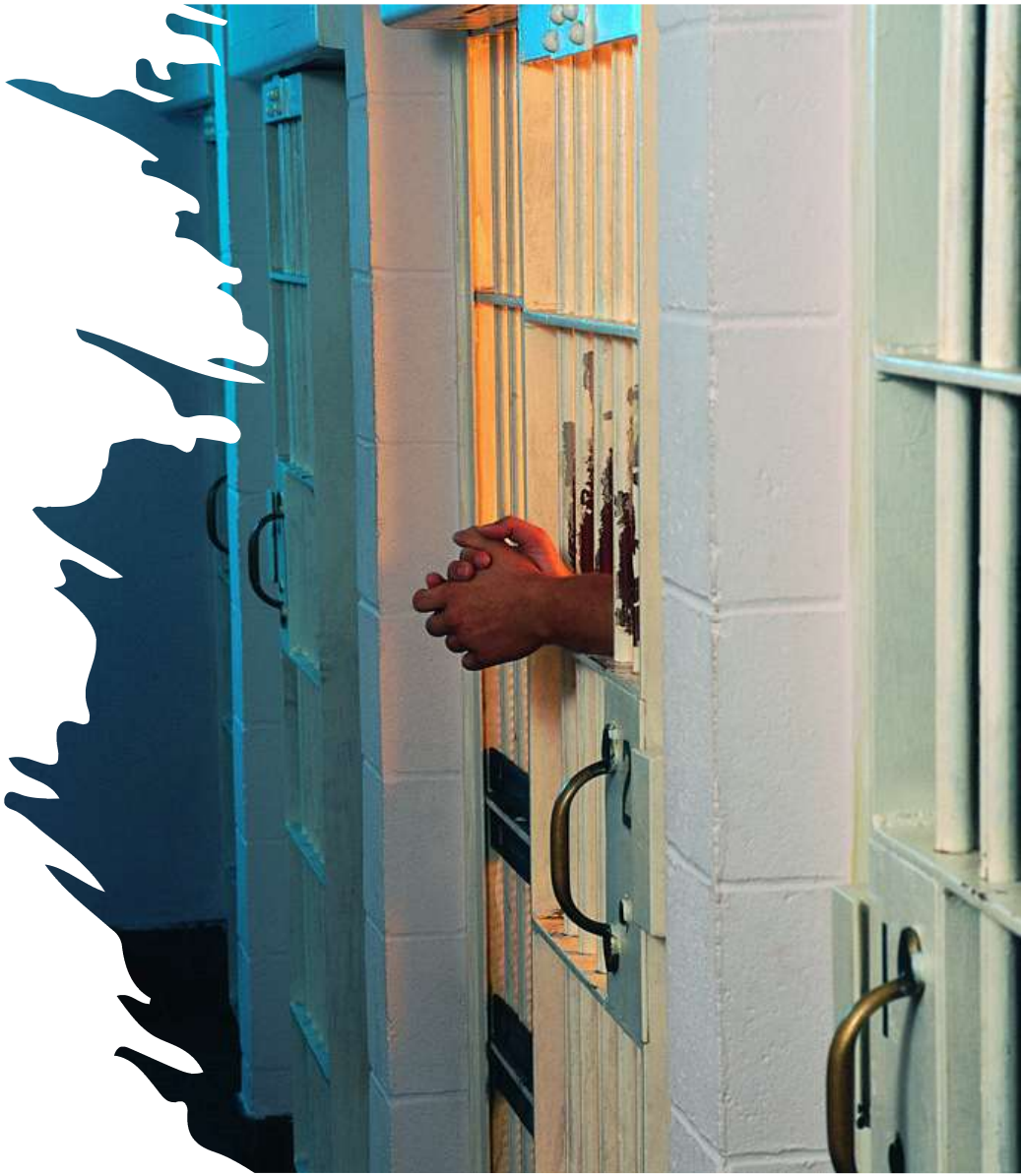
Aggravating Issues

- Computer system offline for maintenance
- Backlog of drug orders waiting to be processed
- Staffing shortage
- IV prep technician planning a wedding
- IV prep area cramped and crowded
- Hypertonic solution within easy reach

Outcome

- Pharmacist license revoked
- Jailed for involuntary manslaughter
- Ohio Board found no system errors of the hospital

There is no evidence to show that this is the proper way to resolve medical mistakes.



