

Privacy & Security in Health IT

November 17, 2015







Agenda

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- Learning Objectives
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 - Applicable State and Federal Regulations
 - Consequences of Non-Compliance
- Myths and Facts
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- Common Issues/Trends
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Introductions







BluePrint Healthcare IT

- BluePrint Healthcare IT is a recognized leader in healthcare IT security, privacy, audit readiness, and compliance (S-PAC). Our security services provide a disciplined, standardsbased approach to patient and business-centered IT security and privacy risk management.
- BluePrint Healthcare IT is a firm dedicated solely to the healthcare industry, hospitals, health systems, ACOs, payers, and the business associate community. We have been able to anticipate the needs and trends for healthcare IT security, privacy and compliance to build solutions and services that are anticipatory and relevant. We have been leaders, nationally and locally, contributing thought leadership and practical tools for the industry, and contribute to national and regional working groups within HIMSS, HITRUST and eHealth Initiative.



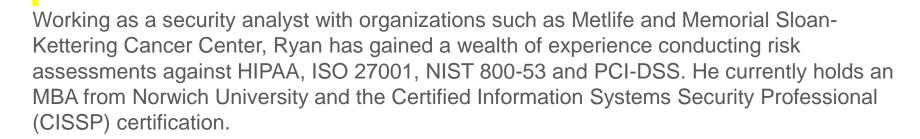




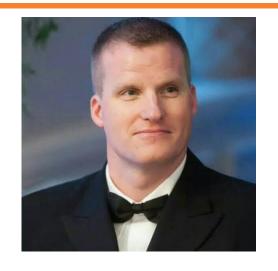
Bio – Ryan Patrick

Ryan Patrick is the Director of BluePrint Healthcare IT's Security, Privacy, Audit Readiness and Compliance services. With 14 years of experience in all facets of security and information technology for both the public and private sectors, Ryan brings an innovative perspective in protecting information and organizational resources.

Prior to joining BluePrint, Ryan served as the Deputy Chief Information Officer for the New York State Division of Military and Naval Affairs. In that position, he led an effort to prepare for the Defense Information Systems Agency's (DISA) Command Cyber Readiness Inspection which includes assessing several key areas: the entity's overall information security program, the classified and unclassified networks and the digital and physical assets used to support them.



Ryan is also a Major in the New York Army National Guard serving as the Chief Information Officer for the 42nd Infantry Division. He is combat veteran of Operation Iraqi Freedom where he received a Bronze Star Medal, Global War on Terrorism Expeditionary Medal and the Global War on Terrorism Service Medal.







Learning Objectives







Learning Objectives

This session is designed to help you:

- Appreciate why Privacy & Security are vital components of Health IT
- Recognize the consequences of non-compliance with applicable state and federal regulations
- Differentiate between Myths and Facts about Security Risk Analysis (SRA) requirements
- Understand the requirements of both the HIPAA Security Rule and the Meaningful Use
 (MU) Security Risk Analysis objective
- Identify the key components of a thorough Security Risk Analysis
- Implement a Risk Management Process in your organization







Background Information: State and Federal Regulations







Massachusetts – 201CMR17.00

This regulation establishes minimum standards to be met in connection with the safeguarding of personal information contained in both paper and electronic records.

The objectives of this regulation are:

- to ensure the security and confidentiality of customer information in a manner fully consistent with industry standards
- protect against anticipated threats or hazards to the security or integrity of such information
- protect against unauthorized access to or use of such information that may result in substantial harm or inconvenience to any consumer

- Not only Protected Health
 Information (PHI)
- Paper or Electronic forms
- Is not a breach unless used in unauthorized manner
- First Initial AND Last Name, PLUS:
 - Social Security Number
 - State-Issued ID (Driver's License, Photo ID)
 - Account Number (even without PIN)







Massachusetts – 201CMR17.00

Every person that owns or licenses personal information about a resident of the Commonwealth shall develop, implement, and maintain a comprehensive information security program that is written in one or more readily accessible parts and contains administrative, technical, and physical safeguards.

