HIPAA RULES FOR BEHAVIORAL HEALTH CARE PROVIDERS

COMPLIANCE EDUCATION

PRESENTED BY
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Behavioral Health HIPAA Compliance

PAUL R. HALES
ATTORNEY AT LAW

Health Information – HIPAA

The HIPAA E-Tool®

Protecting Patient Privacy is Our Job®

Legal Education – Not Legal Advice

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HALESLAWGROUP
HEALTH INFORMATION PRIVACY

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Behavioral Health Information

Is Protected Health Information

PHI – Subject to

The HIPAA Rules

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The HIPAA Rules

Are Easy to Follow

Step-by-Step

When You Know the Steps

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The HIPAA Rules Are a Blueprint To Protect Patients and Your Organization

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May 1, 2024

The New York Times

[June 2023 OCR Cybersecurity Newsletter]

Senators Slam UnitedHealth's C.E.O. Over Cyberattack

Mr. Wyden said that UnitedHealth had failed to enforce the **most basic kind of cybersecurity measure** — so-called multifactor authentication.

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HHS Office for Civil Rights Opens Investigation of Change Healthcare Cyberattack

OCR's investigation of Change Healthcare and UHG will focus on whether a breach of protected health information occurred and Change Healthcare's and UHG's compliance with the HIPAA Rules.

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Tracking Technologies

Kaiser Permanente Notifying 13.4 Million of Tracker Breach

Incident Involves Health Plans' Prior Use of Online Tech in Websites, Mobile Apps

Kaiser Breach is the Largest So Far this Year

According to TechCrunch, the patient information compromised includes

- names and IP addresses
- information that could indicate if members were signed into a Kaiser Permanente account or service
- how members “interacted with and navigated through the website and mobile applications, and search terms used in the health encyclopedia.”

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What Are We Going to Cover?

Alerts – New HIPAA & SUD Rules – Medical Identity Theft

1. What is HIPAA?
   A. HIPAA Law & The HIPAA Rules
2. Who must comply with HIPAA?
4. HIPAA Compliance Basics
   A. Accountability: Responsibility & Delegation of Authority
   B. Risk Analysis & Risk Management
   C. Policies – Procedures – Training
5. Common HIPAA Violations
6. HIPAA Compliance is a Process
7. Questions and Discussion

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ALERT

2024 – SIGNIFICANT MODIFICATIONS TO HIPAA PRIVACY RULE &
PART 2 RULE – SUBSTANCE USE DISORDER CONFIDENTIALITY

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Significant HIPAA Privacy Rule Modifications

HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Effective Date: June 25, 2024

Compliance Date: December 22, 2024

Despite its name, the Final Rule contains two other significant Privacy Rule modifications; one modifies the Notice of Privacy Practices (NPP), and the second coordinates Part 2 substance use confidentiality with HIPAA.

Handout 2 – Fact Sheet 2024 Privacy Rule Modification

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Significant Part 2 Modifications

Substance Abuse Treatment and HIPAA are Better Aligned

Effective Date: April 16, 2024

Final Compliance Date: February 16, 2026

The new rule modifies the Confidentiality of Substance Use Disorder Patient Records regulations - commonly called 42 CFR Part 2 or simply Part 2 to be better aligned with HIPAA.

Promote care coordination & Reduce HIPAA & Part 2 Conflicts

Handouts 3 & 4 - 2024 Modifications & Fact Sheet 42 CFR Part 2 Final Rule

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The HIPAA Rules

Are Easy to Follow

Step-by-Step

When You Know the Steps

How to Find the Steps

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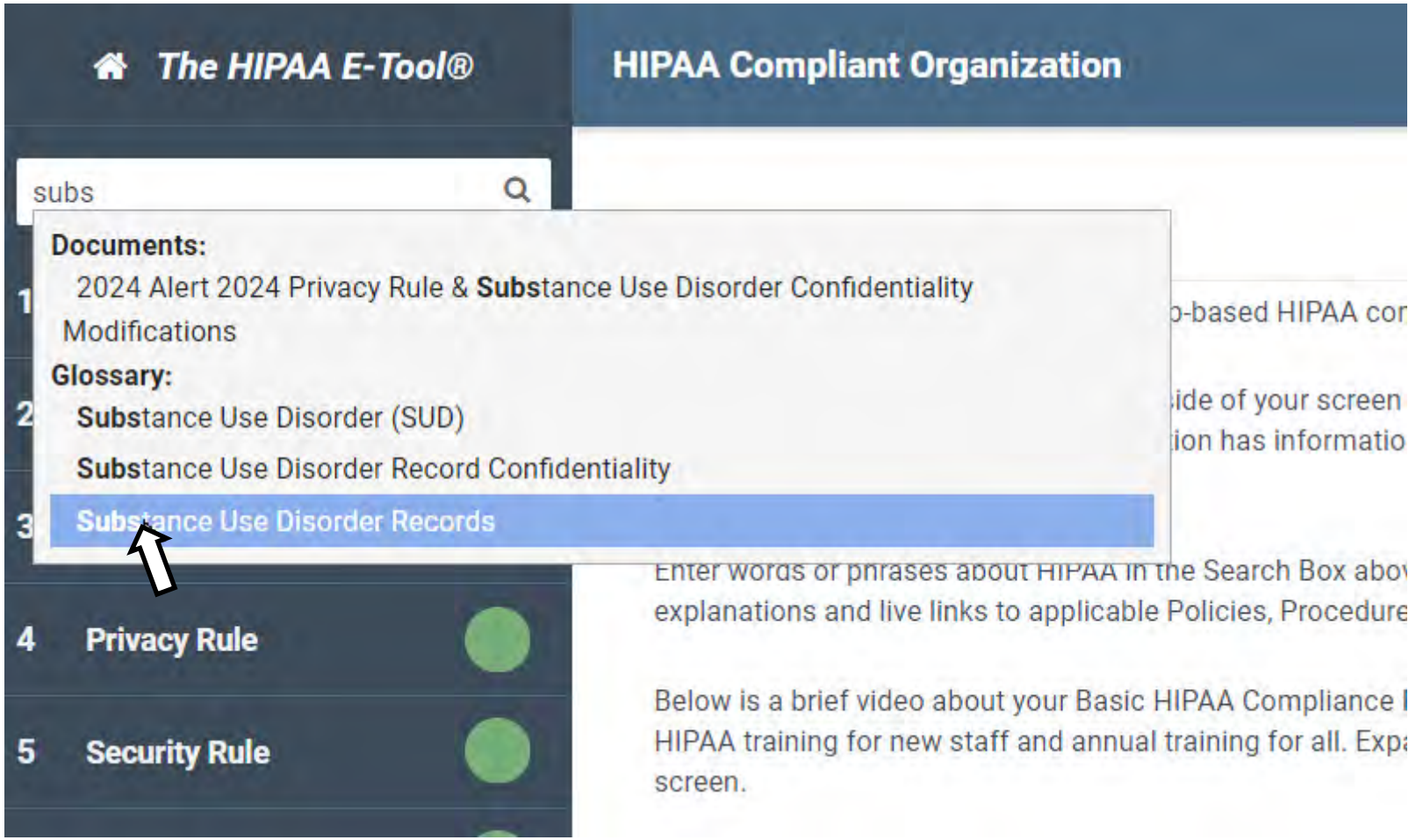
Significant Part 2 Modifications

The HIPAA E-Tool Search Box



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Significant Part 2 Modifications

Substance Use Disorder Records

Substance Use Disorder Records are Records of the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with the performance of any program or activity relating to Substance Use Disorder education, prevention, training, treatment, rehabilitation, or research conducted, regulated, or directly or indirectly assisted by any department or agency of the United States. 42 C.F.R. Part 2, commonly referred to as "Part 2," regulates the Confidentiality of Substance Use Disorder (SUD) Patient Records. Part 2 Is administered by the U.S. Department of Health & Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA). Part 2 regulations governing the Confidentiality, Use and Disclosure of an Individual's SUD are separate from and more strict than HIPAA Rules governing Protected Health Information (PHI). HHS's Office for Civil Rights (OCR) administers the HIPAA Rules. On February 8, 2024, HHS, SAMHSA and OCR announced modifications of Part 2 SUD Confidentiality regulations to reduce conflicts between Part 2 and HIPAA and promote coordinated care. On April 16, 2024, OCR announced HIPAA Privacy Rule modifications that, among other things, coordinate with the earlier Part 2 modifications.

Legal Authorities and References: 42 U.S.C. 290dd-2, 89 FR 12472, 89 FR 32976

Documents: 2024 Alert 2024 Privacy Rule & Substance Use Disorder Confidentiality Modifications

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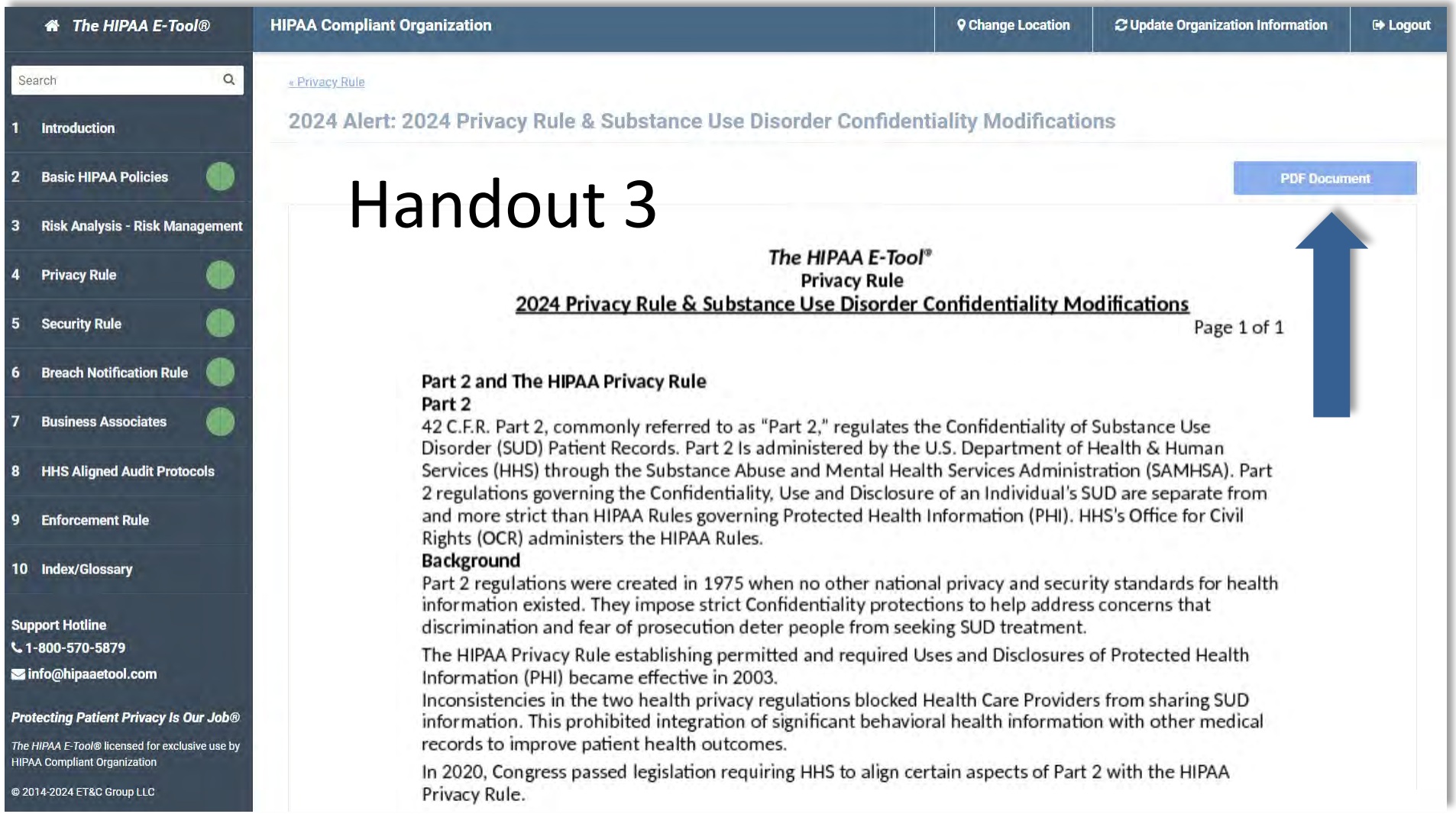