Case Study (Twins being treated for staph infection)

- Patients were given heparin 10,000 units/ml rather than 10 units/ml
- Nursing staff administering the drugs were relieved of duty
- **Concern over the labeling of the products**
- No ill effects on the twins

It is time to do a total health systems checkup

- Internal evaluation of staff skills and abilities
  - Encourage feedback
  - Dialog must be open and honest
- Resources of the delivery system
  - There may be a relationship to cost cutting and increased risk
- Facility environment and layout
- Support of pharmacy administration or management
- Support for self reporting policies

Promoting Positive Quality Related Events?

- Health care personnel should not be evaluated solely upon efficiency, revenue development and expense management.
- Performance assessments and reviews should include evidence of error avoidance and prevention, patient health improvement and documented positive outcomes.

What is a positive quality related event and how does a pharmacist create one?

- **REASON** - Tampa pharmacist participating in the Florida patient care management program receives a prescription refill request for a cholesterol lowering drug
- **ACTION** – Pharmacist does an in-store cholesterol test and finds the patient not responding. Pharmacist calls MD
- **RESOLUTION** – Physician changes medication
- **OUTCOME** – Patient's cholesterol levels drop

What is a negative QRE and how does a pharmacist recognize when it happens?

- **REASON** – Patient brings in a prescription for a benzodiazepine and asks about what dose would make it toxic
- **ACTION** – Pharmacist thought the question odd but provided the information as requested
- **RESOLUTION** – Patient receives filled prescription in a timely and efficient manner and went home
- **OUTCOME** – Patient found unconscious at home from drug overdose

What action should be taken in the event of a negative quality related event?

- Pink slip for the pharmacist and pharmacy technician
- File a complaint with the Department of Health
- Resign your position and drive trucks for a living
- The technician should take over the pharmacist's dispensing duties and send the pharmacist home
- **Research and work the system issue.**

Managing negative quality related events
(video presentation)

- Listen to the patient or patient's caregiver
- Assume that an error has occurred
- Investigate the facts surrounding the event
- Show genuine concern for the patient
- Apologize for the inconvenience but use judgment on accepting full responsibility
- Document the event immediately
- Notify management/owner
- **If its broken, fix it & document the repair**

Questions to answer in documenting a QRE

- Describe the QRE
- Note the date & time when the QRE occurred and the date and time the incident was reported
- How was the QRE discovered
- Was treating physician or other care giver notified
- Disposition of the patient
- Disposition of the physician
- In a dispensing error was the container retrieved (how much of the drug did the patient use or take)?
- What is the status of the patient?
- Who were the staff/caregiver(s) involved?

Things to note in a QRE form

(Report should be considered confidential)

- Date
- Time
- Location
- Reporting staff member
- Brief description of the event
- Type of QRE
  - Incorrect drug, drug strength, dosage form, wrong patient, over or under utilization, interaction, therapeutic duplication, allergy etc
- Action taken
- Staff on duty
- Level of prescription volume
- Turnaround time
- Frequency of interruptions
- Level of telephone call volume
- Environment
  - Lighting, noise distractions etc
- Interpretation
  - Transcription error, look alike-sound alike drugs
- Other factors involved
  - Computer system (including software), fax machine, voice mail, counting machines, IV hood

Contributing causes of negative quality related events (Video)

- Telephone interruptions
- General interruptions
- Prescriber's handwriting
- Look alike/sound alike drug names
  - Cozaar – Zocor
  - Tenex - Xanax
  - Mucomyst – Mucinex
  - Allegra - Viagra
  - http://www.ismp.org/Tools/confuseddrugnames.pdf

