
CYBERSECURITY AND HIPAA



Wyoming HFMA
Kim C. Stanger
(5-19)

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The Threat of Cybersecurity



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NBC News (February 13, 2016)

- Healthcare related hacking up 11,000% since last year.
- 1/3 of Americans have had their health records compromised.
- Health records receive premium on “dark web”
 - ✓ Credit cards: \$1 to \$3
 - ✓ SSNs: \$15
 - ✓ Complete health records: \$60

NEWS

FEB 13 2016, 4:51 AM ET

Hacking of Health Care Records Skyrockets

by TOM COSTELLO

A man types on a computer keyboard in Warsaw in this February 28, 2013 illustration file picture. A barrage of damaging cyberattacks is shaking up the security industry, with some businesses and organisations no longer assuming they can keep hackers at bay, and instead turning to waging a guerrilla war from within their networks. KACPER PEMPEL / Reuters

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For John Kuhn, a simple X-ray after a snowboarding accident turned into an accounting nightmare when the hospital billed him \$20,000 for a surgery he never had.

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Headlines from July - October 2018

- **3 phishing attacks breach 20,000 Catawba Valley patient records (10/25/18)**
 - CMS responds to data breach affecting 75,000 in federal ACA
 - Two phishing attacks on Minnesota DHS breach 21,000 patient records (9/21/18)
 - 3 Massachusetts hospitals fined nearly \$1 million by OCR for HIPAA violations (9/21/18)
 - Employee error exposed Blue Cross patient data for 3 months
 - **Ransomware attack breaches 40,800 patient records in Hawaii (9/13/18)**
 - Phishing attack breaches 38,000 patient records at Legacy Health (9/13/18)
 - 417,000 Augusta University Health patient records breached (9/13/18)
 - 1.4M records breached in UnityPoint Health phishing attack (7/31/18)
 - Ransomware, malware attack breaches 45,000 patient records (7/31/18)
 - LabCorp's network breach puts millions of records at risk (7/15/18)
 - Hackers breach 1.5M Singapore patient records, including the names of 1.5M patients (7/15/18)
 - Patient data exposed for months after phishing attack on Sunspire (7/15/18)
 - Phishing attacks breach Alive Hospice for 1 to 4 months (7/15/18)
 - **Ransomware attack on Cass Regional shuts down EHR (7/11/18)**
 - **270,000 patient records breached in Med Associates hack (6/20/18)**
- (<https://www.healthcareitnews.com/projects/biggest-healthcare-data-breaches-2018>)

Modern Healthcare

Breaches Reported in April 2019

- Doctors Management Services, Inc. 206,695 people affected in a Hacking/IT Incident. Network Servers targeted. (4/22/19)
- Centrelake Medical Group, Inc., 197,661 people affected in a Hacking/IT Incident. Network Servers targeted. (4/16/19)
- Gulf Coast Pain Consultants, LLC. 35,000 people affected in a Unauthorized Access/Disclosure. Electronic Medical Records targeted. (4/5/19)
- EmCare, Inc. 31,236 people affected in a Hacking/IT Incident. Emails were targeted. (4/20/19)
- Kim P. Kornegay, DMD. 27,000 people affected in a Theft. Desktop Computer, Electronic Medical Record, Paper/Films targeted. (4/19/19)
- Pediatric Orthopedic Specialties, PA. 24,176 people affected in a Hacking/IT Incident. Network Servers targeted. (4/18/19)
- Health Recovery Services, Inc. 20,485 people affected in a Unauthorized Access/Disclosure. Network Servers targeted. (4/5/19)
- Baystate Health. 11,658 people affected in a Hacking/IT Incident. Emails targeted. (4/5/19)
- Riverplace Counseling Center, Inc. 11,639 people affected in a Hacking/IT Incident. Network Servers targeted. (4/11/19)
- Minnesota Dept of Human Services. 10,263 people affected in a Hacking/IT Incident. Emails targeted. (4/9/19)

<https://www.modernhealthcare.com/cybersecurity/healthcare-breaches-reported-february-exposed-data-2-million-people>

➤ **Record 2M patients affected**

Cybersecurity in Healthcare

- Ransomware encrypts your IT system so that you may not access it, including:
 - Patient records
 - Financial records
 - Employment records
- Hacker accesses data on your system
- Hacker manipulates or corrupts data on medical devices
- Employee error leads to access to thousands of patient records



What are the consequences to your organization?