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MEDICAL IDENTITY THEFT

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Medical Identity Theft – Criminal Black Market

Cyber criminals are selling the information on the black market at a rate of $50 for each partial EHR, compared to $1 for a stolen social security number or credit card number. EHR can then be used to file fraudulent insurance claims, obtain prescription medication, and advance identity theft. EHR theft is also more difficult to detect, taking almost twice as long as normal identity theft.

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Medical Identity Theft – Criminal Black Market

FEDERAL TRADE COMMISSION

CONSUMER ADVICE

What Is Medical Identity Theft?

Medical identity theft is when someone uses your personal information — like your name, Social Security number, health insurance account number or Medicare number — to see a doctor, get prescription drugs, buy medical devices, submit claims with your insurance provider, or get other medical care.

If the thief's health information is mixed with yours, it could affect the medical care you're able to get or the health insurance benefits you're able to use. It could also hurt your credit.

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Medical Identity Theft – Criminal Black Market

PHI =

Medical Identity Theft – Criminal Black Market

HHS OIG Medical Identity Theft Video

Medical Identity Theft – Criminal Black Market

HHS OIG Medical Identity Theft Video

Medical Identity Theft – Criminal Black Market

Medical Identity Theft is the fastest growing form of Identity Theft

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Medical Identity Theft – Criminal Black Market

Only two things are needed for Medical Identity Theft:
Identity of a Patient – Identity of a Provider

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Medical Identity Theft – Criminal Black Market

Criminals Attack People of All Ages & All Walks of Life

- Social Engineering
  Clever Scripts & Messages
- Vishing
- Phishing

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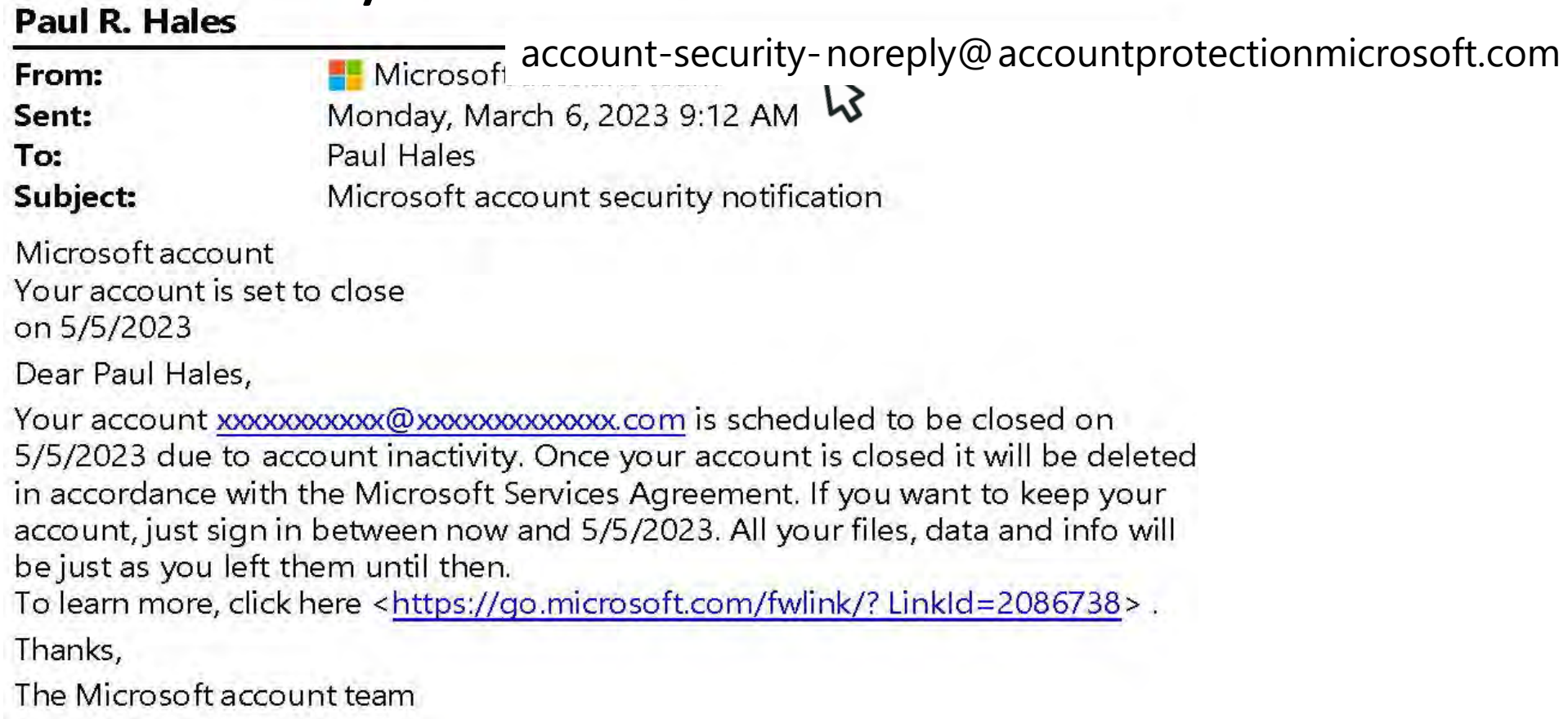
Medical Identity Theft – Criminal Black Market

Phishing



Paul R. Hales

From: Microsoft account-security-noreply@accountprotectionmicrosoft.com
Sent: Monday, March 6, 2023 9:12 AM
To: Paul Hales
Subject: Microsoft account security notification

Microsoft account
Your account is set to close
on 5/5/2023

Dear Paul Hales,

Your account xxxxxxxxxx@xxxxxxxxxxxx.com is scheduled to be closed on 5/5/2023 due to account inactivity. Once your account is closed it will be deleted in accordance with the Microsoft Services Agreement. If you want to keep your account, just sign in between now and 5/5/2023. All your files, data and info will be just as you left them until then.
To learn more, click here <https://go.microsoft.com/fwlink/? LinkId=2086738> .

Thanks,

The Microsoft account team

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Medical Identity Theft – Criminal Black Market

Criminals Attack People of All Ages & All Walks of Life

- Social Engineering
  Clever Scripts & Messages
- Vishing
- Phishing
- Smishing

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Medical Identity Theft – Criminal Black Market

Smishing

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ALERT

Medical Identity Theft – Criminal Black Market

Criminals Attack People of All Ages &
All Walks of Life

- Social Engineering
  Clever Scripts & Messages
- Vishing
- Phishing
- Smishing
- Quishing – Malicious QR Codes – FBI

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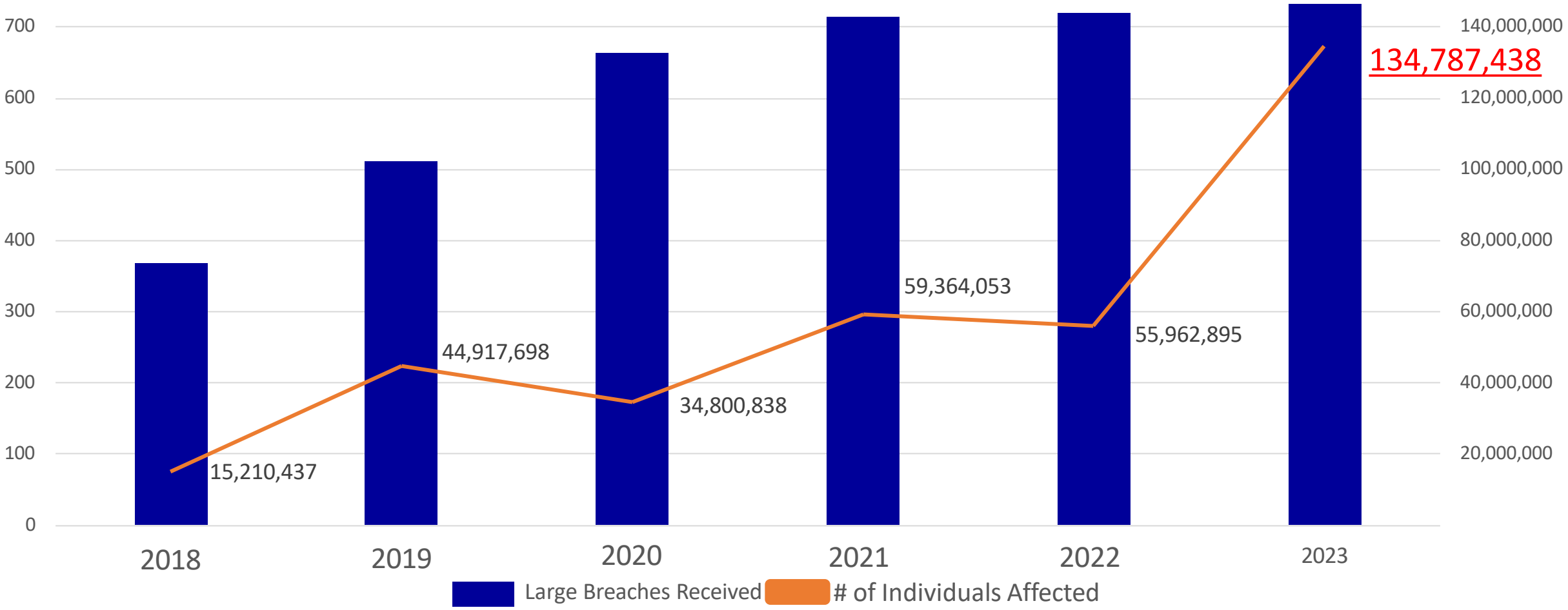
Large Breaches Reported to OCR and # of Individuals Affected 2018 - 2023



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INCREASED ENFORCEMENT OF HEALTH INFORMATION PRIVACY LAWS

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2023 - Health Privacy Enforcement got Serious - More to Come

HIPAA and OCR are not the only enforcers of Health Information Privacy Regulations

Newly active, aggressive enforcers are here now *

- Federal Trade Commission (FTC)
- Private Plaintiffs and Class Action Lawsuits
- State Regulators and Attorneys General

* Handout 5 – Health Information Privacy Enforcement Suddenly Got Serious

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WHAT IS HIPAA?