High Alert Medications

- amiodarone, IV
- colchicine injection
- heparin, low molecular weight, injection
- heparin, unfractionated, IV
- insulin, subcutaneous and IV
- lidocaine, IV
- magnesium sulfate injection
- methotrexate, oral, non-oncologic use
- nesiritide
- nitroprusside sodium for injection
- potassium chloride for injection concentrate
- potassium phosphates injection
- sodium chloride injection, hypertonic (more than 0.9% concentration)
- warfarin

Other contributing causes of negative quality related events

- Prescription volume
- Fatigue
- Verbal orders
- Product labeling and packaging
- Abbreviations
  - D/C (Discharge – Discontinue)
  - IU (International Unit – “IV” – “10”
  - Q.D. (Once Daily - QID)
  - SSRI
  - µg (microgram – milligram)
- **Metrics – Are we at the tipping point?**

Dr. Bled Tanoe
#PizzaIsNotWorking

Workplace & Wellbeing Reporting

- https://www.pharmacist.com/Advocacy/Well-Being-and-Resiliency/pwwr

“Five Rights” of Patients

- Right drug
- Right time
- Right dose
- Right route
- Right patient

What are other types of negative quality related events?

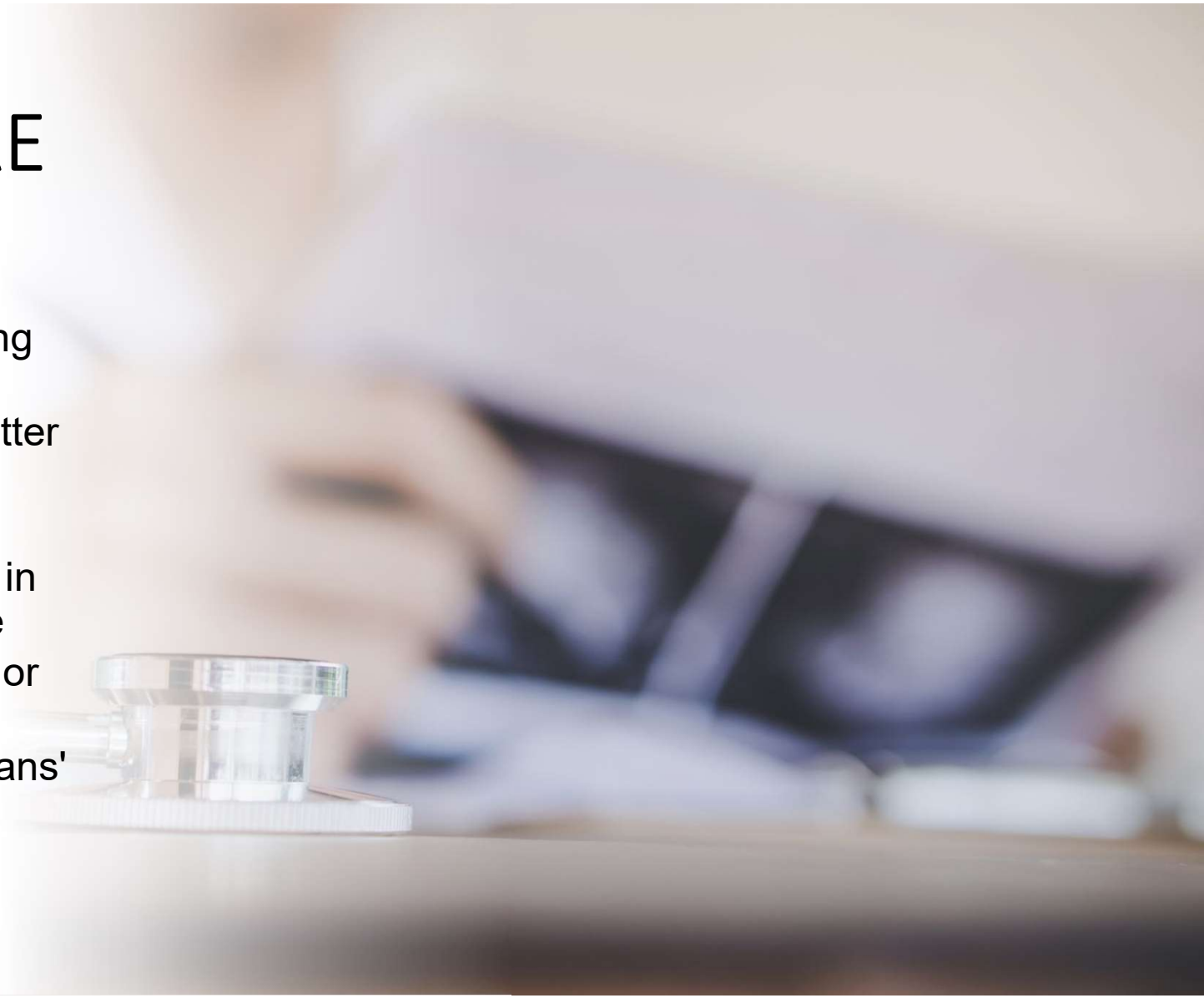
- Incorrect dosage prescribed or administered
- Inappropriate drug prescribed or administered
- Missed documented drug allergy
- Expired drug dispensed or administered
- Improperly compounded drug (USP 797)
- Miss branded prescription drug