The comprehensive security program must include:

- Designating one or more employees to maintain the program
- Identifying and assessing reasonably foreseeable internal and external risks to the security, confidentiality, and/or integrity of any electronic, paper or other records containing personal information
- Developing security policies for employees relating to the storage, access and transportation of records containing personal information outside of business premises.







Massachusetts – 201CMR17.00

The comprehensive security program must include (cont):

- Imposing disciplinary measures for violations of the program rules.
- Preventing terminated employees from accessing records containing personal information
- Third-party service providers that are capable of maintaining appropriate security measures to protect such personal information
- Reasonable restrictions upon physical access to records containing personal information, and storage of such records and data in locked facilities, storage areas or containers.
- Regular monitoring to ensure that the program to prevent unauthorized access to or unauthorized use of personal information
- Reviewing the scope of the security measures at least annually or whenever there
 is a material change in business practices
- Mandatory post-incident review of events and actions taken, if any, to make changes in business practices relating to protection of personal information.







Massachusetts 201CMR17.04

The comprehensive information security program must ensure the establishment and maintenance of a security system covering its computers, including any wireless system, that, at a minimum, and to the extent technically feasible, shall have the following elements:

- User authentication
- Access control
- Encryption (Network)
- System Monitoring
- Encryption (Media)
- Patch Management (Internet-facing)
- Malware
- Education







Massachusetts 201CMR17.00 Breach Notification

"A person who owns or licenses personal information knows or has reason to know of (1) a security breach, or (2) that the personal information of a Massachusetts resident was acquired or used by an unauthorized person or for an unauthorized purpose, that person must notify the Attorney General and the Office of Consumer Affairs and Business Regulation."

* Consumer Affairs and Business Regulation website: http://www.mass.gov/ocabr/data-privacy-and-security/data/requirements-for-security-breach-notifications.html

The notifications to the Office of Consumer Affairs and Business Regulation and to the Attorney General must include:

- A detailed description of the nature and circumstances of the breach of security or unauthorized acquisition or use of personal information;
- The number of Massachusetts residents affected as of the time of notification;
- The steps already taken relative to the incident;
- Any steps intended to be taken relative to the incident subsequent to notification; and
- Information regarding whether law enforcement is engaged investigating the incident.







Federal Law/Regulations

Applicable Federal Law and/or Regulations include:

- HIPAA
- HITECH
- OMNIBUS







^{*}Systems and controls should comply with most stringent requirements

HIPAA & HITECH Background

HITECH (Health Information Technology for Economic and Clinical Health): enacted on February 17, 2009.

- Part of the American Recovery & Reinvestment Act (ARRA)
- Revised HIPAA (Health Insurance Portability and Accountability Act) rule: tougher provisions for security, privacy and enforcement.
- Increased maximum penalties:
 - \$50,000 per incident
 - \$1.5M for the year (willful neglect concept)
- Reporting requirements for security breaches
 - Media outlets, US Department of Health and Human Services, victims
- Ability for state Attorney General to bring legal action against physicians and hospitals for non-compliance
- Individual Liability for criminal violations







Violations = Penalties

Violation Category	Per Violation	Maximum Penalty Per Year
Violation was not known and the organization would not have known by exercising reasonable diligence.	\$100 - \$50,000	\$1.5 M
Violations due to reasonable cause but not willful neglect.	\$1,000 - \$50,000	\$1.5 M
Violation due to willful neglect but corrected within 30 days of discovery of the violation.	\$10,000 - \$50,000	\$1.5 M
Violation due to willful neglect and not corrected within 30 days of discovery.	\$50,000	\$1.5 M







HITECH – New Provisions

- Business Associates and subcontractors are now subject to HIPAA requirements ("Chain of Trust")
- Restrictions on Research, Marketing, Fundraising, Sale of patient information
- Increased patient rights to restrict disclosure of PHI
- Business Associate Agreements must be revised to include language that covers HITECH & OMNIBUS
- Length of time information is considered PHI
- Accounting of Disclosures to include TPO (Treatment, Payment and Operations)







OMNIBUS – New Provisions

- Expanded Business Associate (BA) definition
- Third-Party Risk Assessments
- Strengthened "harm" provision
 - Assumption of harm unless proven otherwise
- Genetic Information Nondiscrimination Act (GINA)
 - Genetic information is protected under the HIPAA Privacy Rule







Background Information: Consequences of Non-Compliance







The Hard Truth!