Cybersecurity in Healthcare

- Ransomware encrypts your IT system so that you may not access it, including:
 - Patient records
 - Financial records
 - Employment records
 - Hacker accesses data on your system
 - Hacker manipulates or corrupts data on medical devices
 - Employee error leads to access to thousands of patient records
- 
- Harm to patients
 - Inability to access data
 - Corruption of data
 - Forced to move patients
 - Disruption of operations
 - Lost revenue
 - Cost of response
 - Loss or damage to equipment
 - Bad public relations
 - Fines and penalties
 - Lawsuits
 - Others?

Cyberliability Costs

2017 TrendMicro Report

- Costs healthcare industry \$6 billion per year

2018 Ponemon Report

- Average cost for breach
 - For hospitals, \$2M over two years
 - \$408 per compromised record



Cyberliability Laws

- **Health Insurance Portability and Accountability Act (“HIPAA”), 45 CFR part 164**
 - Privacy Rule.
 - Security Rule
 - Breach Notification Rule

More about this later...
- **FTC Breach Notification Rule, 16 CFR part 318**
 - Applies to vendors of personal health information (i.e., entities that allow persons to maintain their health info online) and their service providers.
 - Must notify individuals of breaches.

Cyberliability Laws

- **Food and Drug Administration, 21 CFR part 11**
 - Electronic records that are required by FDA must satisfy certain standards to ensure their authenticity, integrity, and confidentiality.
- **Federal Trade Comm'n Act ("FTCA") § 5 (15 USC 45(a))**
 - Prohibits unfair or deceptive acts affecting commerce.
 - Deceit = misrepresentations re privacy policy
 - Unfair = inadequate security measures
 - FTC has authority to regulate a company's cybersecurity efforts. *FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236 (3d Cir. 2015)
 - FTC has filed 50+ complaints against entities based on failure to safeguard personal info.



[Enforcement](#) » [Cases and Proceedings](#) » [LabMD, Inc., In the Matter of](#)

LabMD, Inc., In the Matter of

TAGS: [Health Care](#) | [Consumer Protection](#) | [Privacy and Security](#) | [Data Security](#)

LAST UPDATED: FEBRUARY 5, 2016

In the Matter of LabMD, Inc., a corporation

FTC MATTER/FILE NUMBER: 102 3099

DOCKET NUMBER: 9357

RELATED CASE: [LabMD, Inc. v. Federal Trade Commission](#)

CASE SUMMARY

The Federal Trade Commission filed a complaint against medical testing laboratory LabMD, Inc. alleging that the company failed to reasonably protect the security of consumers' personal data, including medical information. The complaint alleges that in two separate incidents, LabMD collectively exposed the personal information of approximately 10,000 consumers. The complaint alleges that LabMD billing information for over 9,000 consumers was found on a peer-to-peer (P2P) file-sharing network and then, in 2012, LabMD documents containing sensitive personal information of at least 500 consumers were found in the hands of identity thieves. The case is part of an ongoing effort by the Commission to ensure that companies take reasonable and appropriate measures to protect consumers' personal data.

