

Medication Errors: Mitigating Occurrences & Minimizing Risk with New Technologies

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Disclosures

- Activity faculty and reviewers have no disclosures to make

Objectives – Pharmacists

- Define key terms relating to medication errors
- Describe New Jersey Board of Pharmacy regulations pertaining to medication errors
- Identify best practices to minimize error occurrences
- Discuss the impact of electronic prescribing on medication error rates
- Evaluate state and federal regulations regarding e-prescribing
- Explain cybersecurity risks in the pharmacy practice setting

What is a medication error?

**What are the most common errors
you have encountered in your
practice?**

What is a Medication Error?

- "A medication error is **any preventable event that may cause or lead to inappropriate medication use or patient harm** while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

- National Coordinating Council for Medication Error Reporting and Prevention

ISMP's "Ten Key Elements" of the Medication-Use System

- **Patient information:** Failure to obtain the patient's pertinent demographic (age, weight) and clinical (allergies, lab results) information
- **Drug information:** Failure to provide accurate and usable drug information
- **Communication of drug information:** Miscommunication between MD, R.Ph. and RN
- **Drug labeling, packaging and nomenclature:** Drug names that look-alike or sound-alike, as well as products that have confusing drug labeling and non-distinct drug packaging
- **Drug storage, stock, standardization, and distribution:** Lack of Standard drug administration times, drug concentrations
- **Drug device acquisition, use and monitoring:** Lack of safety assessment of drug delivery devices and/or a system of independent double-checks
- **Environmental factors:** Environmental factors that often contribute to medications errors include poor lighting, noise, interruptions and a significant workload.
- **Staff competency and education:** Staff education should focus on priority topics, such as: new medications being used in the hospital, high- alert medications, medication errors that have occurred both internally and externally, protocols, policies and procedures related to medication use.
- **Patient education:** Patients must receive ongoing education
- **Quality processes and risk management:** The way to prevent errors is to redesign the systems and processes that lead to errors rather than focus on correcting the individuals who make errors.

Pharmacy Errors in the News – Traditional

- In 2007, a Polk County jury in Florida awarded \$28.5 million for the family of Beth Hippely, whom a Walgreens pharmacist allegedly gave blood-thinner medication 10 times stronger than her doctor had prescribed.¹
- In 2010, Alabama jury ordered Rite Aid to pay \$2.5 Million for pharmacy misfill after patient allegedly received steroid instead of pain medication.²

1.Lawsuit: Walgreens prescription error killed man, USA Today, November 2, 2007

2.Rite Aid to Pay \$2.5 M for Drug Mix-up, Montgomery Advertiser, January 27, 2010

Pharmacy Errors in the News – HIPAA

- In 2014 the Indiana Court of Appeals upheld a \$1.4 million verdict against Walgreen Co. and one of its pharmacists who shared confidential medical information about a client that had once dated the pharmacist's husband.
- The lawsuit alleged the pharmacist improperly reviewed the prescription history of the patient and then divulged that confidential information to her husband. The pharmacist's husband had previously fathered a child with the patient.¹

1. \$1.44M HIPAA award upheld after Walgreen pharmacist shared patient data, IndyStar, November 17, 2014
Ernest Mario School of Pharmacy

Pharmacy Errors in the News – Compounding

- In April 2009, 21 polo horses from a Venezuela-based team died while preparing to compete at the U.S. Open Polo Championship.¹
 - The deaths later were alleged to have occurred due to a medication that was mixed incorrectly by an independent pharmacy, a “high-volume compounding operation” that prepared veterinary drugs in addition to human medications.
- Owners of the horses filed a lawsuit seeking more than \$4 million in damages from the pharmacy.

1. Harsh punishments rare for drug compounding mistakes, USA Today, March 20, 2013

Pharmacy Errors in the News – Employment

- A veteran pharmacist, who worked at CVS Caremark Corp., filed a civil lawsuit against his former employer, alleging he was wrongfully discharged—in part, because he complained to management that staff cutbacks were contributing to increased pressure on pharmacists, causing prescribing errors.¹
- His lawsuit asserts that in early 2011, a 20% cutback in pharmacy technician hours led to "a greater number of mistakes in filling and labeling prescriptions."
- He and his staff were "berated...for not meeting the prescription sales metrics," by the store's district manager and others, the lawsuit alleges.