HIPAA LAW
THE HIPAA RULES

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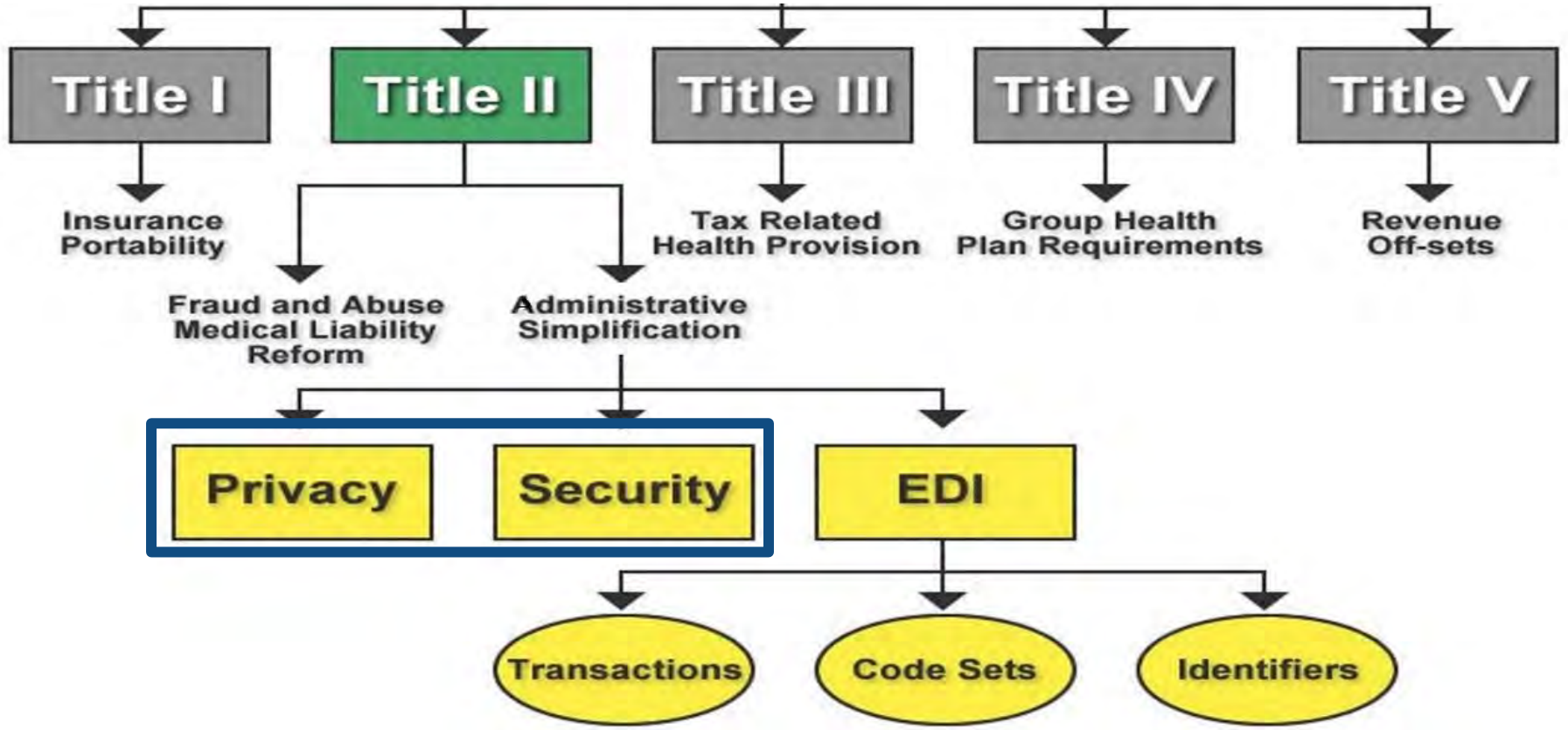
HIPAA LAW AND THE HIPAA RULES

Health Insurance Portability and Accountability Act of 1996



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HIPAA LAW AND THE HIPAA RULES

Health Insurance Portability and Accountability Act of 1996

Directs the Secretary of the U.S. Department of Health and Human Services (HHS) to develop and implement regulations to protect the **Privacy** and **Security** of individually identifiable health information

The HIPAA Rules

HHS Office for Civil Rights (OCR) administers and enforces HIPAA Rules

Some violations of HIPAA Rules carry criminal penalties

The U.S. Department of Justice (DOJ) enforces HIPAA criminal violations

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HIPAA Law and The HIPAA Rules

Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

The HIPAA Rules

1. Privacy Rule ← *The Fundamental Rule*
2. Security Rule
3. Breach Notification Rule
4. Enforcement Rule

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HIPAA LAW AND THE HIPAA RULES

Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

The Privacy Rule is made up of:

- Standards (rules, conditions or requirements with respect to the privacy of Protected Health Information (PHI) and
- Implementation Specifications (specific requirements or instructions for implementing a Standard)

Privacy Rule Standards cover three topics:

1. Uses and Disclosures of Protected Health Information (PHI)
2. PHI Privacy Rights of an Individual
3. Administrative Technical and Physical Safeguards to protect PHI

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HIPAA LAW AND THE HIPAA RULES

Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

The Privacy Rule is the Fundamental Rule

Security Rule

Covered entities and business associates must … protect against any reasonably anticipated uses or disclosures of electronic protected health information *that are not permitted or required under the* Privacy Rule.

45 CFR 164.306(a)(3)

Breach Notification Rule

Breach means the acquisition, access, use, or disclosure of protected health information *in a manner not permitted under the* Privacy Rule which compromises the security or privacy of the protected health information.

45 CFR 164.402 "Breach"

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HIPAA LAW AND THE HIPAA RULES

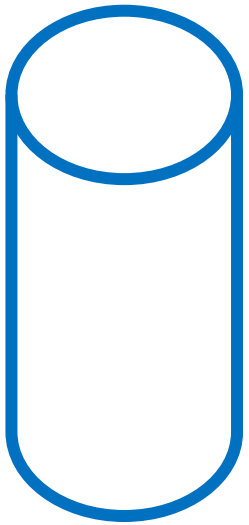
Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

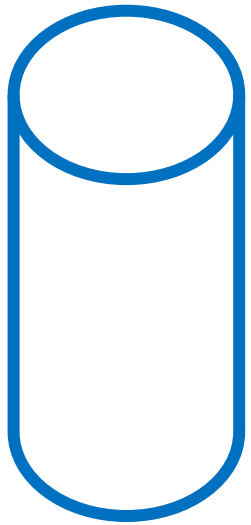
4 HIPAA Rules

Silos

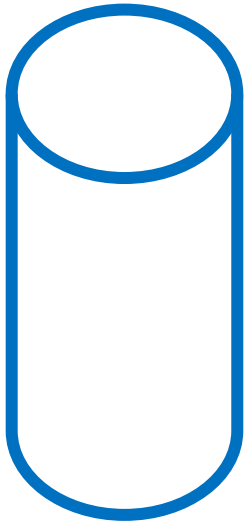
Privacy Rule



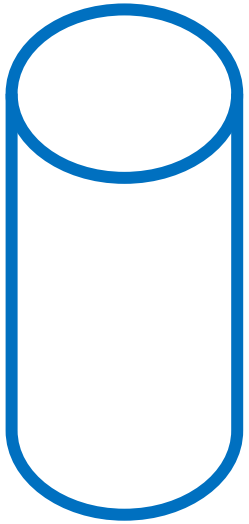
Security Rule



Breach Notification Rule



Enforcement Rule



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HIPAA LAW AND THE HIPAA RULES

Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

4 HIPAA Rules

Silos

Privacy Rule

Security Rule

Breach Notification Rule

Enforcement Rule

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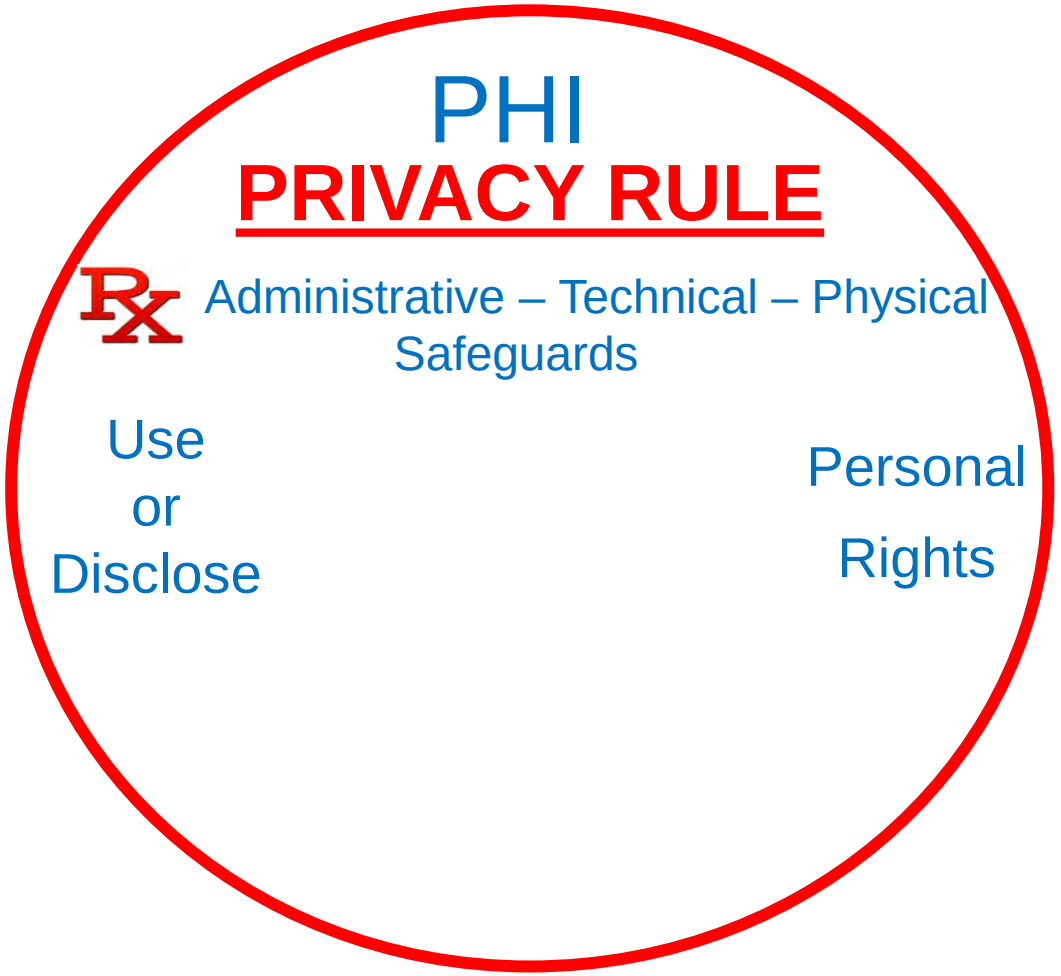
HIPAA Law and The HIPAA Rules

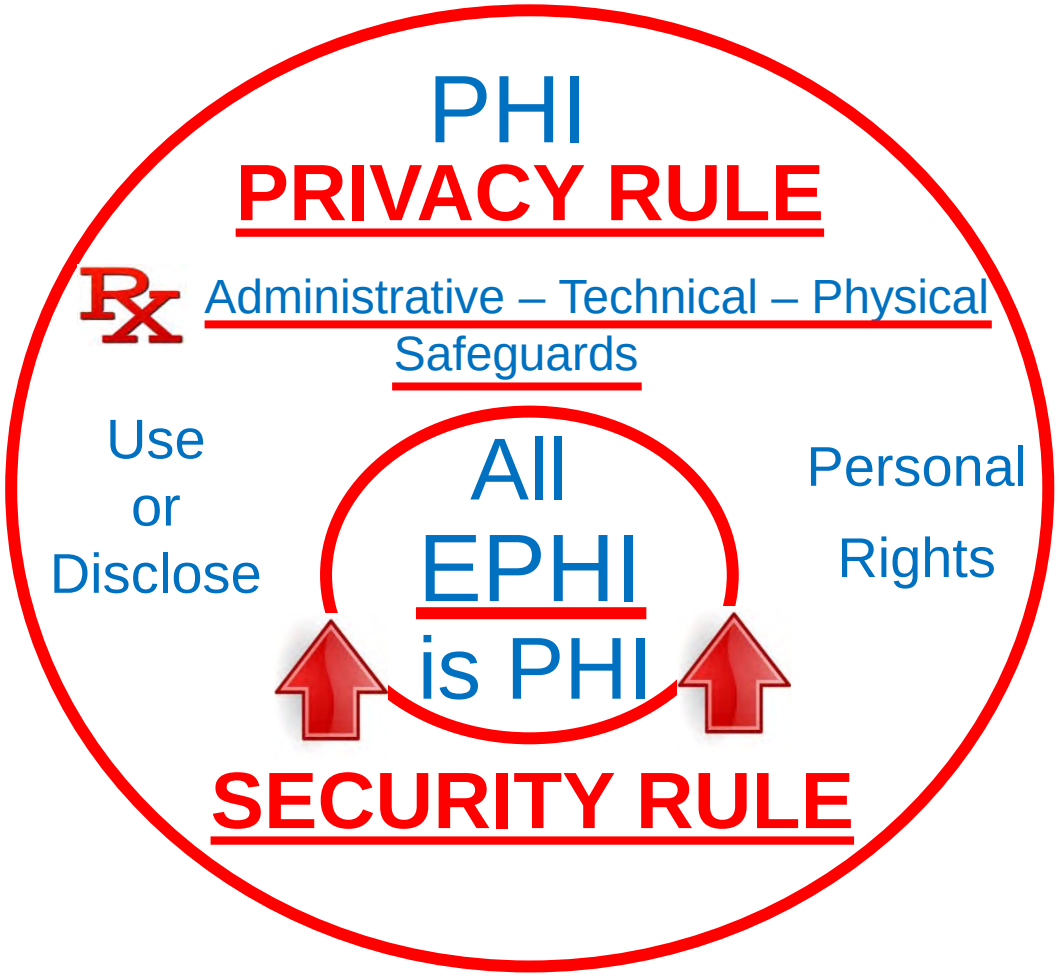
Health Insurance Portability and Accountability Act of 1996

Health Information Technology for Economic and Clinical Health Act

4 HIPAA Rules

The HIPAA Rules are designed to work together
to Protect the
Privacy and Security of
Protected Health Information (PHI)





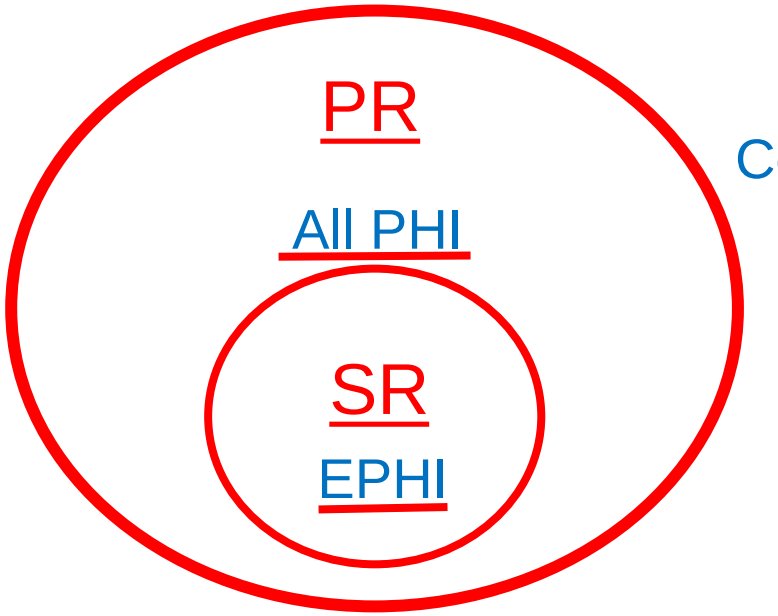
Use or Disclose

PHI

not Permitted by PR?

Breach of

Unsecured PHI?



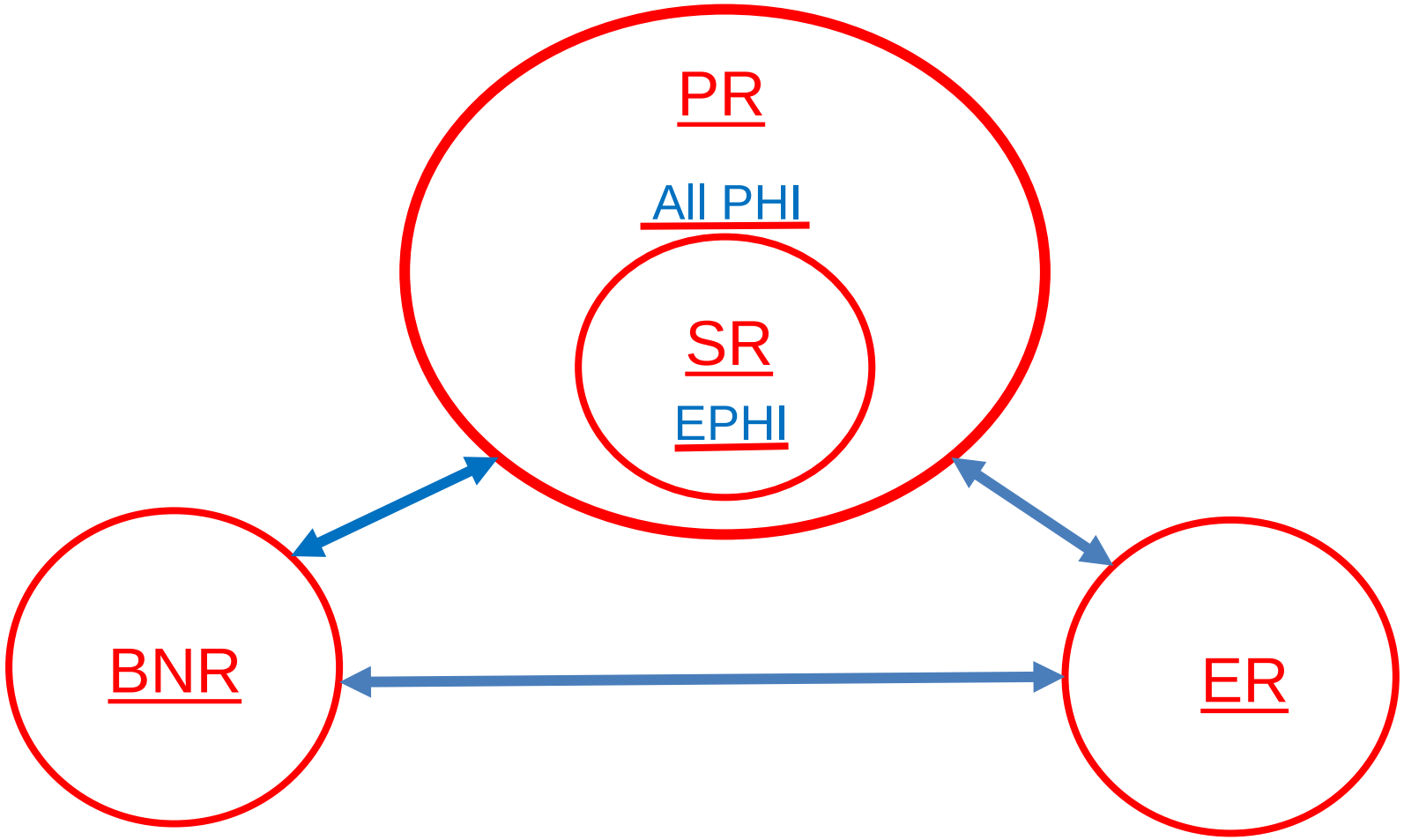
Complaint or Breach?