FTC v. LabMD

“The Commission’s complaint alleges that LabMD failed to take reasonable and appropriate measures to prevent unauthorized disclosure of sensitive consumer data – including health information – it held. Among other things, the complaint alleges that the company:

- did not implement or maintain a comprehensive data security program to protect this information;**
- did not use readily available measures to identify commonly known or reasonably foreseeable security risks and vulnerabilities to this information;**
- did not use adequate measures to prevent employees from accessing personal information not needed to perform their jobs;**
- did not adequately train employees on basic security practices; and**
- did not use readily available measures to prevent and detect unauthorized access to personal information.”**

Cyberliability Laws

- **State Breach Notification Laws**
 - Typically require notice to individuals if certain personal info is compromised by a security breach.
- **State Privacy Statutes**
 - May require confidentiality of personal info.
 - May require notification of breaches reports.
- **State Consumer Protection Statutes**
 - Prohibit unfair or deceptive practices.
- **Others?**

Cyberliability Contract Issues

- **Payment Card Industry Data Security Standards (PCI-DSS)**
 - Agreements with major credit cards require businesses to comply with certain data security rules.
- **Business Associate Agreements**
 - Requires BAs to comply with HIPAA security standards.
- **Insurance Coverage**
 - Insurer may deny coverage if misrepresent data security practices. (*Columbia Casualty Co. v. Cottage Health Sys.*, challenging coverage for \$4.1 million settlement)
- **Others?**

Cyberliability Lawsuits

- Private Lawsuits
 - Consumer protection statutes.
 - Breach of fiduciary duty.
 - Infliction of emotional distress.
 - Negligence.
 - Negligence *per se* based on HIPAA or state laws.
 - Intrusion upon seclusion or solitude, or into private affairs.
 - Public disclosure of embarrassing private facts.
 - Publicity which places a person in a false light in the public eye.
 - Appropriation of name or likeness.
 - Whatever a creative plaintiff's lawyer may cook up...

Cybersecurity Act of 2015

- Establishes framework to develop cybersecurity guidance for industry segments and share info re cybersecurity attacks.
 - HHS must develop voluntary cybersecurity guidance for the healthcare industry.
 - Allows entities to share info relevant to cyberattacks without liability.
 - Must remove personal info.
- Law is currently voluntary.

<https://www.phe.gov/Preparedness/planning/405d/Pages/hic-practices.aspx>

- Required by Cybersecurity Act of 2015
- Task force of 150 cybersecurity experts
- Issued 12/18
- Compliance not mandatory

The screenshot shows a web browser window displaying the PHE website. The URL in the address bar is <https://www.phe.gov/Preparedness/planning/405d/Pages/hic-practices.aspx>. The page header includes the U.S. Department of Health & Human Services logo and the Office of the Assistant Secretary for Preparedness and Response. The main navigation bar has tabs for Preparedness, Emergency, and About ASPR. The page title is "Public Health Emergency" with the tagline "Public Health and Medical Emergency Support for a Nation Prepared". The breadcrumb trail is "PHE Home > Preparedness > Planning > Aligning Health Care Industry Cybersecurity Approaches > Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients". The main content area features the title "Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients" and a search bar. A sidebar on the right contains a "Cybersecurity Act of 2015, Section 405(d)" menu with links to "Health Industry Cybersecurity Practices", "About the CSA 405(d) Task Group", "Cybersecurity Reports and Tools", and "Guided". A large blue arrow points from the sidebar to the main content area, labeled "Suggested Practices". The Windows taskbar is visible at the bottom of the browser window.

Cybersecurity Act of 2015, Section 405(d)

- ▶ Health Industry Cybersecurity Practices
- ▶ About the CSA 405(d) Task Group
- ▶ Cybersecurity Reports and Tools
- ▶ Guided

Suggested Practices

PHE Home > Preparedness > Planning > Aligning Health Care Industry Cybersecurity Approaches > Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients

Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients

Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP), the primary publication of the Cybersecurity Act of 2015, Section 405(d) Task Group, aims to raise awareness, provide vetted cybersecurity practices, and move organizations towards consistency in mitigating the current most pertinent cybersecurity threats to the sector. It seeks to aid healthcare and public health organizations to develop meaningful cybersecurity objectives and outcomes. The publication includes a main document, two technical volumes, and resources and templates:

- ▶ **Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP):** The HICP examines cybersecurity threats and vulnerabilities that affect the healthcare industry. It explores (5) current threats and presents (10) practices to mitigate those threats.
- ▶ **Technical Volume 1: Cybersecurity Practices for Small Health Care Organizations:** Technical Volume 1 discusses the ten Cybersecurity Practices along with Sub-Practices for small health care organizations.
- ▶ **Technical Volume 2: Cybersecurity Practices for Medium and Large Health Care Organizations:** Technical Volume 2 discusses the ten Cybersecurity Practices along with Sub-Practices for medium and large health care organizations.