You may be wondering...

Why are you telling me all of this?

What does this mean to me?

Why are we here?







What does a data breach cost?

The story behind the numbers

Global cost per record¹ in 2013



Global cost per incident in 2013



What it will cost you depends on a number of key factors.











Consumer

Highly regulated industries have the highest per-record cost of data breach



Energy

THIS is why we are here...



Hospitality



\$105



3 The type of attack

Malicious or criminal attacks are the leading root cause of a data breach... and result in the highest cost per record











What can save you money

Taking these actions can reduce the average per-record cost



\$14.14
Build a strong security posture



\$8.98 Involve your Business Continuity Management team



\$12.77
Develop an incident response plan



\$6.59

Appoint a Chief Information Security Officer

How well are you doing?

Study participants say there is much room for improvement in their security operations. How would you answer?



Do you have a security strategy to protect your:

Information assets?

Online presence?

IT infrastructure?

55% said

58% said

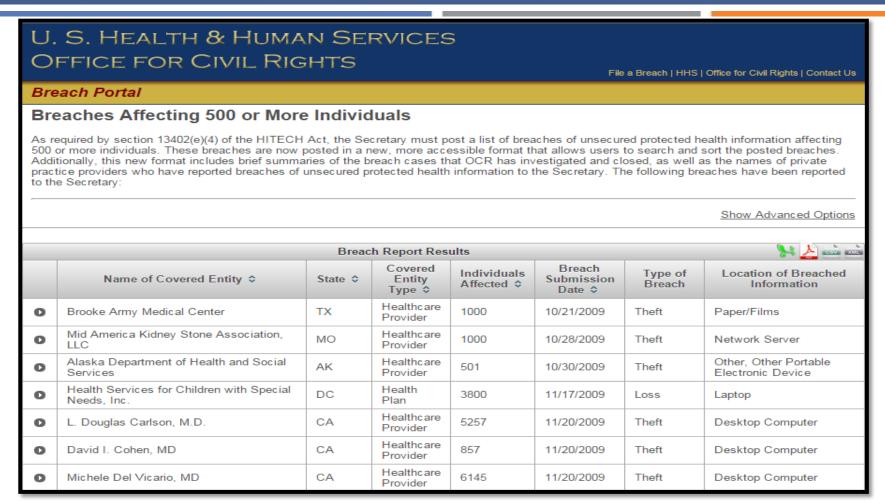
62% said







HHS Breach Notification Site



There have been 1,366 reported breaches of 500 records or more since October 21, 2009. 224 since March 2015 alone...

https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf







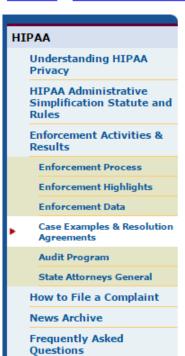
Settlements Reached with HHS

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Health Information Privacy

Office for Civil Rights Civil Rights Health Information Privacy

OCR Home > Health Information Privacy > Enforcement Activities & Results > Case Examples & Resolution Agreements



Data Breach Results in \$4.8 Million HIPAA Settlements

New York and Presbyterian Hospital

New York and Presbyterian Hospital (NYP) has agreed to pay OCR \$3,300,000 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, and will adopt a corrective action plan to evidence their remediation of these findings.

- Read the Resolution Agreement
- HHS Press Release

Columbia University

Columbia University (CU) has agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, including a \$1,500,000 monetary settlement and corrective action plan to address deficiencies in its HIPAA compliance program.

- · Read the Resolution Agreement
- HHS Press Release







Settlements Reached with HHS

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Health Information Privacy

Office for Civil Rights Civil Rights Health Information Privacy

OCR Home > Health Information Privacy > Enforcement Activities & Results > Case Examples & Resolution Agreements



HIPAA Settlement Underscores the Vulnerability of Unpatched and Unsupported Software

Anchorage Community Mental Health Services (ACMHS) has agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule with the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).ACMHS will pay \$150,000 and adopt a corrective action plan to correct deficiencies in its HIPAA compliance program.