Investigations

Penalties

Breach Notification Rule

ENFORCEMENT RULE

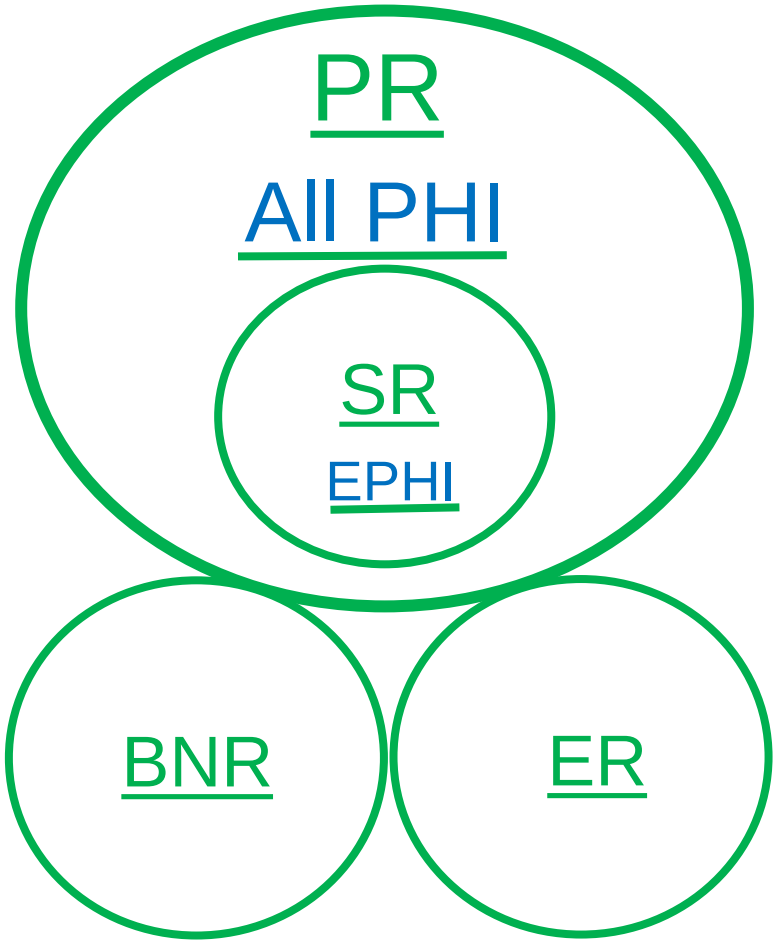


And That's It

Clear

and

Coordinated



HIPAA Rules – Easy to follow – When You Know the Steps

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WHO MUST COMPLY WITH HIPAA?

TYPES OF ORGANIZATIONS LIABLE FOR HIPAA COMPLIANCE

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Organizations that must comply with HIPAA

Covered Entities

Health Care Provider – Health Plan – Health Care Clearinghouse

Business Associates

On behalf of a Covered Entity

- Creates, Receives, Maintains or Transmits Protected Health Information (PHI) for a function or activity regulated by the HIPAA Rules
- Provides Services involving disclosure of PHI from a Covered Entity or from another Business Associate

Subcontractor Business Associates

On behalf of a Business Associate

- Creates, Receives, Maintains or Transmits PHI for function or activity regulated by the HIPAA Rules

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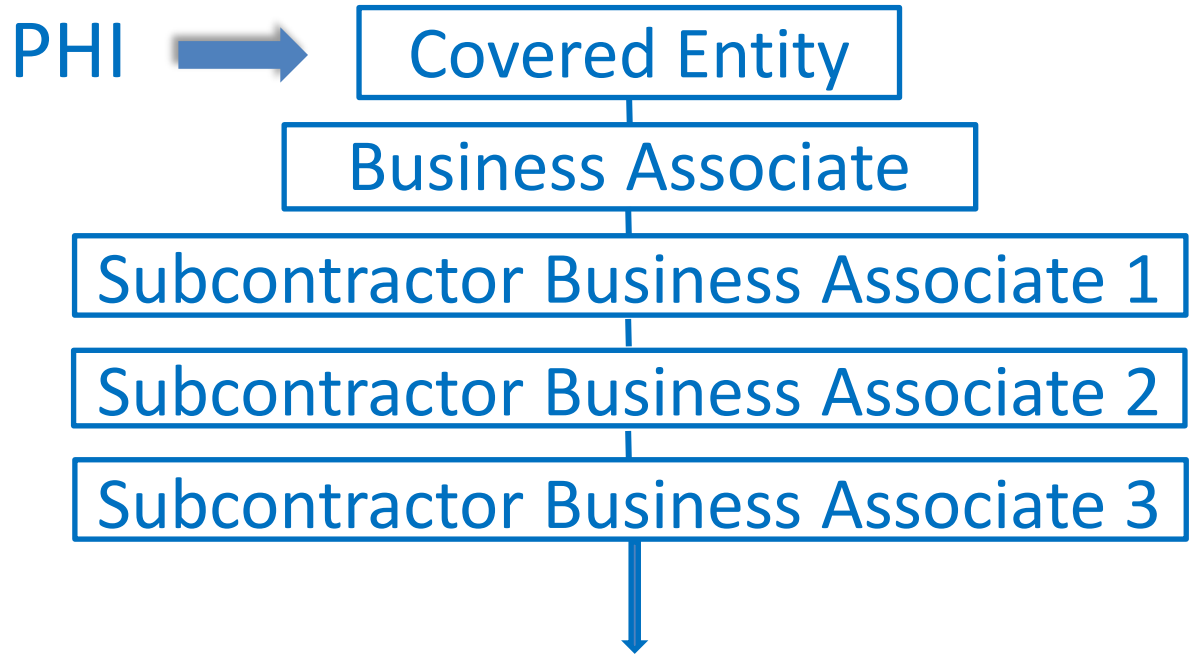
Organizations that must comply with HIPAA

PHI Chain of Trust



Business Associate Agreement required at each link of Chain

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HIPAA COMPLIANCE BASICS

ACCOUNTABILITY: RESPONSIBILITY & DELEGATION OF AUTHORITY

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Accountability

Senior Management is Responsible

- Senior Management may delegate *Authority* to develop and implement the organization's HIPAA Compliance Program
  - Privacy Official – (Privacy Officer)
  - Security Official – (Security Officer)
- Senior Management cannot delegate legal *Responsibility*

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Accountability

Senior Management is Responsible

"We didn't realize this violated HIPAA"

OCR's position:

A Covered Entity or Business Associate
cannot claim "lack of knowledge" because
it failed to inform itself about compliance obligations

75 FR 40878, July 14, 2010

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Accountability

OCR's Corrective Action Plan for iHealth Solutions is a roadmap to review, revise, develop and implement any organization's HIPAA Compliance Program

- An attestation signed by an owner or officer of iHealth stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.
- Risk Analysis and Risk Management
- HIPAA Policies and Procedures including management of identified Risks
  - Privacy Rule – Security Rule – Breach Notification Rule
- Workforce Training
  - Privacy, Security & Breach Notification Policies & Procedures

False Attestation is a Felony – 18 U.S.C. § 1001

Behavioral Health HIPAA Compliance

Accountability

1. Make HIPAA Compliance a **Core Value** of the Organization
2. Designate a **Privacy Official**
   Duties:
   Develop and Implement organization's **Privacy Rule** and **Breach Notification Rule HIPAA compliance Policies and Procedures**
   45 CFR 164.530(a)(1)(i)
2. Identify the **Security Official**
   Duties:
   Develop and Implement organization's **Security Rule HIPAA compliance Policies and Procedures**
   45 CFR 164.308(a)(2)

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Accountability

Behavioral Health HIPAA Compliance

HIPAA COMPLIANCE BASICS

RISK ANALYSIS & RISK MANAGEMENT

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Risk Analysis and Risk Management

HIPAA Rules – Easy to Follow

Step-by-Step

When You Know the Steps

No RA-RM Steps in the HIPAA Rules!

OCR/NIST Guidance

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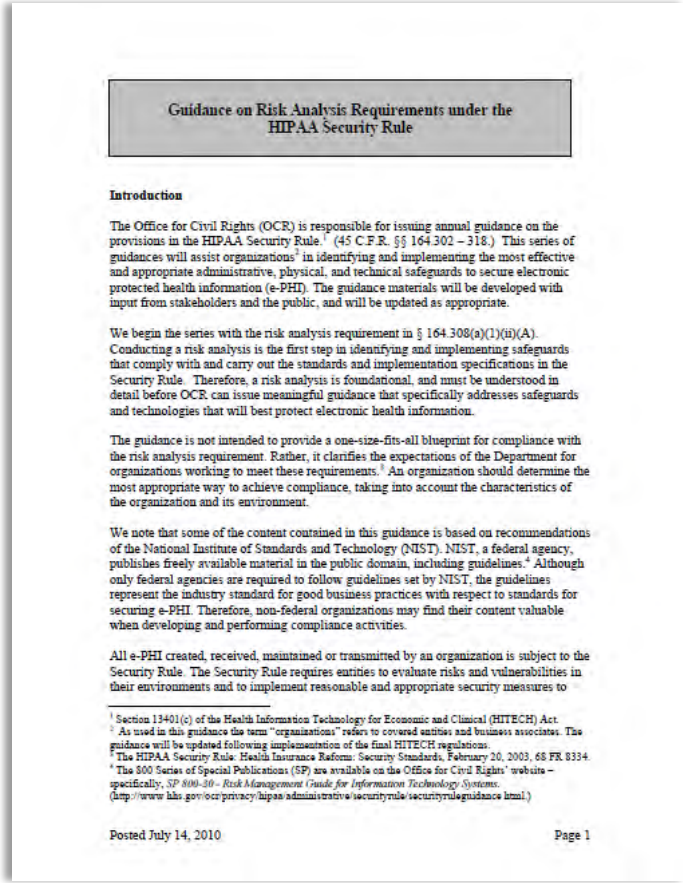
Risk Analysis and Risk Management

OCR Risk Analysis Guidance – July 14, 2010

1. Scope of the Analysis
2. Data Collection
3. Identify and Document Potential ***Threats*** and ***Vulnerabilities***
4. Assess Current Security Measures (***Controls***)
5. Determine the ***Likelihood*** of Threat Occurrence
6. Determine the Potential ***Impact*** of Threat Occurrence
7. Determine the ***Level of Risk***
8. Finalize ***Documentation***
9. Periodic ***Review*** and ***Updates***



Guidance on Risk Analysis Requirements under the HIPAA Security Rule

Introduction

The Office for Civil Rights (OCR) is responsible for issuing annual guidance on the provisions in the HIPAA Security Rule.[1] (45 C.F.R. §§ 164.302 – 318.) This series of guidances will assist organizations[2] in identifying and implementing the most effective and appropriate administrative, physical, and technical safeguards to secure electronic protected health information (e-PHI). The guidance materials will be developed with input from stakeholders and the public, and will be updated as appropriate.