Top Cyber Threats in Healthcare



- 1. E-mail phishing attacks**
- 2. Ransomware attacks**
- 3. Loss or theft of equipment or data**
- 4. Insider, accidental or intentional data loss**
- 5. Attacks against connected medical devices that may affect patient safety**

1. E-mail Phishing Attacks



- **Cybercriminal attempts to trick you into:**
 - Giving access to system by entering passwords, or
 - Downloading malicious software.
- **Cybercriminal may:**
 - Obtain your e-mail from publicly available sources.
 - Identify contacts through publicly available sources or social media.
 - Send you e-mail that appears to be from a known contact.
- **E-mail usually contains an active link that:**
 - Solicits sensitive information, or
 - Downloads malicious software.
- **Some attacks are very convincing...**

Important : We noticed unusual activity in your PayPal account

What's going on ?

We're concerned that someone is using your PayPal account without your knowledge. Recent activity on your account seems to have occurred from a suspicious location or under circumstances that may be different than usual.

What to do ?

Log in to your PayPal account as soon as possible. We may ask you to confirm information you provided when you created your account to make sure you're the account holder. We'll then ask you to Confirm your password and security questions. You should also do the following for your own protection:

Confirm Your Account Now

[Log in to confirm your account](#)

E-mail Phishing Attacks

“Anthem failed to implement appropriate measures for detecting hackers who had gained access to their system to harvest passwords and steal people’s private information.... We know that large health care entities are attractive targets for hackers, which is why they are expected to have strong password policies and to monitor and respond to security incidents in a timely fashion or risk enforcement by OCR.”

115M to: x | +

/15/anthem-pays-ocr-16-million-record-hipaa-settlement-following-largest-health-data-breach-history.html

FOR IMMEDIATE RELEASE

October 15, 2018

Contact: HHS Press Office

202-690-6343

media@hhs.gov

Anthem Pays OCR \$16 Million in Record HIPAA Settlement Following Largest U.S. Health Data Breach in History