Pharmacy Errors in the News – Admin. Penalties

- In New Jersey, the Attorney General fined CVS \$650,000 in 2013 after it found multiple stores made medication mistakes, including as many as 50 children receiving the breast cancer drug tamoxifen instead of fluoride pills.¹
 - The pills were similar in shape and color but had different imprint codes on them.
- As part of its agreement, CVS was required to retrain staff members, increase oversight and quality assurance measures, in part by providing color images of medications on their website.

Pharmacy Errors in the News – Crim. Penalties

- A New England Compounding Center supervising pharmacist was arrested on charges related to an ongoing criminal investigation. NECC is the compounding center connected to the deadly fungal meningitis outbreak in 2012.¹
- The criminal complaint charges the pharmacist with participating in a scheme to cause one lot of the injections to be labeled as fit for human use.
- One of the NECC's customers injected their patients and as a result, 217 contracted fungal meningitis and 15 died.
- He is the first person to face criminal charges, but he isn't expected to be the last.

The image features a solid red background. In the top left corner, the word "RUTGERS" is written in a large, white, serif font. Below it, in a smaller, white, sans-serif font, are the words "THE STATE UNIVERSITY OF NEW JERSEY". A large, faint, circular seal of Rutgers University is visible in the background, centered behind the text. The seal contains the text "RUTGERS UNIVERSITY" and "THE STATE UNIVERSITY OF NEW JERSEY" around its perimeter, with a central emblem.

RUTGERS

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OF NEW JERSEY

**What changes – if any – have
occured in your practice
environment in light of these
cases?**

Examples of Pharmacy Lawsuit Advertisements

- “You may have suffered from 24-48 hours of vomiting, headaches, nausea, sleeplessness, diarrhea or any combination of these symptoms. Many of our prospective clients question whether it's worth their time to pursue a pharmacy error claim. However, these claims can have many benefits.”
- “The standard defense in a pharmacist malpractice case is that it only has an obligation to fill a prescription accurately. This argument flies in the face of current pharmaceutical education and training which stresses that a pharmacist is a professional with professional obligations. There is no question that the pharmacists themselves have recognized that the scope of their responsibilities is expanding. The courts are beginning to recognize this and to hold that failure to meet this expanding responsibility constitutes pharmaceutical negligence.”

Elements of a Negligence Case

- A. Duty
- B. Standard of Care
- C. Breach
- D. Cause in Fact
- E. Proximate Cause
- F. Damages
- G. Vicarious Liability
- H. Joint and Several Liability

Damages

1. Mental Pain and Suffering
2. Physical Pain and Suffering
3. Medical Expenses
4. Lost Wages and Future Earnings
5. Child Care Costs
6. Loss of Consortium
7. Negligent Infliction of Emotional Distress
8. Punitive

Lessons to be Learned

- Medication errors probably cannot be completely eliminated, but utilizing best practices can greatly reduce them.
- Medication errors are a common subject of litigation and can carry both civil and administrative penalties. In rare circumstances they may also carry criminal penalties.
- Professional Liability insurance – both employer and individual should obtain

Laws and Regulations Impacting Practice

- All licensed pharmacy practice sites (licensed in NJ) shall report to the board the occurrences of any of the following:
 - Any pharmacy malpractice liability insurance claim settlement, judgment or arbitration award in excess of \$10,000 to which an owner, an employee of, or the pharmacy practice site itself is a party;

N.J.S.A. 45:14-74

Laws and Regulations Impacting Practice (cont.)

- Many states have established tort reform provisions that raise the bar for patients who sue health professionals. One such provision is the requirement that a lawsuit against a health professional be filed with an **affidavit of merit** signed by a qualified expert who verifies that malpractice has occurred.
- Where required, the failure to timely serve an appropriate Affidavit of Merit can be fatal to the case, and, can result in the case being dismissed.

