

# Pharmacy Practice Law Update: Medication Error and Prevention

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# Karl Williams

*Professor of Pharmacy Ethics and Law  
Interim Associate Dean  
Wegmans School of Pharmacy  
and  
PSR Representative to PSSNY  
[kwilliams@sjfc.edu](mailto:kwilliams@sjfc.edu)*

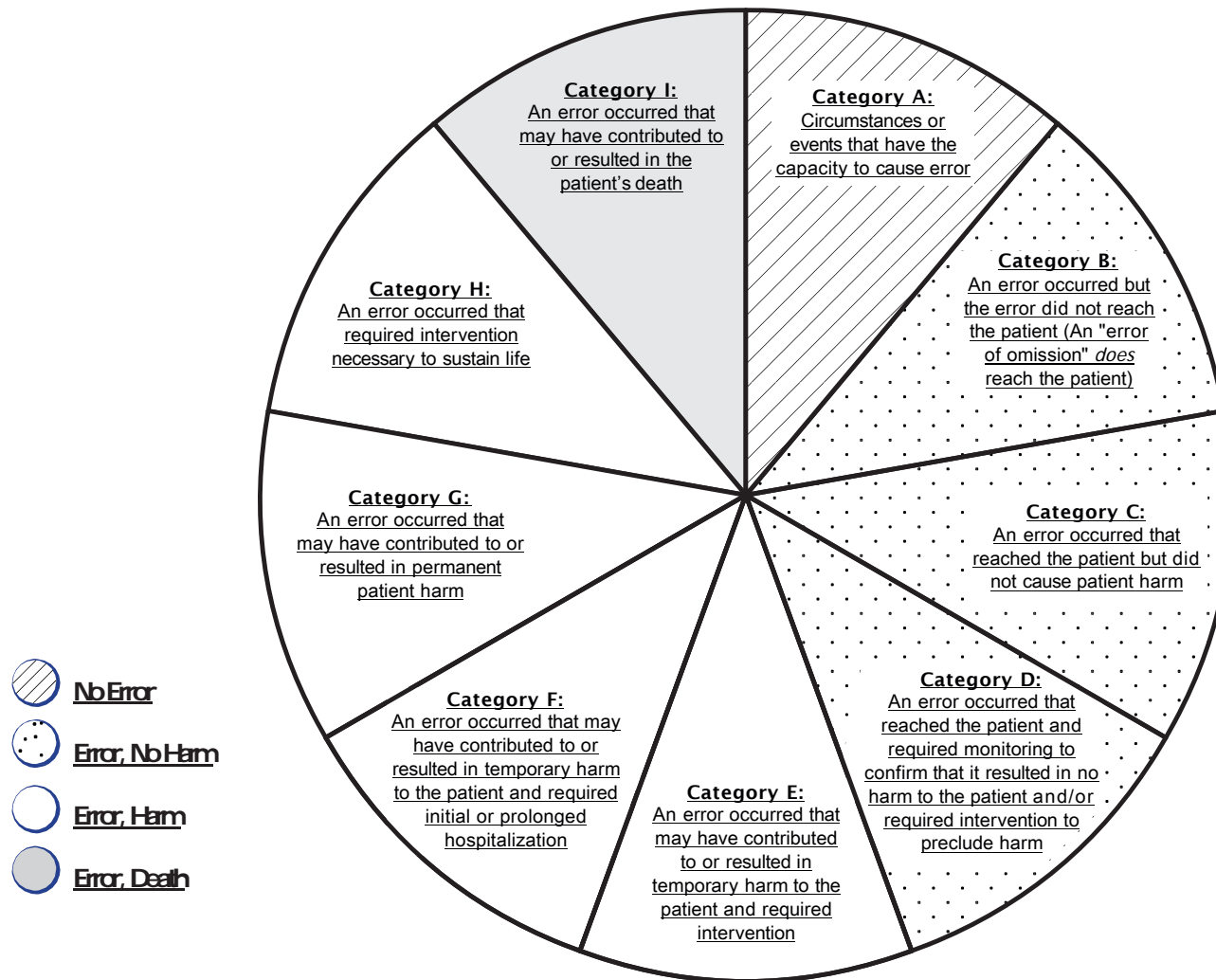
# Objectives

At the end of this program you should be able to:

- Review process-related approach to preventable adverse drug events (i.e., errors)
- Discuss NYS legislative session activity affecting pharmacy practice
- Describe the pharmacy-related provisions of the federal Comprehensive Addiction and Recovery Act (CARA)
- Explain new case law with regard to counseling and warnings

- **Medical Errors Are No. 3 Cause Of U.S Deaths, Researchers Say**
- BMJ 2016;353:i2139
- Is this accurate?

# NCCMERP Index for Categorizing Medication Errors



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# NCCMERP Index

- Category:
- A: Circumstances that have the capacity to cause
- B: Error occurred, but did not reach patient
- C: Reached patient, but did not harm
- D: Reached patient, required additional monitoring
- E: Temporary harm
- F: Temporary harm with prolonged hospitalization
- G: Permanent harm
- H: Intervention to sustain Life
- I: Contribute to, or resulted in patient's death

# Characterizing Error

- *Omission or Commission*
  - Omission: Fail to do something that should be done
  - Commission: Do something that should not be done
  
- *Mechanical or Intellectual*
  - Dispensing errors or cognitive errors

# Medication Use Process

- Contemplated by the NCCMERP diagram
- *Systems* point of view
- Question: which steps are more, or less, prone to error?
- The BEST question: how do we address the circumstances that have the capacity to cause error?