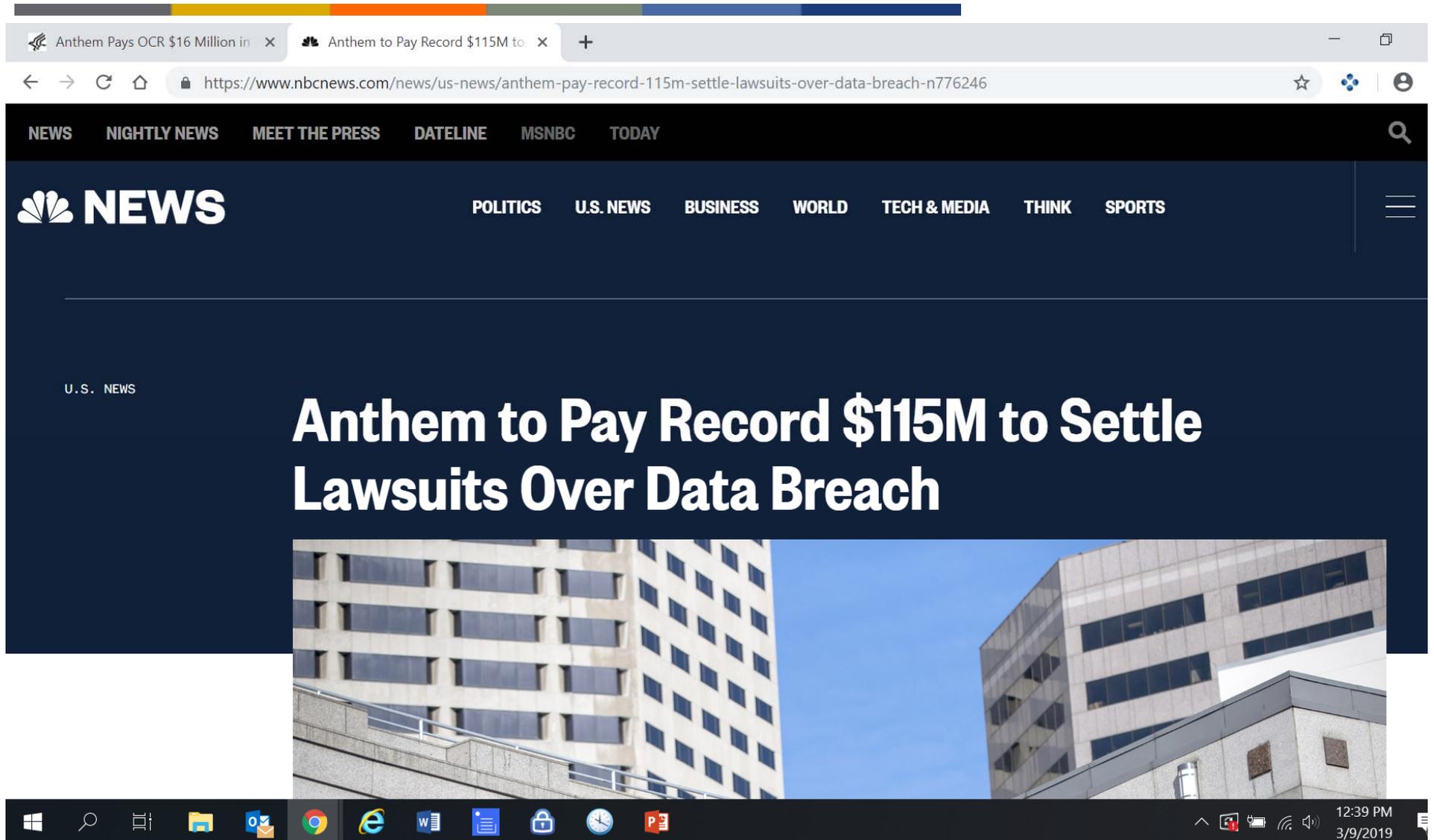
Anthem, Inc. has agreed to pay \$16 million to the U.S. Department of Health and Human Services, Office for Civil Rights (OCR) and take substantial corrective action to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules after a series of cyberattacks led to the largest U.S. health data breach in history and exposed the electronic protected health information of almost 79 million people.

The \$16 million settlement eclipses the previous high of \$5.55 million paid to OCR in 2016.

Anthem is an independent licensee of the Blue Cross and Blue Shield Association operating throughout the United States and is one of the nation’s largest health benefits companies, providing medical care coverage to one in eight Americans through its affiliated health plans. This breach affected electronic protected health information (ePHI) that Anthem, Inc. maintained for its affiliated health plans and any other covered entity health plans.

On March 13, 2015, Anthem filed a breach report with the HHS Office for Civil Rights detailing that, on January 29, 2015, they discovered cyber-attackers had gained access to their IT system via an undetected continuous and targeted cyberattack for the apparent purpose of extracting data, otherwise known as an advanced persistent threat attack. After filing their breach report, Anthem discovered

E-mail Phishing Attack



The image is a screenshot of a web browser displaying an NBC News article. The browser's address bar shows the URL: <https://www.nbcnews.com/news/us-news/anthem-pay-record-115m-settle-lawsuits-over-data-breach-n776246>. The page features the NBC News logo and a navigation menu with categories like NEWS, NIGHTLY NEWS, MEET THE PRESS, DATELINE, MSNBC, TODAY, POLITICS, U.S. NEWS, BUSINESS, WORLD, TECH & MEDIA, THINK, and SPORTS. The main headline reads "Anthem to Pay Record \$115M to Settle Lawsuits Over Data Breach". Below the headline is a photograph of a modern, multi-story office building with a grid of windows. The Windows taskbar at the bottom shows the time as 12:39 PM on 3/9/2019.