We begin the series with the risk analysis requirement in § 164.308(a)(1)(ii)(A). Conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the Security Rule. Therefore, a risk analysis is foundational, and must be understood in detail before OCR can issue meaningful guidance that specifically addresses safeguards and technologies that will best protect electronic health information.

The guidance is not intended to provide a one-size-fits-all blueprint for compliance with the risk analysis requirement. Rather, it clarifies the expectations of the Department for organizations working to meet these requirements.[3] An organization should determine the most appropriate way to achieve compliance, taking into account the characteristics of the organization and its environment.

We note that some of the content contained in this guidance is based on recommendations of the National Institute of Standards and Technology (NIST). NIST, a federal agency, publishes freely available material in the public domain, including guidelines.[4] Although only federal agencies are required to follow guidelines set by NIST, the guidelines represent the industry standard for good business practices with respect to standards for securing e-PHI. Therefore, non-federal organizations may find their content valuable when developing and performing compliance activities.

All e-PHI created, received, maintained or transmitted by an organization is subject to the Security Rule. The Security Rule requires entities to evaluate risks and vulnerabilities in their environments and to implement reasonable and appropriate security measures to

[1] Section 13401(c) of the Health Information Technology for Economic and Clinical (HITECH) Act.
[2] As used in this guidance the term "organizations" refers to covered entities and business associates. The guidance will be updated following implementation of the final HITECH regulations.
[3] The HIPAA Security Rule: Health Insurance Reform: Security Standards, February 20, 2003, 68 FR 8334.
[4] The 800 Series of Special Publications (SP) are available on the Office for Civil Rights' website – specifically, *SP 800-30 - Risk Management Guide for Information Technology Systems.* (http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html.)

Posted July 14, 2010 Page 1

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OCR and NIST RA-RM Guidance

Sources for
The HIPAA E-Tool®
RA-RM Procedures

[OCR Guidance – 2010]

OCR Published RA-RM Resolution Agreements & Corrective Action Plans

OCR Webinars & Conference Presentations Posted Guidance

NIST Special Publication 800-30
Revision 1

Guide for Conducting Risk Assessments

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

JOINT TASK FORCE
TRANSFORMATION INITIATIVE

[NIST Risk Management Framework]
[NIST Special Publication 800-66 Rev. 2]
[NIST Special Publication 800-53 Rev. 5]
[NIST Special Publication 800-53A Rev. 5]

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How to do HIPAA RA-RM – Preview – OCR/NIST Guidance

It's just –

A 3 Act Play

Act 1 – Setup

Risk Analysis

1. Assemble Information
   - PHI Locations in your Information System
   - Workforce – Business Associates
   - Identify Threats, Vulnerabilities and Risks
2. Assess Level of Risks

Behavioral Health HIPAA Compliance

How to do HIPAA RA-RM – Preview – OCR/NIST Guidance

It's just –

A 3 Act Play

Act 2 – Confrontation

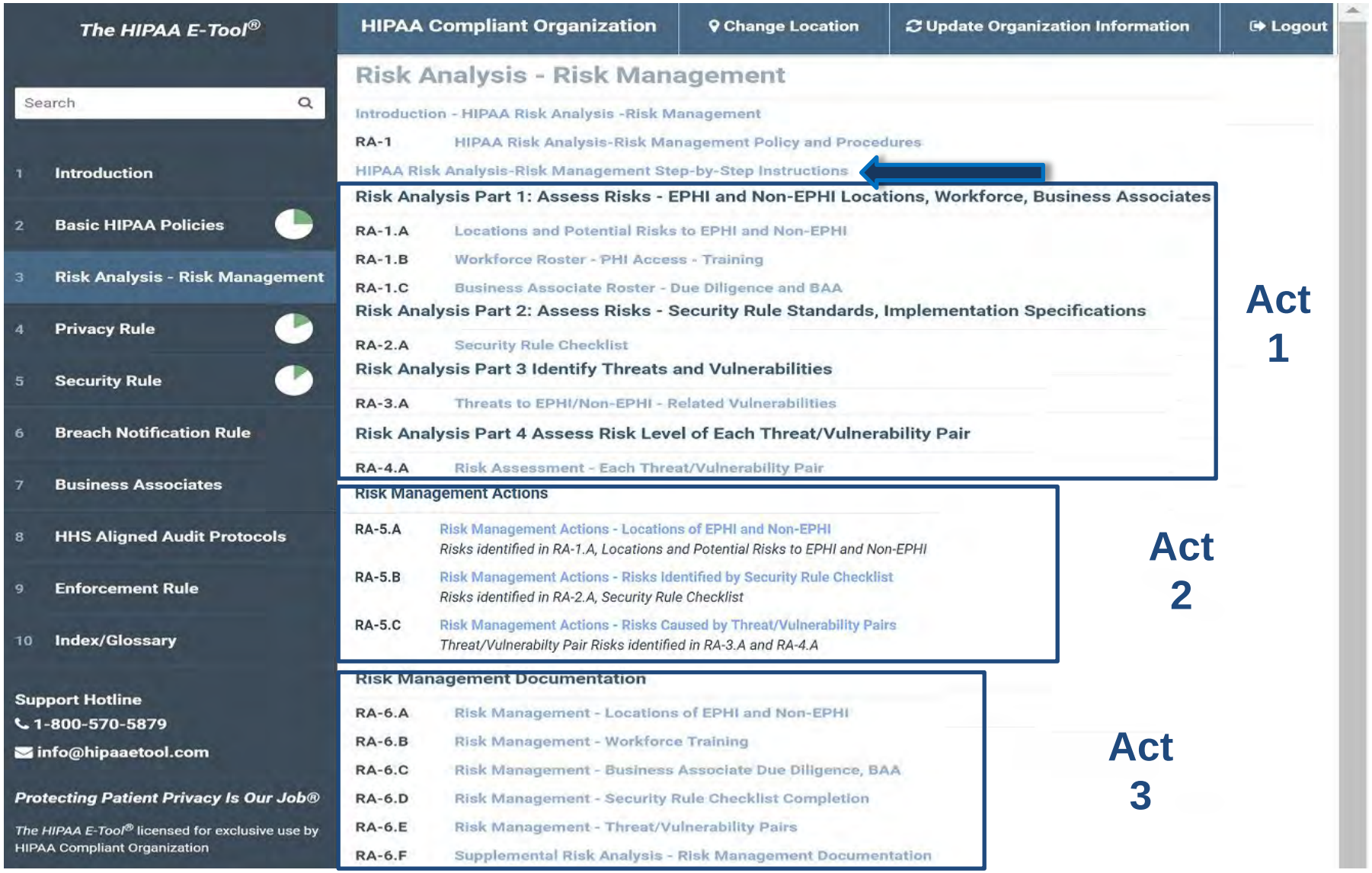
Risk Management Actions

Reduce Risks to Reasonable and Appropriate Level

Act 3 – Resolution

Risk Management Program

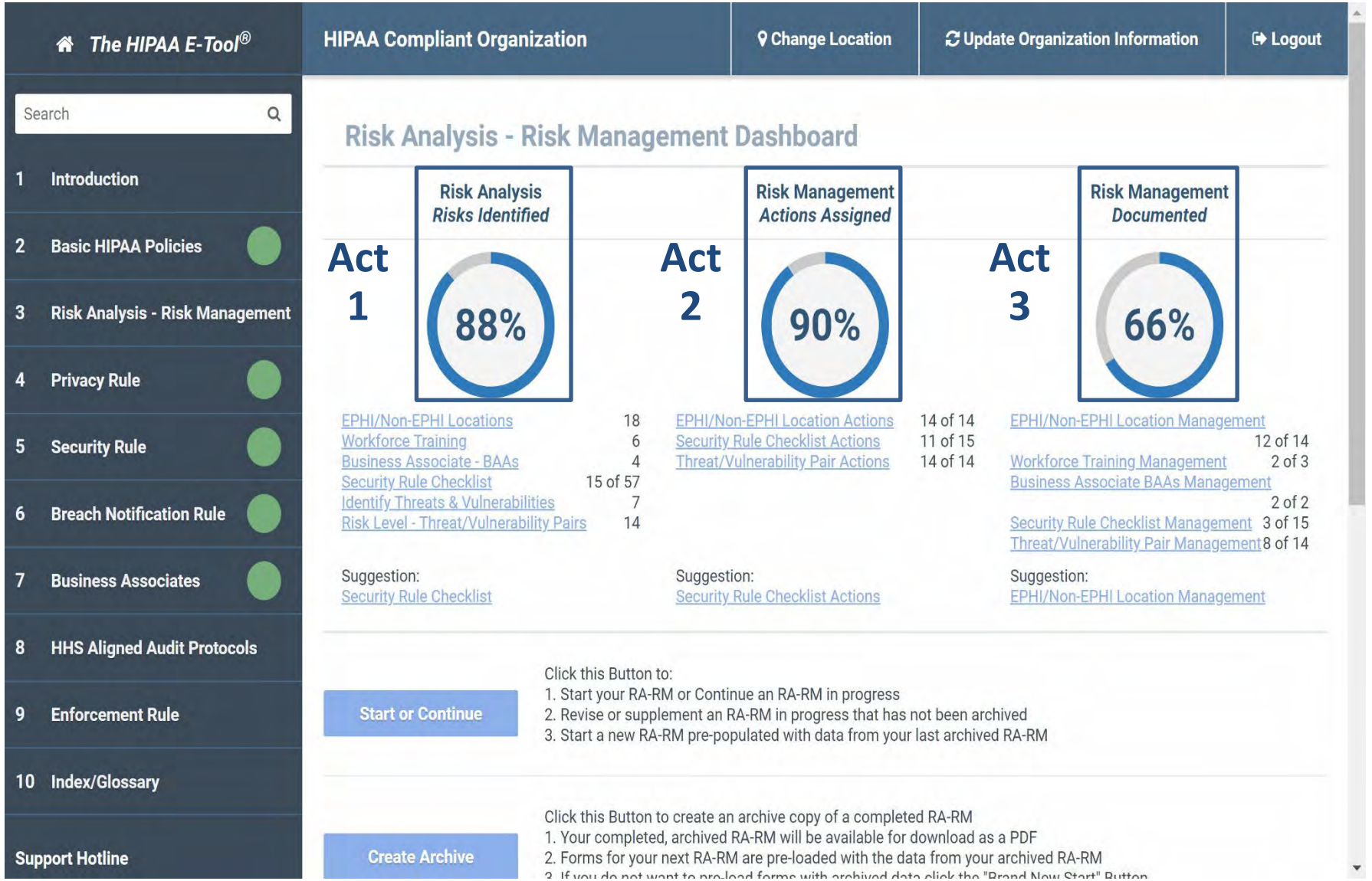
Active – Documented – In Place



Act 1 — Risk Analysis 4 Steps

Act 2 — Risk Management Actions

Act 3 — Risk Management Plan



Behavioral Health HIPAA Compliance

HIPAA COMPLIANCE BASICS

POLICIES – PROCEDURES – TRAINING

Behavioral Health HIPAA Compliance

Policies – Procedures – Training

1. A covered entity must implement Policies and Procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of the Privacy Rule and Breach Notification Rule