- Read the Bulletin
- Read the Resolution Agreement







Privacy & Security Rule: Myths and Facts







Myth Fact

The security risk analysis is optional for small providers

False. All providers who are "covered entities" under HIPAA are required to perform a risk analysis. In addition, all providers who want to receive EHR incentive payments must conduct a risk analysis

Installing a certified EHR fulfills the security risk analysis MU requirement

False. Even with a certified EHR, you must perform a full security risk analysis. Security requirements address all electronic protected health information you maintain, not just what is in your EHR

My EHR vendor took care of everything I need to do about privacy and security

False. EHR vendors are not responsible for making their products compliant with HIPAA Privacy and Security Rules. It is solely your responsibility to have a complete risk analysis conducted

Myth Fact

I have to outsource the security risk analysis

False. It is possible for small practices to do risk analysis themselves. However, doing a thorough and professional risk analysis that will stand up to a compliance review will require expert knowledge

A checklist will suffice for the risk analysis requirement

False. Checklists can be useful tools, especially when starting a risk analysis, but they fall short of performing a systematic security risk analysis or documenting that one has been performed.

There is a specific risk analysis method that I must follow

False. A risk analysis can be performed in countless ways. OCR has issued Guidance on Risk Analysis Requirements of the Security Rule.

Myth Fact

My security risk analysis only needs to look at my EHR

False. Review all electronic devices that store, capture, or modify electronic protected health information. Include your EHR hardware and software and devices that can access your EHR data (e.g., your tablet, your mobile phone, etc)

I only need to do a risk analysis once

False. To comply with HIPAA, you must continue to review, correct or modify, and update security protections.

Myth Fact

Before I attest for an EHR incentive program, I must fully mitigate all risks

False. The EHR incentive program requires correcting any deficiencies (identified during the risk analysis) during the reporting period, as part of its risk management process

Each year, I'll have to rompletely redo my security risk analysis

False. Perform the full security risk analysis as you adopt an EHR. Each year or when changes to your practice or electronic systems occur, review and update the prior analysis for changes in risks

Requirements of HIPAA Security Rule and Meaningful Use







Privacy and security is the responsibility of physicians and their staff.







HIPAA Security Risk Analysis – General Categories

PHYSICAL SAFEGUARDS

- Facility Access Control
- Workstation Use
- Workstation Security
- Device and Media Controls

ADMINISTRATIVE SAFEGUARDS

- Security Management Process
- Assigned Security Responsibility
- Workforce Security
- Information Access Management
- Security Awareness and Training
- Security Incident Procedures
- Contingency Plan
- Evaluation

TECHNICAL SAFEGUARDS

- Access Control
- Audit Controls
- Integrity
- Person or Entity Authentication
- Transmission Security

POLICIES AND PROCEDURES AND DOCUMENTATION REQUIREMENTS

- Written policies and procedures to assure HIPAA security compliance
- Documentation of security measures

ORGANIZATIONAL REQUIREMENTS

- Business Associate Contracts and Other Arrangements
- Requirements for Group Health Plans







HIPAA Security Rule – Risk Management

Under the Administrative safeguards, a covered entity must:

- Establish and maintain a security management process
- Implement policies and procedures to prevent, detect, contain, and correct security violations
- Implementation specifications:
 - ✓ Risk analysis (Required): Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.
 - ✓ Risk management (Required): Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level







HIPAA Security Rule – Risk Analysis Guidance

Health and Human Services issued guidance for conducting the required risk analysis:

- Scope
- Data Collection
- Identify and document threats and vulnerabilities
- Assess current security measures
- Determine likelihood of threat occurrence
- Determine potential impact of threat occurrence
- Determine level of risk
- Finalize documentation
- Periodic review and updates to the risk analysis

