

E-Prescribing: Pharmacy Practice in the Digital Age & Cybersecurity Concerns

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Disclosures

- ▶ The speakers have no financial interest or relationships to disclose.

Objectives

- Define key terms related to e-prescribing
- Discuss the impact of e-prescriptions on medication error rates
- Describe cybersecurity concerns in light of increase in e-prescriptions
- Explain state and federal regulations regarding e-prescribing
- Identify state and federal regulations regarding the filling of e-prescriptions for CDS

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 Frameworks in Healthcare, Part 2. Jeff Kabachinski, January 15, 2016

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

E-Prescribing & Cybersecurity

- 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”

Electronic Prescription for Controlled Substances: A Cybersecurity Perspective, Samuel Tan, Rebecca Shapiro, Sean W. Smith

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

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

Effect on Medication Errors: Systematic Review

- Twenty-five studies reported on the risk of medication errors. Twenty-three of these studies showed a significant relative risk reduction, with a risk ratio between 0.01 and 0.87. This indicates a relative risk reduction for medication errors of 13% to 99%.
- Only analyzed those errors that were reported by the staff members themselves (voluntary reporting system)—this constitutes a potential detection bias.

Effect on Medication Errors: Systematic Review (cont'd)

Sub-Group Analysis:

- Seven studies compared advanced electronic prescribing with limited electronic prescribing and 18 studies compared electronic prescribing with handwritten ordering
 - Results showed a higher relative risk reduction for the comparison made between advanced electronic prescribing and handwritten ordering.
- The 14 studies with an advanced decision-support reported a higher relative risk reduction than the 11 studies with limited or no decision-support.
- The sub-group analysis comparing different methods to detect errors showed higher relative risk reductions with the manual chart review of prescriptions (11 studies) than with the automatic database analysis of prescriptions (6 studies).

Effect on Adverse Drug Events: Systematic Review

- Four out of seven studies showed a significant relative risk reduction for ADEs (RR between 0.16 and 0.70). This indicates a relative risk reduction for ADEs of 30% to 84%.
- Shulman (2005) – excluded because there was no event in either the intervention group or the comparison group.
- Mullett (2001) – non-statistically significant relative risk reduction of 13%.
- Bates (1998) – small, non-statistically significant increase of 9%.

Effect on Potential Adverse Drug Events: Systematic Review

- Six out of nine studies showed significant relative risk reduction (RR between 0.02 and 0.65). This indicates a relative risk reduction for potential ADEs of 35% to 98%.
- Two studies showed inconclusive effects (Bizovi 2002 and Gandhi 2005).

Key Terms

- ▶ **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).

Why E-Prescribing?

- ▶ The current system of prescribing and dispensing medications in the United States has widespread problems with safety and efficiency.
- ▶ Experts predicted that a shift to electronic prescribing (e-prescribing) systems could avoid more than 2 million adverse drug events annually, of which 130,000 are life-threatening.
- ▶ E-prescribing also has enormous potential to create savings in health care costs, through reduction of adverse drug events and in improved workflows.
- ▶ One study estimated the potential savings at \$27 billion per year in the United States.

Why E-Prescribing? (cont.)

- Because of e-prescribing's potential to reduce errors and costs, Congress mandated the establishment of standards for the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

MMA & E-Prescribing

- ▶ E-Prescribing is a prescriber's ability to electronically send an **accurate, error-free and understandable prescription** directly to a pharmacy from the point-of-care - is an important element in improving the quality of patient care.
- ▶ The inclusion of electronic prescribing in the Medicare Modernization Act (MMA) of 2003 gave momentum to the movement, and the July 2006 Institute of Medicine report on the role of e-prescribing in reducing medication errors received widespread publicity, helping to build awareness of e-prescribing's role in enhancing patient safety.
- ▶ Adopting the standards to facilitate e-prescribing is one of the key action items in the government's plan to expedite the adoption of electronic medical records and build a national electronic health information infrastructure in the United States.
- ▶ The MMA created a new voluntary prescription drug benefit under Medicare Part D. Although e-prescribing will be optional for physicians and pharmacies, Medicare Part D will require drug plans participating in the new prescription benefit to support electronic prescribing.

MMA & E-Prescribing (cont.)

- On November 7, 2005, CMS published the first set of adopted standards known as the foundation standards. The foundation standards became effective on January 1, 2006. These standards apply to all electronic prescribing done under Part D of the MMA.
- MMA required CMS to implement pilot projects to test additional standards. These additional standards were pilot tested in 2006.

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2008-Press-releases-items/2008-04-02.html>

MMA & E-Prescribing (cont.)