   45 CFR 164.530(i)(1)

2. A covered entity or business associate must implement reasonable and appropriate Policies and Procedures to comply with the standards, implementation specifications, or other requirements of the Security Rule

   45 CFR 164.316(a)

Behavioral Health HIPAA Compliance

Policies – Procedures – Training

HIPAA Compliance Policies and Procedures must cover
All Standards and Implementation Specifications of the
Privacy Rule
Breach Notification Rule
Security Rule

And be customized when necessary and appropriate to:

- Address specific circumstances unique to your organization
- Reduce identified risks to the privacy and security of your organization's PHI to a reasonable and appropriate level
- Incorporate changes in HIPAA Rules or other applicable law
- Address changed circumstances in your organization

Behavioral Health HIPAA Compliance

Policies – Procedures – Training

1. A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by the Privacy Rule and Breach Notification Rule as necessary and appropriate for the members of the workforce to carry out their functions ← Role-based Training

   45 CFR 164.530(b)(1)

2. A covered entity or business associate must implement a security awareness and training program for all members of its workforce (including management).

   45 CFR 164.308(a)(5)(i)

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS

EASY TO FIND – EASY TO CORRECT

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Notice of Privacy Practices

Not Posted Prominently on the Organization's Home Page

HIPAA Privacy Rule

45 CFR §164.520 (c)(3)(i)

A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Notice of Privacy Practices

Not Posted Prominently on the Organization's Home Page

HHS Phase 2 HIPAA Compliance Audit

Audit Inquiry
Determine whether the entity maintains a web site. If so, observe the web site to determine if the notice of privacy practices is prominently displayed and available. An example of prominent posting of the notice would include a direct link from homepage with a clear description that the link is to the HIPAA Notice of Privacy Practices.

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Notice of Privacy Practices

Not Posted Prominently on the Organization's Home Page

Covered Entity Web Site NPP Link correctly posted on Home Page

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts

Without following 3 Step Safeguard

1. Notify "Duty to Warn"
   Some level of risk information in an Unencrypted Email or Text Message can be read by someone else
2. Let the Patient Decide
   If the Patient prefers Unencrypted Email or Text Message the **Patient has the right** to receive them

Privacy Rule 78 FR 5634, Jan. 25, 2013

Security Rule 79 FR 7302, Feb. 6, 2014

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts

Without following 3 Step Safeguard

1. Notify "Duty to Warn"
   Some level of risk information in an Unencrypted Email or Text Message can be read by someone else
2. Let the Patient Decide
   If the Patient prefers Unencrypted Email or Text Message thePatient has the right to receive them
3. Document
   Your Warning and Patient's Decision to receive Unencrypted Email or Text Message 45 CFR 164.530(j)(1)

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts

Without following 3 Step Safeguard

If individuals are notified of the risks and still prefer unencrypted email, the individual has the right to receive protected health information in that way, and covered entities are not responsible for unauthorized access of protected health information while in transmission to the individual based on the individual's request.

Further, covered entities are not responsible for safeguarding information once delivered to the individual.

78 FR 5634, Jan. 25, 2013

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts Without following 3 Step Safeguard

If individuals are notified of the risks and still prefer unencrypted email, the individual has the right to receive protected health information in that way, and covered entities are not responsible for unauthorized access of protected health information while in transmission to the individual based on the individual's request.

Further, covered entities are not responsible for safeguarding information once delivered to the individual.

78 FR 5634, Jan. 25, 2013

HIPAA Safe Harbor

NO HIPAA Violation

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts

Without following 3 Step Safeguard

2013 Privacy Rule – effective September 23, 2013 "Duty to Warn"

January 25, 2013 – 78 FR 5634

2014 Security Rule – Encryption Reasonable & Appropriate Safeguard

Unencrypted Email permitted *if Individual warned of risks prefers Unencrypted Email*

February 6, 2014 – 79 FR 7302

2016 Privacy Rule Access Guidance – Reviewed by OCR - January 5, 2024

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

2018 Text Message "Duty to Warn" Confirmation

OCR Director Roger Severino – HIMSS Annual Conference

March 6, 2018

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HIGHLY VISIBLE

Communicating with Patients using Regular Email & Texts

Without following 3 Step Safeguard

Recorded exchange between attendee and OCR Director

Q. Do OCR guidelines for Unencrypted Email apply to Unencrypted Text Messages – if a patient is educated and agrees to the risk and doesn't want to use secure texting?

A. "I don't see a difference." – between an Unencrypted Email and an Unencrypted Text Message

Q. "I guess I have to avoid the secure texting vendors who may want to shoot me now."

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Tracking Technologies

Major New HIPAA Web Site Liability

June 16, 2022 The Markup article

Facebook Is Receiving Sensitive Medical Information from Hospital Websites

December 1, 2022 updated March 28,2024 OCR Bulletin

Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates

Tracking technologies are used to collect and analyze information about how users interact with regulated entities' websites or mobile applications ("apps").

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Tracking Technologies

Major New HIPAA Web Site Liability

Key Points

- Tracking Technologies are complex
- There are many types of Tracking Technologies
- Until 2022, Tracking Technology functions and risks were largely unknown to Health Care Provider senior management and compliance officials

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Tracking Technologies

Major New HIPAA Web Site Liability

How to Avoid Tracking Tech Liability

- ***Risk Analysis & Risk Management***
- Identify Tracking Technology Locations
- Assemble Multi-Specialty Team
  - Senior Management
  - Outside Experts – Business Associates with BAAs
  - Information Technology – Security – Legal – Others

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Patient's Right of Access to their PHI

Melanie Fontes Rainer
OCR Director
February 27, 2024

OCR Update and 2024 Priorities

Right of Access Initiative

- HIPAA Privacy Rule gives individuals a right to timely access to their health records (30 days with a possibility of one 30-day extension), and at a reasonable, cost-based fee
- OCR receives many complaints alleging denial or no access to health records
- Announced Enforcement Initiative in February 2019
  - OCR Enforcement Priority
  - Investigations launched across the country
  - To date; forty-four settlements and two CMPs

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Patient's Right of Access to their PHI

Using the Wrong Form

As explained elsewhere in the guidance, a HIPAA authorization is not required for individuals to request access to their PHI, including to direct a copy to a third party – and because a HIPAA authorization requests more information than is necessary or that may not be relevant for individuals to exercise their access rights, requiring execution of a HIPAA authorization may create impermissible obstacles to the exercise of this right.

Privacy Rule Access Guidance – Reviewed by OCR - January 5, 2024

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Patient's Right of Access to their PHI

Use Correct Form

CONFIDENTIAL – This Form Contains Protected Health Information
HIPAA Compliant Organization

Request for Access to Protected Health Information (PHI)

Today's Date: _____

First Name: Middle Initial: Last Name:

Name at Time of Treatment (if different than above):

Last 4 numbers of Social Security Account Number

Date of Birth (MM/DD/YYYY): Phone: Email (optional):

Street Address: City: State: Zip:

What records do you want? (Check appropriate boxes below):

Dates of Service: from _____ to _____

☐ Complete Health Record ☐ Complete Billing Records ☐ Test Results (X-Rays, Lab/Pathology Results) Please Describe Below

☐ Other Specific Records Described Below

I request that PHI specified above be provided:

☐ To me in the way I choose, like U.S. Mail or another reasonable agreed upon manner

☐ To the following person/entity - Enter name and address of person/entity you want to receive your PHI

Access Requested: **Inspect Onsite** at no cost ☐ **Get Copies** - a reasonable, cost-based fee may be charged – see **Fees** below ☐

If **Copies** - Choose Form: Paper ☐ CD ☐ USB ☐ Attached to regular unencrypted Email to the Email Address listed below ☐

Regular Email I acknowledge that I have been informed there is some level of risk that information in a regular unencrypted email can be intercepted and seen by others. I understand prefer unencrypted email and accept this risk.

Email Address:

Important Information about Sensitive PHI

The PHI you have requested may contain sensitive information such as test results and/or diagnosis and treatment information concerning substance use/abuse, psychiatric/behavioral health information, Genetic information, AIDS/HIV and sexually transmitted diseases and other PHI that you believe to be sensitive. **Copies will be provided unless you tell us not to by checking a box below.**

Do not provide copies of my PHI related to:

☐ Alcohol, Drug and Substance Use/Abuse
☐ Psychiatric/Behavioral Health
☐ Genetic Information
☐ AIDS/HIV testing or sexually transmitted diseases
☐ Other – please specify in box below

Fees We may charge a reasonable, cost-based fee to provide copies of requested health information to cover cost of labor, supplies and/or postage. If mailed to you. You may also request an explanation or summary of the PHI and we may charge a reasonable, cost-based fee to prepare the explanation or summary.