*http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/radraftguidance.pdf

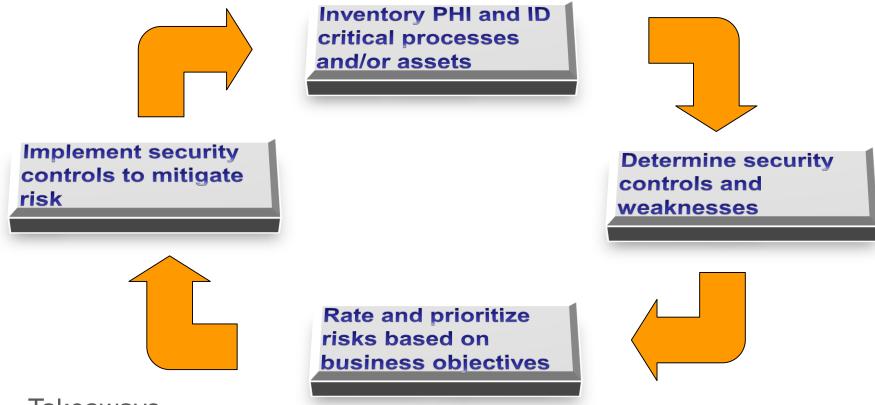








HIPAA Security Rule – Risk Management Process



Takeaways

- Know how and where your organization is at risk and determine the appropriate strategy
- Implement continuous risk management process
- The operative word is process







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^{*}http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/radraftguidance.pdf

HIPAA Security Rule and Meaningful Use

- For the Medicare and Medicaid EHR Incentive Programs, providers have to demonstrate that they are meaningfully using their EHRs by meeting thresholds for a number of objectives.
- CMS recently released a Final Rule that defines a revised set of Meaningful Use objectives and measures.
- All EPs attest to Modified Stage 2 objectives, with accommodations for Stage 1 EPs in 2015 and 2016.

- Meaningful Use Objectives Modified Stage 2
 - 1. Protect Patient Health Information Security Risk Analysis
 - 2. Clinical Decision Support (CDS)
 - Computerized Provider Order Entry (CPOE)
 - 4. Electronic Prescribing (eRx)
 - 5. Health Information Exchange (HIE) previously known as "Summary of Care"
 - 6. Patient Specific Education
 - 7. Medication Reconciliation
 - 8. Patient Electronic Access (Patient Portal)
 - 9. Secure Electronic Messaging (Eligible Professionals only)
 - 10. Public Health and Clinical Data Registry Reporting
 - a. Immunization Registry Reporting
 - b. Syndromic Surveillance Reporting
 - c. Specialized Registry Reporting
 - d. Reportable Lab Results Reporting (Eligible Hospitals only)







Meaningful Use – Security Risk Analysis Objective

From the CMS Final Rule published October 16, 2015

Objective 1: Protect Patient Health Information

Objective:

Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

Measure:

Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAH's risk management process.

Exclusion: None

Note: A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.







MU Security Risk Analysis – Key Components

Security Areas to Consider		Examples of Potential Security Measures
Physical Safeguards	Your facility and other places where patient data is accessed Computer equipment Portable devices	Building alarm systems Locked offices Screens shielded from secondary viewers
Administrative Safeguards	Designated security officer Workforce training and oversight Controlling information access Periodic security reassessment	Staff training Monthly review of user activities Policy enforcement
Technical Safeguards	Controls on access to EHR Use of audit logs to monitor users and other EHR activities Measures that keep electronic patient data from improper changes Secure, authorized electronic exchanges of patient information	Secure passwords Backing-up data Virus checks Data encryption
Policies & Procedures	Written policies and procedures to assure HIPAA security compliance Documentation of security measures	Written protocols on authorizing users Record retention
Organizational Requirements	Business associate agreements	Plan for identifying and managing vendors who access, create or store PHI Agreement review and updates

Source: https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/securityriskassessment_factsheet_updated20131122.pdf







Common Issues or Trends BluePrint sees...

We conduct a Security Risk Analysis for variety of healthcare organizations:

- Large multi-hospital systems
- Business associates
- ACOs
- Community practices

Three most commons issues or trends:

- Ineffective security awareness training
- Organizational policies and procedures
- System configurations and maintenance







Tools and Resources







Helpful Links

- CMS Security Risk Assessment Tip Sheet
- ONC Privacy & Security Guide
- ONC Security Risk Analysis Video
- ONC Privacy & Security Webpage
- CMS Final Rule: Stage 3 and Modifications to MU for 2015-2017
- HIPAA Security Rule
- HIPAA Privacy Rule
- HIPAA Risk Analysis Guidance