# Two kinds of people in the world:

- Those that can learn from the mistakes of others, AND
- ???
- The “Others”. Don’t one of the Others!

# Question: Is there an error?

- Prescription:
- Hydromorphone 8mg q3h prn (mdd: 32mg)
- Question: is dispensing this an error?

## Does it matter whether:

- The patient had received this before?
- The pharmacist indicated on the label an mdd of 64mg, when 32mg contemplated?
- The patient died after the first dose?

# Abrams v. Bute

(138 AD 3<sup>rd</sup> 179, March 2016)

- These were the facts of this case.
- Question for the court: did the pharmacist have a legal duty to intervene in this case?
- Nothing beyond mere “technical accuracy” in filling the prescription (defendant’s argument).

# The court's definition of "duty"

- “Clearly contraindicated” for the particular patient, then independent professional judgment must be exercised, and intervention is required
- So, is hydromorphone 8mg q3h prn, “clearly contraindicated”?

# Legislation in 2016

# Medication Errors and the Legislative Session 2015-2016

- Recall: “circumstances that have the capacity to cause error”

# Prescriptions

- Numerous bills that have the capacity...
- Question: for each new law, is there a capacity to increase (or reduce) error?



# “Oral prescriptions”

- Exception to e-prescribing:
  - in hospitals;
  - nursing homes;
  - residential health care facilities;
  - and facilities operated by OPDD.
- Deemed necessary to ensure timely access to medication from facilities where prescribers are not always available

# Exception to eRx

- No longer need to notify DoH in the event of:
  - Temporary electrical/technical failure
  - Delay that would cause adverse impact
  - Out-of-state Rx
- A notation in the medical record is now sufficient.

# Transfer of eRx

- Initial prescription may be transferred to another pharmacy on the request of the patient or other authorized party. (PHL 281(3-a), and Ed Law 6810(10-a)).
- Software not yet available for this

# Cloud-based storage of eRx

- Allow prescriber to send eRx to a secure intermediate site from which pharmacy may download
- DoH to make regulations concerning security/integrity of system
- Again, the technology is not yet available for this

# Refilling 90-day supply

- Refills may contain greater than initial quantity
- If:
  - Refill follows initial prescription and does not exceed 90-day supply
  - No contrary instruction from prescriber
  - Pharmacist informs prescriber within 5 days, and
  - Insurance covers with no additional co-insurance, co-pay, or other out-of-pocket expense

# Heroin/Opioid Epidemic

- A great deal of legislative/governmental interest this year
- Reports
  - Governor: Combatting the Heroin and Opioid Crisis
  - Joint Senate Task Force on Heroin and Opioid Addiction
  - Comptroller: Prescription Opioid Abuse and Heroin Addiction in NYS

# Initial quantity for acute pain

- 7-day supply
- Note: not the pharmacist's role to police this
- Statute also addresses co-pays
  - May be pro-rated (7/30's), or paid in-full provided that additional dispensing at zero co-pay.

# Pharmacist's Role

- Naloxone: 3309(3)b, expanding access
  - Requires chains with 20 or more to either:
    - Have a standing order, or
    - Register as an opioid overdose prevention program under the DoH
- Good Samaritan protection for professionals who administer (A10726, adds Education Law 6509-d)



# Good Samaritan

- Affects pharmacists directly
- Permitted to administer only vaccines, if certified
- Ed Law 6509-d exempts any professional from misconduct for administration of naloxone in emergency

# Federal Legislation: Comprehensive Addiction and Recovery Act

- Title I: Prevention and Education
  - Funding to establish a program ‘prescribing’ naloxone
  - Grants to states to enhance access via pharmacies
- Title III: Buprenorphine prescribing: add nurse practitioners
- Title VII: partial fill of C-II, remove ‘unable to supply’ requirement
  - Allow remainder within 30 days from the date of prescription

# Abuse deterrent opioid coverage

- Requires insurers to include at least one abuse-deterrent “tamper resistant” opioid on formularies

# Expanded Syringe Access Program

- Participating pharmacies may offer counseling and referral services to purchasers concerning:
  - Injecting drug abuse
  - Dependence treatment
  - Hepatitis C
  - Overdose prevention
  - HIV testing
    - Pre- and post-exposure prophylaxis
- Professional discretion of pharmacist

# Epinephrine auto-injectors

- Authorize administration by trained individuals to people experiencing anaphylactic symptoms
- Authorize, not mandate, public venues and retail establishments to stock and administer epinephrine
- Training

# Prescription drug donation and redispensing program

- New section PHL 280-b; Pharmacies, health care facilities, manufacturers, wholesalers, distributors
  - “Donor entities” and “recipient entities”
  - Inspected by pharmacist/other licensed HCP
  - Tamper-evident packaging
  - DoH regulations
  - No-cost distribution