Laws and Regulations Impacting Practice (cont.)

- In NJ, Public Law 2013, Chapter 46 is also known as the “Overdose Prevention Act” (the Act).
- The Act provides immunity for civil and criminal liability for non-health care professionals who administer in an emergency naloxone hydrochloride, or any other similarly acting drug approved by the United States Food and Drug Administration, to a person believed in good faith to be experiencing an opioid overdose.
- The Act also provides civil, criminal, and professional disciplinary immunity for health care professionals and pharmacists involved in prescribing or dispensing the opioid antidote in accordance with the Act.

Laws and Regulations Impacting Practice (cont.)

- A pharmacist who meets the experience requirements and who is employed by or otherwise affiliated with a facility shall be permitted to enter into a written agreement or protocol with a physician authorizing **collaborative drug therapy management**
- Collaborative drug therapy management shall mean the performance of services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or disease state, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with the policies, procedures, and protocols of the facility.

Laws and Regulations Impacting Practice (cont.)

- Collaborative Practice (cont.)
- Adjusting or managing a drug regimen of a patient, pursuant to a patient specific written order or protocol made by the patient's physician, which may include **adjusting drug strength, frequency of administration or route of administration**. Adjusting the drug regimen shall not include substituting or selecting a different drug which differs from that initially prescribed by the patient's physician unless such substitution is expressly authorized in the written order or protocol. The pharmacist shall be required to immediately enter into the patient record any change or changes made to the patient's drug therapy and shall use any reasonable means or method established by the facility or the department to notify any of the patient's other treating physicians with whom he or she does not have a written agreement or protocol regarding such changes. The patient's physician may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist;
- Evaluating and, only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, **ordering clinical laboratory tests related to the drug therapy management for the specific disease or disease state** specified within the protocol; and
- Only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, **ordering or performing routine patient monitoring functions as may be necessary in the drug therapy management, including the collecting and reviewing of patient histories, and ordering or checking patient vital signs, including pulse, temperature, blood pressure and respiration.**

Laws and Regulations Impacting Practice (cont.)

- Collaborative Practice laws expand the scope of traditional pharmacy practice
- Pharmacist engaging in collaborative practice should confirm that professional liability insurance will cover such activities

Laws and Regulations Impacting Practice (cont.)

- Audit trail applies to each step of prescription handling
 - Intake
 - Processing
 - Fulfillment
 - Dispensing
- ❑ All Entries to the audit trail made by a pharmacy technician, intern, or extern shall be reviewed and approved by the pharmacist;
- ❑ Audit trail documentation shall be generated at the time each function is performed
- ❑ If more than one R.Ph. involved, the unique identifier of R.Ph. responsible for the accuracy and appropriateness of each function must be recorded

N.J.A.C. 13:39-4.19; 7.6

What role do pharmacy technicians play in medication error prevention?

What tasks, according to regulations, may technicians perform?

Laws and Regulations Impacting Practice (cont.)

A pharmacy technician may:

- Retrieve prescription files, patient files and profiles, and other pharmacy records
- Enter data
- Prepare labels
- Count, weigh, measure, pour and compound prescription medications
- Fill automated systems
- Accept authorization for renewals and requests for refills
 - Provided that the prescription remains unchanged
 - The pharmacy technician or applicant shall identify him/herself as a pharmacy technician when accepting authorization from a physician or his/her agent

N.J.A.C. 13:39-6.15

Laws and Regulations Impacting Practice (cont.)

A pharmacy technician may not:

- Receive new verbal prescriptions
- Interpret a prescription or medication order for therapeutic acceptability and appropriateness
- Verify dosage and directions
- Engage in prospective drug review
- Provide patient counseling
- Monitor prescription usage
- Override computer alerts without first notifying pharmacist
- Transfer prescriptions from one pharmacy to another pharmacy
- Violate patient confidentiality

Laws and Regulations Impacting Practice (cont.)