MeHI Member Portal

MeHI Member Portal Features and Tools

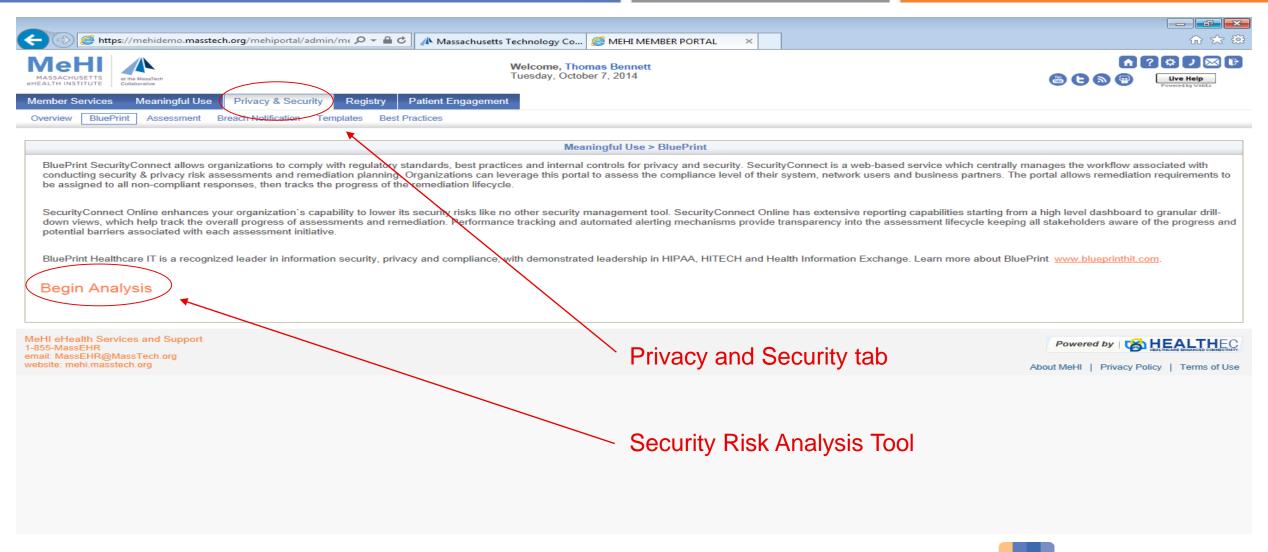
- Meaningful Use Gap Analysis
- Privacy and Security / BluePrint: Secure™
- Patient Engagement / Consumer eHealth Readiness Tool™
- Registration and Attestation
- Data collection and other forms
- Policy and government regulations guidance
- CMS-qualified Registry
- Document storage and audit preparation
- Secure messaging
- Live Help
- Frequently Asked Questions (FAQs)
- Administrative tools







MeHl Member Portal

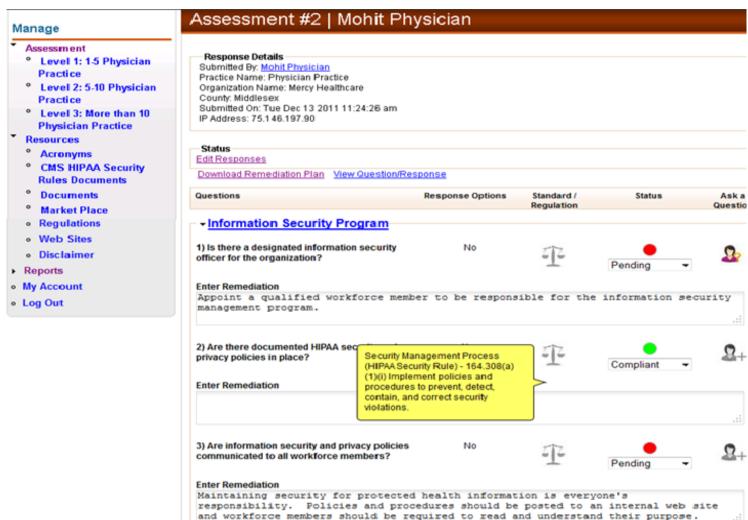








BluePrint SecurityConnect - Assessment









What's on your mind?

Questions?







Contact Us

