- ▶ The final E-Prescribing rule was published at the Federal Register on April 7, 2008. The final rule provides three electronic tools for use in E-Prescribing:
 - **NCPDP Formulary and Benefit Standard Implementation Guide Version 1.0**: gives prescribers information about which drugs are covered by a Medicare beneficiary's prescription drug benefit plan.
 - **NCPDP SCRIPT 8.1 Medication History Transactions**: provides prescribers with information about medications a beneficiary is already taking, including those prescribed by other providers, to help reduce the number of adverse drug events.
 - **Fill Status notifications** (RxFill): allows prescribers to receive an electronic notice from the pharmacy telling them that a patient's prescription has been picked up, not picked up, or has been partially filled, to help monitor medication adherence in patients with chronic conditions.

<https://healthit.ahrq.gov/sites/default/files/docs/page/08-1094.pdf>

MMA & E-Prescribing (cont.)

- ▶ Section 132 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorized a new and separate incentive program for eligible professionals who are successful electronic prescribers (e-Prescribers) as defined by MIPPA.
- ▶ The program began January 1, 2009 and provides incentives for eligible professionals who are "successful e-prescribers".
- ▶ 2013 was the final program year for participating and reporting in the Medicare Electronic Prescribing (eRx) Incentive Program.

MMA & E-Prescribing (cont.)

▶ Successful Electronic Prescriber

- The eligible professional reported the applicable e-prescribing quality measure (e.g., e-prescribing measure # 125) in at least 50 percent of the cases in which such measure is reportable by the eligible professional during the reporting year; or
- The eligible professional electronically submitted a sufficient number of prescriptions (as determined by the Secretary) under Part D during the reporting period.

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.

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.)

- ▶ 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.

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.

Electronic Prescriptions – Federal

- ▶ DEA's rule, "Electronic Prescriptions for Controlled Substances" revised DEA's regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule was published in the Federal Register Wednesday, March 31, 2010 and became effective on June 1, 2010.

Electronic Prescriptions – Federal (cont.)

- A pharmacy will be able to process electronic controlled substance prescriptions only when the application the pharmacy is using to process prescriptions complies with the requirements in the interim final rule.

Electronic Prescriptions – Federal (cont.)

- ▶ The application requirements are detailed in 21 C.F.R. 1311.205.
- ▶ Generally, the application must be able to import, display, and store the required contents of a controlled substance prescription accurately and consistently.
- ▶ The application must be able to digitally sign and archive the controlled substance prescription or import and archive the record that the last intermediary digitally signed.
- ▶ The application must electronically accept and store all of the information that DEA requires to be annotated to document the dispensing of a prescription.

Electronic Prescriptions – Federal (cont.)

- ▶ The application must allow the pharmacy to limit access for the annotation, alteration (to the extent such alteration is permitted by DEA regulations), or deletion of controlled substance prescription information to specific individuals or roles.
- ▶ The application must have an internal audit trail that documents whenever a prescription is received, altered, annotated, or deleted.
- ▶ The application must conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified.
- ▶ Many of these requirements are standard functionalities for pharmacy applications

E-Prescribing CDS in NYS

▶ NYS Regulations

- Providers must
 - Use software that complies with federal standards; and
 - Register software with NYS DOH/Bureau of Narcotic Enforcement (BNE)
 - The certified pharmacy software application must be registered with BNE at least every two years or whenever functionality related to controlled substance prescription requirements is altered, whichever occurs first.

E-Prescribing CDS in NYS (cont.)

▶ NYS Regulations (cont.)

- Proper safeguarding of credentials
- 5 year record retention
- Records must be readily retrievable
- Oral prescriptions may be reduced to electronic memorandum
- To meet the New York State Public Health Law data submission requirements for electronic prescribing of controlled substances, the pharmacy must submit controlled substance dispensing data to the Department of Health, Bureau of Narcotic Enforcement, using the American Society for Automation in Pharmacy (ASAP) format Version 4.2 or greater.

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”)

Statutory Responsibility

- A prescription for a controlled substance, to be effective, must be issued for a **legitimate medical purpose** by an individual practitioner acting in the **usual course of his professional practice.**

21 C.F.R. 1306.04 (2009)

Statutory Responsibility (cont.)

- The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility** rests with the pharmacist who fills the prescription. Id.

Statutory Responsibility (cont.)

- DEA imposes this “corresponding responsibility” on:
 - Physicians
 - Pharmacies
 - Pharmacists
 - Wholesalers

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.

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.

Helpful Links

- Office of Civil Rights - HIPAA Enforcement
<http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/>
- NY DOH E-Prescribing
http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/
- DEA's Final Rule on Electronic Prescriptions for Controlled Substances (EPCS)
http://www.dea diversion.usdoj.gov/ecommm/e_rx/faq/pharmacies.htm
- <http://drugtopics.modernmedicine.com/drug-topics/news/protect-your-pharmacy-against-cyber-and-physical-attacks>

Questions?

Please email any questions to the
program faculty

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