Pharmacists shall not supervise more than 2 pharmacy technicians unless...

- Written job descriptions, task protocols, and policies and procedures regarding technician duties to perform
- Each pharmacy technician passes the National Pharmacy Technician Certification Examination (or a board approved certification program) AND fulfills the requirements to maintain this status
 - OR completes a program that includes a testing component that has been approved by the board

Laws and Regulations Impacting Practice (cont.)

- Greater number of Board of Pharmacy inspections focusing on Patient Profiles
- Recommend random self-audits
- Verify Information
- Maintaining accurate and complete profiles helps reduce medication errors

Laws and Regulations Impacting Practice (cont.)

- The following information shall be recorded in the profile system (N.J.A.C. 13:39-7.19):
 - Family name and first name;
 - Address and telephone number;
 - DOB;
 - Original or refill date the medication is dispensed;
 - Prescription number;
 - The practitioner's name;
 - Name, Strength, and Quantity of the drug dispensed;
 - Pharmacist's comments relevant to the patient's drug therapy; and
 - Any allergies
 - If no allergies, then that must be documented

Laws and Regulations Impacting Practice (cont.)

- “All prescription patients who patronize a pharmacy shall have a profile record . . . and ***the pharmacist shall inquire as to whether other prescription drugs are being concomitantly utilized*** in order to establish a current drug history for the patient.”

Id.

What are some strategies and safeguards that have been implemented in your practice environment to reduce medication errors?

Preventing Medication Errors: Use of Best Practices

- Use of technology – electronic prescribing (e-prescribing)/ complete patient profiles
- Identification of possible causes for errors
 - Encourage error reporting through formal process
 - Evaluate errors when they occur for systemic flaws
- Proper staffing (sufficient number and quality)
- Address environmental factors (lighting, clean work area, etc.)
 - Implement work flow process
- Patient education – counseling
- Quality assurance – self auditing
- Use of qualified wholesalers

Preventing Medication Errors: Use of Best Practices (cont.)

- Importance of documenting actions including phone calls to M.D.
- Inventory controls
 - Routine checks for expired medication
 - Purging the “Will Call Bin”
 - Separate look alike/ sound alike medications
- Educate employees
 - Not limited to those within the pharmacy department
 - Downstream activities (i.e. drivers) should be included
- Written Policies and Procedures

Overview: Benefits of E-Prescribing

- Gives providers an important tool to safely and efficiently manage patient's medications
- E-prescribing improves:
 - Medication safety
 - Better management of medication costs
 - Prescribing accuracy and efficiency
 - Increase practice efficiency while improving quality of care
 - Reduce healthcare costs through the reduction of ADRs and increased prescribing of generic meds

Greater Efficiency

- On average, it takes 20 more seconds per patient to enter an e-prescription compared to actually writing a prescription
- BUT, time is offset by the time saved from less need for clarification of e-prescriptions
- At the pharmacy, e-prescriptions produce less paperwork and fewer issues that need to be resolved

Improved Patient Safety

- E-prescribing makes prescriptions more legible
- Decreases the time needed to prescribe and dispense medications
- Reduce medication errors
 - Study conducted at 12 community-based practices found that error rate dropped from 42.5 to 6.6 per 100 prescriptions one year after adopting e-prescription transmission
 - A prospective study of 17 physicians in an ambulatory clinics: error rate decreased from 35.7 to 12.2 per 100 prescriptions after one year of e-Rx

Cost Savings and Patient Adherence

- Cost savings due to improved patient outcomes and decreased patient visits are estimated to be between \$140 billion and \$240 billion over 10 years for practices that implement e-prescribing
- A study from 2008 to 2010 found a 10 percent increase in prescriptions picked up when e-prescribed is utilized compared to written prescription

Porterfield A., Engelbert K., Coustasse A. Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting. Perspectives in Health Information Management. 2014.

What is happening with medication error reporting and electronic prescribing in New York state?