The fee for your request is $

Signature Required to Submit Request

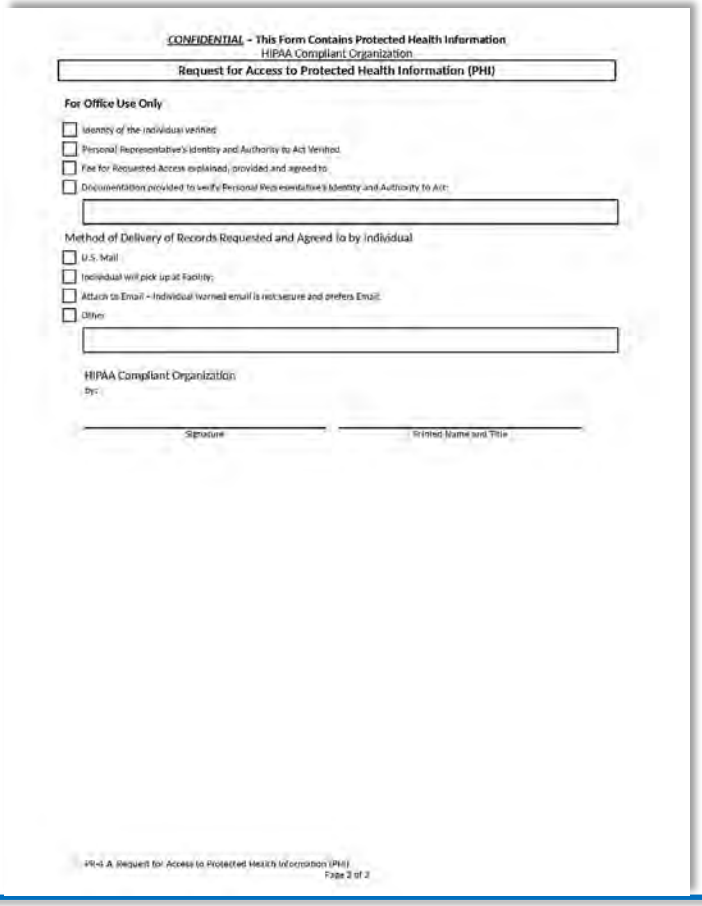
Signature of Individual or Personal Representative: _____

Signer's Printed Name: _____

If Personal Representative: Title/Authority to Act

A Personal Representative's Authority to Act for the Individual must be verified. Documentation such as a health care power of attorney, court order or other documentation may be requested to accept and process a Request for Access submitted on behalf of an individual by a Personal Representative.

PR-4 A Request for Access to Protected Health Information (PHI)
Page 1 of 2



CONFIDENTIAL – This Form Contains Protected Health Information
HIPAA Compliant Organization

Request for Access to Protected Health Information (PHI)

For Office Use Only

☐ Identity of the Individual Verified
☐ Personal Representative's Identity and Authority to Act Verified
☐ Fee for Requested Access explained, provided and agreed to
☐ Documentation provided to verify Personal Representative's Identity and Authority to Act:

Method of Delivery of Records Requested and Agreed to by Individual

☐ U.S. Mail
☐ Individual will pick up at Facility;
☐ Attach to Email – Individual warned email is not secure and prefers Email
☐ Other

HIPAA Compliant Organization

By: _____

Signature _____ Printed Name and Title _____

PR-4 A Request for Access to Protected Health Information (PHI)
Page 2 of 2

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Risk Analysis - Risk Management

Melanie Fontes Rainer
OCR Director
February 27, 2024

OCR Update and 2024 Priorities

Risk Analysis Initiative

- New Enforcement Initiative
- Focus on compliance with key HIPAA Security Rule requirement
- Most OCR large breach investigations reveal a lack of a compliant risk analysis
- Drive better practices to protect electronic protected health information (ePHI)
- Better overall security of data

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

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Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – OCR INVESTIGATIONS

Risk Analysis - Risk Management

HHS Phase 2 HIPAA Compliance Audit

Risk Analysis

1. Providers commonly submitted documentation of some security activities of a third party security vendor

   Responsibility for Risk Analysis rests with the Entity
2. Entities offered third party template policy manuals that contain no evidence of entity-specific review or revision and no evidence of implementation

Risk Management

1. Because audited Entities largely failed to conduct appropriate Risk Analyses, they were unable to link their security plans to management of identified risks
2. Most Entities failed to produce policies and procedures, or implement security measures, sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS

Hybrid Entity

This applies to an organization which is a single legal entity with functions that do not involve health care but has components that do provide health care services regulated by HIPAA.

Examples are:

- A County Government that has a Health Department
- A manufacturing company that has a health clinic for employees
- A non-profit organization that provides many types of community services but also provides some HIPAA-covered health care services
- A federally recognized Indian Tribe that provides HIPAA-covered health care services

HIPAA defines the entire organization as a Covered Entity that is responsible for HIPAA compliance.

To avoid HIPAA compliance liability for non-health-related activities, the organization must designate itself as a Hybrid Entity, and identify its Health Care Components that must comply with HIPAA.

Behavioral Health HIPAA Compliance

COMMON HIPAA VIOLATIONS – HYBRID ENTITY

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COMMON HIPAA VIOLATIONS – HYBRID ENTITY

Search Results

Hybrid Entity

Hybrid Entity means a single legal entity that is a Covered Entity whose business activities include both Covered Functions and non-covered functions that identifies components that perform Covered Functions and designates them as Health Care Components.

Legal Authorities and References: 45 CFR § 164.103, 45 CFR § 164.105

Documents: HIPAA-7 Hybrid Entity , HIPAA-7.A Designation of Health Care Component , Section 2 Introduction - HIPAA Compliance Program Basic Policies

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Common HIPAA Violations – Hybrid Entity

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Common HIPAA Violations – Hybrid Entity

Behavioral Health HIPAA Compliance

HIPAA COMPLIANCE IS A PROCESS

ONGOING AND ADJUSTED WHEN NECESSARY

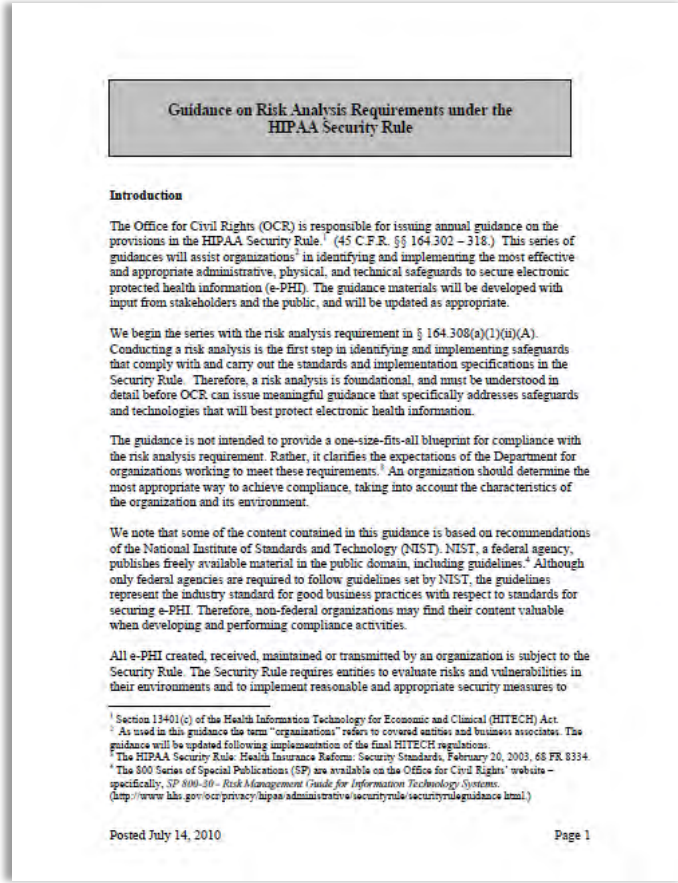
Behavioral Health HIPAA Compliance

HIPAA Compliance is a Process

For example

The OCR Risk Analysis Guidance – July 14, 2010 calls for "… a *truly integrated risk analysis and management process*… ."

"Performing the risk analysis and **adjusting risk management processes to address risks** in a timely manner will allow the covered entity to reduce the associated risks to *reasonable and appropriate levels*."



Guidance on Risk Analysis Requirements under the HIPAA Security Rule

Introduction

The Office for Civil Rights (OCR) is responsible for issuing annual guidance on the provisions in the HIPAA Security Rule.[1] (45 C.F.R. §§ 164.302 – 318.) This series of guidances will assist organizations[2] in identifying and implementing the most effective and appropriate administrative, physical, and technical safeguards to secure electronic protected health information (e-PHI). The guidance materials will be developed with input from stakeholders and the public, and will be updated as appropriate.

We begin the series with the risk analysis requirement in § 164.308(a)(1)(ii)(A). Conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the Security Rule. Therefore, a risk analysis is foundational, and must be understood in detail before OCR can issue meaningful guidance that specifically addresses safeguards and technologies that will best protect electronic health information.

The guidance is not intended to provide a one-size-fits-all blueprint for compliance with the risk analysis requirement. Rather, it clarifies the expectations of the Department for organizations working to meet these requirements.[3] An organization should determine the most appropriate way to achieve compliance, taking into account the characteristics of the organization and its environment.

We note that some of the content contained in this guidance is based on recommendations of the National Institute of Standards and Technology (NIST). NIST, a federal agency, publishes freely available material in the public domain, including guidelines.[4] Although only federal agencies are required to follow guidelines set by NIST, the guidelines represent the industry standard for good business practices with respect to standards for securing e-PHI. Therefore, non-federal organizations may find their content valuable when developing and performing compliance activities.

All e-PHI created, received, maintained or transmitted by an organization is subject to the Security Rule. The Security Rule requires entities to evaluate risks and vulnerabilities in their environments and to implement reasonable and appropriate security measures to

[1] Section 13401(c) of the Health Information Technology for Economic and Clinical (HITECH) Act.
[2] As used in this guidance the term "organizations" refers to covered entities and business associates. The guidance will be updated following implementation of the final HITECH regulations.
[3] The HIPAA Security Rule: Health Insurance Reform: Security Standards, February 20, 2003, 68 FR 8334.
[4] The 800 Series of Special Publications (SP) are available on the Office for Civil Rights' website – specifically, *SP 800-30 - Risk Management Guide for Information Technology Systems.* (http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html.)

Posted July 14, 2010 Page 1

Behavioral Health HIPAA Compliance

HIPAA Compliance

Is about Fundamentals

A Core Value of Your Organization

Risk Analysis and Risk Management

Policies – Procedures – Training

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The HIPAA Rules

Are Easy to Follow

Step-by-Step

When You Know the Steps

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The HIPAA Rules Are a Blueprint To Protect Patients and Your Organization

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Your Questions Please

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Thank You

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