Factors that contribute to positive quality related events

- Influence and support by management
- Use of information provided by computers
- Motivation of the staff/caregiver
- Involvement of the patient or patient's caregiver
- Continuous staff training and system upgrades

Negative QRE Prevention

- Pay attention to the warning signs
  - Patient does not get better or gets worse
  - Computer messages
  - Recognizable changes in medication appearance
  - Questions from patient or patient’s caregiver
  - Questions from physicians' office
  - Insurance claim denial



Negative QRE Prevention

- Examine the patient's health information
  - Refill schedule out of sync
  - Age (especially in children)
  - Weight
  - Sex
  - Medical history
  - Allergies

Negative QRE Prevention

- Examine dispensing procedures
  - Question illegible prescriptions
  - Question strange therapy
  - Question high doses
  - Modify final check process
    - **CONFIRMATION BIAS**
  - Verify patient identification

Negative QRE Prevention

- Adopt system wide QRE prevention policies
  - Physician electronic order entry
  - Have two health care licensees verify and document the dispensing of problem related drugs (Heparin, Sodium Warfarin, digoxin, IV potassium, etc.)
  - Remove concentrated drug solutions from patient care areas
  - Sterilize final check area
  - Implement bar code/RFID technology

Negative QRE Prevention

- Checklists
  - Promotes redundancy and consistency
  - Establishes a standardized system
  - Encourages habit forming behavior
  - Reduces opportunity for an omission or oversight

Standards of Practice – Continuous Quality Improvement Programs 64B16-27.300

- (1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events, and improve patient care.

Standards of Practice – Continuous Quality Improvement Programs 64B16-27.300

- (2) "Quality-Related Event" means the inappropriate dispensing 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.

Standards of Practice – Continuous Quality Improvement Programs 64B16-27.300

- (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.

Standards of Practice – Continuous Quality Improvement Programs
64B16-27.300

(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;----------

Standards of Practice – Continuous Quality Improvement Programs
64B16-27.300

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager of the consultant 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, access and improve the quality of patient care;
4. The procedure for reviewing Quality Related Events.

Standards of Practice – Continuous Quality Improvement Programs
64B16-27.300

(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.

Standards of Practice – Continuous Quality Improvement Programs
64B16-27.300

(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 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. Pharmacist 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.