Key Terms Under NY Law

- ▶ **Electronic prescriptions:** a prescription created, recorded or stored by electronic means; issued and validated with an electronic signature; and transmitted by electronic means.
See 8 NYCRR § 63.6
 - Transmission directly between physician and pharmacy

- ▶ **Electronic signature:** an electronic sound, symbol, or process, attached to or logically associated with an electronic prescription, executed or adopted by a person with the intent to sign the prescription, and effectively secured from alteration by an unauthorized third party. Id.

Key Terms (cont.)

- ▶ **Transmission of an electronic prescription:** A pharmacist may, based upon his or her professional judgment, accept an electronic prescription from a prescriber, **to the pharmacy of the patient's choice**, subject to the following requirements:
 - (a) The prescription shall contain the **electronic signature** of the prescriber;
 - (b) In the case of an electronic prescription, such prescription shall be **electronically encrypted**, meaning protected to prevent access, alteration or use by any unauthorized person;
 - (c) an electronic prescription or a hard copy of an electronic prescription stored securely and permanently shall be maintained at the pharmacy **for a period of five years from the date of the most recent filling**, provided that, if the prescription is maintained electronically, it shall be made available to the Department in hard copy upon request.

Key Terms (cont.)

- ▶ Transmission of an electronic prescription (cont.)
 - Except when the prescriber inserts an electronic direction to dispense the drug as written, **the prescriber's electronic signature shall designate approval of substitution by a pharmacist** of a drug product pursuant to section 206(1)(o) of the Public Health Law.
 - Notwithstanding any other provision of this section or any other law to the contrary, **when a generic drug is not available** and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required.
 - **If the generic drug product is not available and a medical emergency exists**, which for purposes of this section shall be defined as a condition requiring the alleviation of severe pain or a condition which threatens to cause disability or death if not promptly treated, the pharmacist may dispense the brand name product at the regular price. In such instances, the pharmacist shall record the date, hour and nature of the medical emergency on the back of the prescription or within the electronic record of the prescription and shall keep a hard copy or electronic record of all such prescriptions;

Key Terms – Summary

- An electronic prescription is a prescription that is:
 - Created, recorded, transmitted or stored by electronic means;
 - Issued and validated with the prescriber's electronic signature;
 - Electronically encrypted to prevent unauthorized access, alteration or use of the prescription; and,
 - Transmitted electronically directly from the prescriber to a pharmacy or pharmacist.

Key Terms – Summary

- Emailed prescriptions are **NOT** considered electronic prescriptions since EMAIL is not considered a secure method of electronically transmitting a prescription.
- A faxed prescriptions are **NOT** considered an electronic prescription.
- A prescription generated on an electronic system that is printed out to the Official New York State Prescription form or faxed is **NOT** an electronic prescription.

Key Terms – Summary

- ▶ Electronic prescription computer technology must comply with federal and New York regulations.
- ▶ These regulations require prescribers and pharmacists to have a secure (encrypted and encoded) system for electronic transmission of the prescription from computer to computer in order to protect the confidentiality and security of patient information.
- ▶ Electronic prescribing computer applications must also be “certified” (i.e., audited by an organization or certified by the federal Drug Enforcement Agency to ensure it meets technical standards acceptable to federal government).

Mandatory E-Prescribing

- Notwithstanding any other provision of this section or any other law to the contrary, . . . no practitioner shall issue any prescription in this state, unless such prescription is made by electronic prescription from the practitioner to a pharmacy, except for prescriptions: (a) issued by veterinarians; (b) issued or dispensed in circumstances where electronic prescribing is not available due to temporary technological or electrical failure, as set forth in regulation; (c) issued by practitioners who have received a waiver or a renewal thereof for a specified period determined by the commissioner of health, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the commissioner of health, in consultation with the commissioner due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner; (d) issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subdivision, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition, provided that if such prescription is for a controlled substance, the quantity that does not exceed a five day supply if the controlled substance was used in accordance with the directions for use; or (e) issued by a practitioner to be dispensed by a pharmacy located outside the state, as set forth in regulation.

