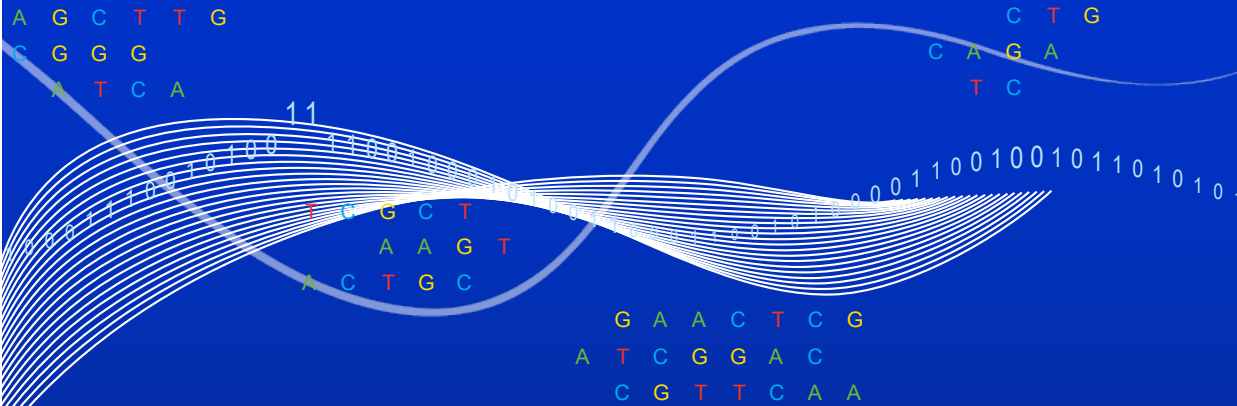


Protecting Patient Health Information A Regulatory and Technical Overview



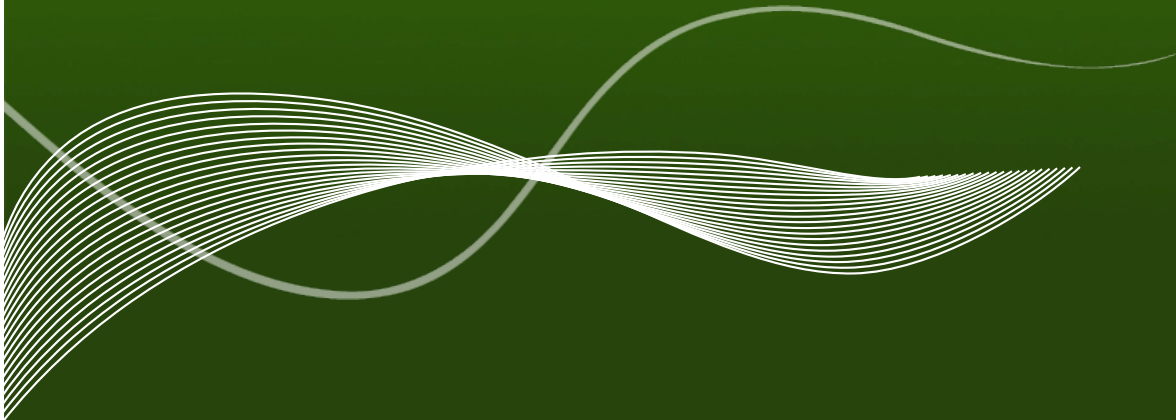
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Disclosures:

Steve Belovich is the CEO of IQware, Inc. The conflict of interest was resolved by peer review of the slide content.

Mary Jo Carden is the Director of Federal Regulatory Affairs with Medco Health. The conflict of interest was resolved by peer review of the slide content.