U.S. NEWS

Anthem to Pay Record \$115M to Settle Lawsuits Over Data Breach



12:39 PM
3/9/2019

This might be a phishing message and is potentially unsafe. Links and other functionality have been disabled. Click here to enable functionality (not recommended).

From: PayPal [service@paypal-australia.com.au]
To: [redacted]
Cc:
Subject: Your account has been limited

1. Fake sender domain.
(not service@paypal-australia.com.au)

PayPal™

How to restore your PayPal account

Dear PayPal member,
To restore your PayPal account, you'll need to log in your account.

2. Suspicious Subject and content.

3. Bad grammar

It's easy:

1. Click the link below to open a secure browser window.
2. Confirm <http://69.162.70.169/ppau/> the account, and then follow the instructions.
Click to follow link

[Log in your account now](#)

4. Hovering over link reveals suspicious URL.

PayPal Email ID PP32260008777636

May also appear to be internal e-mails

Ben Woelk

From: Edu Help Desk <info@pa.com>
Sent: Tuesday, September 08, 2015 3:16 AM
To: info@pa.com
Subject: [Suspected Spam] Edu Email Upgrade Against Spam.

Attn: Email User,

Due to the high risk of spam emails going on in the internet, we have decide to upgrade all educational email set by our admin panel, and access to your mailbox via our mail portal will be unavailable expect you upgrade your email account against fraudulent spam.

To upgrade and re-validate your mailbox, do click on the link to upgrade: [Upgradepage](#)

Thanks,
Educational Ad

<http://www.designrepublic.cz/wp-content/advanced/cache/upgrade/account/webmail.php>
Click to follow link

Spelling

Generic addressee

Link goes to external site

E-mail Phishing Attack

From: Costco Shipping Agent <manager@cbcbuilding.com>
Subject: Scheduled Home Delivery Problem
Date: January 6, 2014 10:54:37 PM MST
To:
Reply-To: Costco Shipping Agent <manager@cbcbuilding.com>