Update to New York Requirements

- Governor Andrew Cuomo has signed legislation into law extending the deadline for required e-prescribing of medications for one year, to **March 27, 2016 (now in effect)**.
- All prescribers should continue to diligently establish their e-prescribing capability as required by the law so that they will be in compliance by the new effective date (March 27, 2016).

Mandatory E-Prescribing (cont.)

- ▶ Effective March 27, 2016, a new law requires nurse practitioners, midwives, dentists, podiatrists, physicians, physician assistants and optometrists in New York State ("prescribers") to issue prescriptions electronically directly to a pharmacy, with limited exceptions.
- ▶ The new law requires electronic prescribing for all types of medications (controlled substances and non-controlled substances) and for syringes and other medical devices dispensed at a pharmacy in New York.
- ▶ Does not apply to non-prescription items

Mandatory E-Prescribing (cont.)

- Official New York State Prescription forms may be used in the event of a power outage or technical failure, or by practitioners who meet one of the exceptions.
- Prescription written on an Official New York State Prescription form prior to the effective date of the statute are still acceptable.
- Same applies to refills.

Mandatory E-Prescribing (cont.)

- Official New York State Prescription forms received after March 27, 2016
 - Pharmacists are not required to verify that the practitioner properly falls under one of the exceptions from the requirement to electronically prescribe;
 - However, a **corresponding liability** for the proper prescribing and dispensing of controlled substances rests with the pharmacist who fills the prescription.

Why is NYS going Mandatory?

- ▶ New York Education Law Article 137 §6810 requires that all prescriptions be transmitted electronically two years from the Department of Health's promulgating regulations allowing for the electronic prescribing of controlled substances. These regulations became effective on March 27, 2013.
- ▶ Utilizing modern prescription technology has the potential to minimize medication errors for patients in New York State.
- ▶ Electronic prescribing also allows for the integration of prescription records directly into the patient's electronic medical record.
- ▶ Electronic prescribing has the potential to reduce prescription theft and forgery.

Mandatory E-Prescribing (cont.)

- ▶ The law will not require a prescriber to issue a prescription electronically when:
 - Veterinarians
 - Electronic prescribing is not available due to temporary technological or electronic failure;
 - **The prescriber has a waiver granted by the New York State Commissioner of Health;**
 - The prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner; or,
 - **The prescription will be dispensed at a pharmacy located outside New York State.**

Mandatory E-Prescribing (cont.)

- Waivers
 - Practitioners may apply for a waiver from the requirement to electronically prescribe controlled substances.
 - Waivers will be granted upon a proper showing of economic hardship, technological limitations outside of the practitioner's control or other exceptional circumstances.
 - By statute, waivers are good for one year, after which a practitioner may apply for a renewal.

Mandatory E-Prescribing (cont.)

- Non-resident pharmacies registered with the New York State Board of Pharmacy must register their certified pharmacy software application with NYS DOH/Bureau of Narcotic Enforcement (BNE) to receive electronic prescriptions for controlled substances.

Mandatory E-Prescribing (cont.)

- ▶ Prescribers must personally generate and transmit electronic prescriptions to pharmacies or pharmacists and are **not legally allowed to delegate this responsibility to other individuals.**
- ▶ Electronic prescriptions must include the same information that written prescriptions do except that:
 - All electronic prescriptions must include an NPI number;
 - Electronic prescriptions must be electronically signed; and
 - The prescriber must specify whether a prescription must be dispensed as written, if a brand-name product is therapeutically required.

**How will these changes in
prescription transmission in New
York influence your practice?**

Implications for Pharmacies

- The New York model may be adopted by other states.
- Even if not required by statute, pharmacies are filling an increased number of e-prescriptions.
 - By April 2014, all states had physicians e-prescribing using an EHR at a rate above 40 percent and 28 states had at least 70 percent of their physicians e-prescribing using an EHR.
(<https://www.healthit.gov/sites/default/files/oncdataabriefe-prescribingincreases2014.pdf>)
 - As of April 2014, every state has at least nine in ten community pharmacies enabled to accept e-prescriptions. Id.