Standards of Practice – Continuous Quality Improvement Programs
64B16-27.300

(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 four (4) years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Grounds for Citation
64B16-30.003

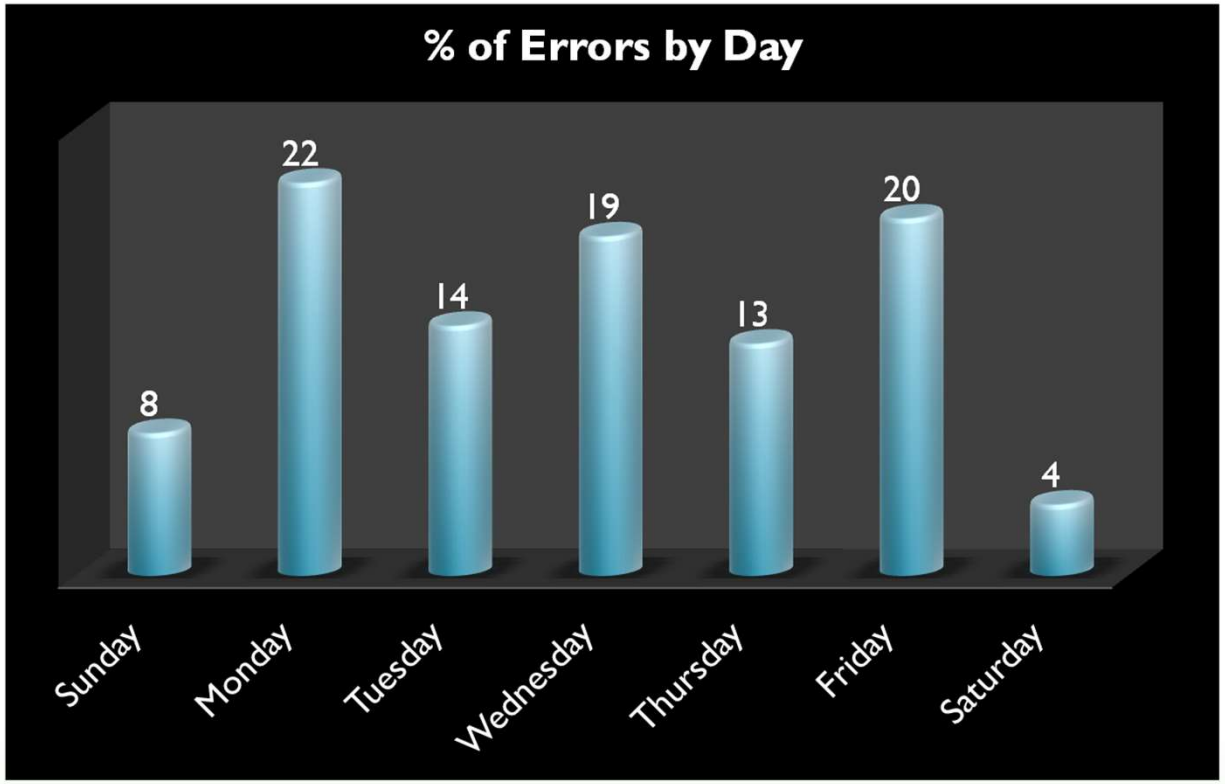
Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested.

Disciplinary Guidelines - $250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.

Things to note in a summary form
(Must be made available for DOH inspectors)

- Quality related event **category**
  - Drug dispensed to wrong patient, incorrect drug selected, prescribing error noted etc
  - What were the staffing levels, remedial action taken, prescription volume, etc?
  - There must be no reference to patient or staff information in this document.

Sample Summary Reporting Form



Sample Summary Reporting Form

Summary

Questions

This is so demeaning.

I am a Corgi and I am too dignified to be embarrassed this way.

Michael Jackson, BPharm, CPh, FAPhA
Eminent Scholar in Pharmacy Practice
FPA EVP CEO Retired
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References:

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- ISMP Safety Alerts: https://www.ismp.org/medication-safety-alerts?field_alert_type_target_id%5B36%5D=36#alerts--alerts_list
- http://www.ismp.org/Tools/confuseddrugnames.pdf
- http://www.ismp.org/Tools/highalertmedications.pdf
- Florida Administrative Code 64B16-27.300 - Standards of Practice – Continuous Quality Improvement Programs