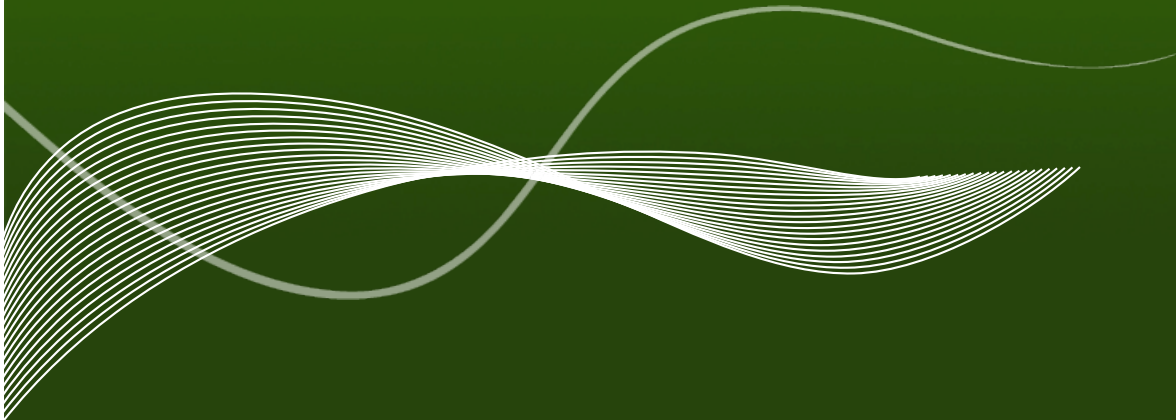
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Pharmacist Learning Objectives

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

- Describe and evaluate their electronic infrastructure.
- Outline patient data protection.
- Discuss operational continuity.
- Discuss new regulations and new technologies as they emerge.



Presentation Overview

- Review provisions from the HITECH Privacy and Security Final Rule and impact to pharmacy and pharmacy vendors
- Overview of HHS-OCR privacy and security audits
- Update on NCPDP D.0 compliance and implementation
- Overview of other legislative and regulatory efforts to protect consumer privacy and security and impact on health care vendors



The views presented do not represent those of Medco



HHS-OCR Privacy and Security Audits and Other Actions



HHS Audits for CEs & BAs

■ KPMG selected as contractor

- > Minimum of 150 random audits

■ Scope of audits for privacy and security

- > Onsite visits for all audits to meet with CIOs, privacy officers, legal counsel, and medical records/information personnel
- > Examine physical safeguards
- > Ensure policies are enacted and consistent
- > Examine compliance with regulatory requirements

HHS Audits for CEs & BAs

■ Post audit report

- > Timeline and methodology of audit
- > Best practices
- > Materials/data collected
- > Certification of completion
- > Specific recommendations for correction and a corrective plan

HHS Audits for CEs & BAs

■ Final report

- > Detailed information regarding entity and contact information
- > Methods used
- > For each finding
 - Condition: defect or noncompliant status
 - Criteria: cite privacy and security rules
 - Cause: reason for condition
 - Effect: risk or noncompliant status
 - Recommendations to address findings
 - Corrective actions by entity
 - Acknowledgement of best practices

Stepped up enforcement efforts HHS means business!

- UCLA Hospital

\$865,000

- Cignet Health

\$4.3 million

- Mass General

\$1 million

Common security rule issues

■ Administrative

- > Response & reporting
 - 179 counts
- > Awareness & training
 - 144 counts
- > Information access management
 - 126 counts

■ Technical

- > Access control
 - 141 counts

■ Physical

- > Workstation security
 - 84 counts

D.0 Implementation



D.0 Implementation

- Compliance date January 1, 2012
- Enforcement by CMS begins in April 2012
- Complaints must be initiated by other covered entities
- California state health system unprepared to accept claims

Legislation to protect consumer privacy and IT security



Potential new laws could result in further requirements for health care entities

- Changes to privacy's accounting for disclosures and breach might be considered
- Data security, consumer knowledge and control of online data collection top areas of focus
 - > National notification standards for breaches
 - > Policies and procedures to protect data containing personal information
 - > More consumer notices for breach
 - > More information for consumers to track information collected and used online
 - > Standards of conduct for entities that capture and use individually identifiable information online

De-Identified Data after *Sorrell v IMS Health*



Impact of *Sorrell v IMS Health*

- Supreme Court struck down VT law that bans transmission of de-identified data from pharmacies to physicians
- Unconstitutional restraint on commercial speech
- Other states may seek more narrowly tailored laws or federal legislation could result