Implications for Pharmacies (cont.)

- Prescribers and pharmacists must have a secure (encrypted or encoded) system for electronic transmission from computer to computer.
- Any equipment used for electronic transmission of prescriptions must be so located to ensure the security and confidentiality of the transmission.
- **Procedures for electronic transmission of prescriptions should be documented.**

Implications for Pharmacies (cont.)

NY Board of Pharmacy Guidance

- ▶ Electronically transmitted prescriptions must:
 - Contain the electronic signature of the prescriber
 - Shall be electronically encrypted to prevent unauthorized access, alteration or use
 - Have the signature or initials of the pharmacist or pharmacy intern entered into the pharmacy's records to indicate acceptance of the prescription by the pharmacy.
- ▶ The information retained electronically should be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.

Implications for Pharmacies (cont.)

- ▶ All records required under laws, rules and regulations administered by the NY Education Department may be maintained in an electronic format. At this time, certain records for controlled substances and for programs such as Medicare may have additional, hard-copy requirements. Pharmacists should check with these programs directly for specific requirements.
- ▶ Pharmacists and pharmacy interns may sign and initial prescriptions and other required records in an electronic format

Implications for Pharmacies (cont.)

- A hard copy is not required to be maintained as long as the electronic prescription is securely stored and maintained. The same applies to refills.
- Similar to other records, the electronic records must be maintained for five (5) years and must be reproducible in hard copy and provided to the NY Department of Education upon demand.

Implications for Pharmacies (cont.)

- Pharmacies may accept an electronic prescription that contains an electronic signature and an electronic DAW. See NY CLS Educ § 6810
- Facsimile (fax) prescription are not considered an electronic prescription. See NY CLS Educ § 6802

Implications for Pharmacies (cont.)

- Patients have the right to choose the pharmacy where they wish to have their prescription(s) filled. Practitioners who exert undue influence on a patient (known as steering) to have a prescription filled at any one pharmacy over another whether electronically transmitted or via a written or oral prescription are subject to charges of unprofessional conduct.

Implications for Pharmacies (cont.)

- ▶ If a prescriber cannot legally order the prescription based upon the prescriber's scope of practice, the pharmacist must not fill the prescription.
- ▶ Each pharmacist must practice according to his or her best professional judgment and the law. If there are concerns that a prescription can cause harm to a patient, a pharmacist may contact the prescriber. If a pharmacist believes that a prescription can cause harm to a patient, even after discussion with the prescriber, the pharmacist can choose not to fill the prescription.

Implications for Pharmacies (cont.)

- ▶ Pharmacists are responsible for assuring the validity of all written, oral and electronic prescriptions.
- ▶ There are a number of ways to do this, such as using new software programs that require a password; personal identification numbers (PINs) or other authentication of the prescriber. These programs also notify the pharmacist if an encrypted or encoded electronic message or "envelope" has been tampered with or altered.
- ▶ If a pharmacist has reason to question the authenticity of an electronic prescription, **the pharmacist's professional judgment must prevail**. If verification is not possible, the pharmacist can choose not to accept the electronic prescription and can request transmission by another means from the prescriber.

**What industries are most
susceptible to cybersecurity
threats?**

**Does your environment have any
vulnerabilities to electronic
attacks?**

Cybersecurity at the Pharmacy

- According to the Identity Theft Resource Center, 3 years ago the rate of cyber-attacks in healthcare in terms of the percentage of total data records breached was at 9.6%, two and a half times higher than in the credit and finance industry and more than 10 times than in banking.
- With more healthcare organizations moving from paper records to online, the risk of cyber-crimes has risen.
- Community pharmacies and other small businesses are targets for criminals who are out to profit from stolen merchandise, medical identities or credit cards.

Cybersecurity Concerns

- Healthcare and pharmaceutical companies have the worst cyber security among Standard & Poor's (S&P) 500, and could suffer from large-scale security breaches in 2014 similar to those experienced by retail companies such as Target and Neiman Marcus, according to a recent report.
- BitSight Technologies, a securities ratings company, examined the cyber health of companies on the S&P 500, and found that 82% had been victims of some sort of security breach. Healthcare and pharmaceutical companies ranked the lowest among the four industry categories studied, because of its high volume of incidents and slow response times.

Examples of Sensitive Information

- Electronic Protected Health Information (ePHI)
- Name
- Address (smaller than state)
- Birth Date and exact age
- Telephone or Fax number
- Email address
- Social Security number
- Medical record or Health Plan Beneficiary Numbers
- Any other characteristic that could uniquely identify the individual (Dr's Appointment emails, Invoices etc.)

Cybersecurity at the Pharmacy cont.

- In February 2015, Anthem, the second-largest health insurer in the United States, announced that it was hit by a massive cyberattack.
- While the attack does not appear to involve medical or financial information, the company said hackers were able to obtain names, birthdays, Social Security numbers, street and email addresses, and employment information for current and former consumers and employees.
- Anthem did not say how many people were affected by the data breach; however, it is suspected that the records of tens of millions of people were breached. As of year-end 2014, Anthem had nearly 40 million medical members.

Anthem, a major health insurer, suffered a massive hack. Here's what you need to know. Robert Hackett 2/5/2015

Potential Vulnerabilities

- Software Security
 - Practitioner and Pharmacy Systems
- False authentication
 - E-Signatures
- Network Security
- Physical Security
 - Passwords

Potential Costs

- A data breach costs, on average, a total about \$80,000 per pharmacy location. Once a data breach is detected, a forensic audit is necessary, at a price tag of between \$20,000 and \$30,000. <http://drugtopics.modernmedicine.com/drug-topics/news/six-tips-protecting-your-pharmacy-data-breaches>
- Loss of business
 - Credit cards
 - Good will

Cybersecurity Concerns

- The U.S. Senate passed the Cybersecurity Information Sharing Act.
- Offering companies legal immunity when sharing threat data with the federal government, the bill has big implications for healthcare data privacy and security.
- The bill would enable a voluntary information sharing system that would be managed by the Department Homeland Security. If an organization were to detect unusual or questionable activity on its networks, it could share that information with DHS, which would then put out alerts to other companies

Cybersecurity Concerns

- Most pharmacies rely on their software companies to ensure that they are in compliance with privacy regulations.
- Additionally, pharmacies often contract with outside vendors to submit insurance claims. In the age of e-prescribing, pharmacies may also utilize vendors to receive and process e-prescriptions.
- However, the ultimate responsibility for cyber-security rests with the pharmacy. Accordingly, it is important that pharmacies conduct due diligence to ensure that its vendors also have proper cyber security measures put in place.
- These business associates are also required to have contracts with the pharmacies to address electronic data that they receive. The department of Health and Human Services provides guidance for covered entities (health plans, health care providers, healthcare clearinghouses) and their business associates on requirements for protecting ePHI.

Cybersecurity Concerns

- In addition to ensuring that its vendors have adequate security measures, the pharmacy must also implement internal controls.
 - Pharmacies are responsible for recognizing areas of potential security risk such as hard drives, laptops, or other portable devices that may contain ePHI and these devices should be secured and encrypted.
- Pharmacies must also implement physical access controls to ensure that there is limited access to workstations that contain ePHI as well as technical safeguards (e.g. unique user ID's and passwords for all individuals with access ePHI). Pharmacies are also required to provide training for their employees on appropriate handling of ePHI.

Impact of E-Prescribing on Drug Diversion

- On March 31, 2010, the DEA published an Interim Final Rule with Request for Comment entitled “Electronic Prescription for Controlled Substances” (EPCS) in the Federal Register.
- This set of regulations, which became effective June 1, 2010, aimed to “provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances”

Impact of E-Prescribing on Drug Diversion

- Corresponding liability and responsibility
- Valid prescription vs. legitimate medical purpose
- Issues not addressed by e-prescribing
- Signs of Diversion
- Internet System for Tracking Over-Prescribing - Prescription Monitoring Program (“ISTOP-PMP”)