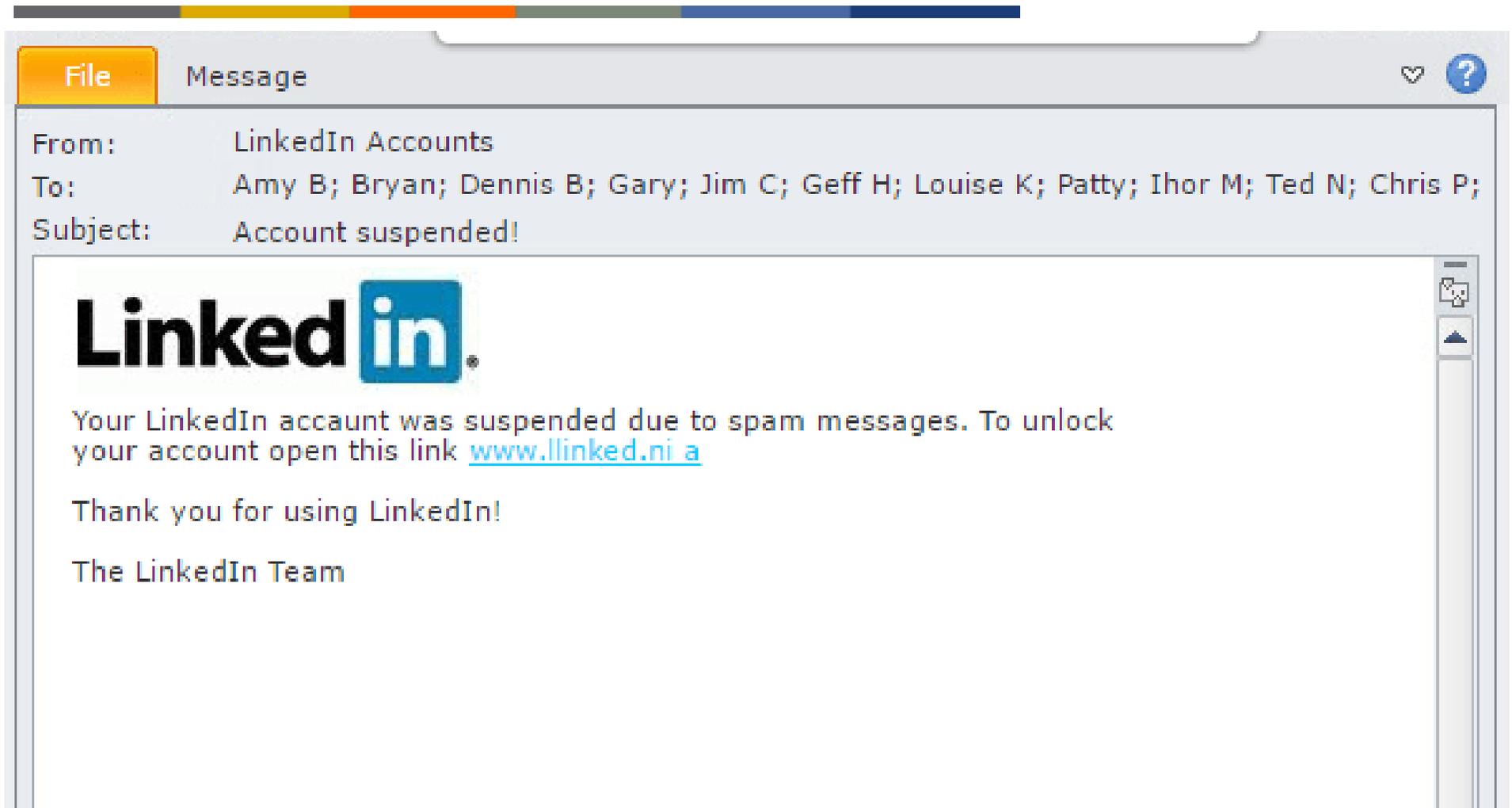
[Hide](#)



Unfortunately the delivery of your order [COS-0077945599](#) was cancelled since the specified address of the recipient was not correct. You are recommended to complete [this form](#) and send it back with your reply to us.

Please do this within the period of one week - if we dont get your timely reply you will be paid your money back less 21% since your order was booked for Christmas.

E-mail Phishing Attacks



From: HelpDesk [mailto:xxxxx@connect.ust.hk]

Sent: Wednesday, April 12, 2017 2:23 PM

To: [redacted]

Subject: Validate Email Account

This is to notify all Students, Staffs of University that we are validating active accounts.

Kindly confirm that your account is still in use by clicking the validation link below:

[Validate Email Account](#)

Sincerely

IT Help Desk

Office of Information Technology

The University



Refund Notification

Due to a system error you were double charged for your last order, A refund process was initiated but could not be completed due to errors in your billing information

REF CODE:2550CGE

You are required to provide us a valid billing address

[Click Here to Update Your Address](#)

After your information has been validated you should get your refund within 3 business days

We hope to see you again soon.

[Amazon.com](https://www.amazon.com)

Email ID: 

E-mail Phishing Attacks

- Do you know the sender?
- Did you expect the e-mail?
- Is the subject generic, urgent, or suspicious?
- Are there spelling, grammar, or other indicators that the tone or style is off?
- Does the e-mail require you to take some action, e.g.,
 - Disclose confidential info
 - Click on link
 - Open attachment
- Did you hover over link to see the URL destination?



Do NOT

- ***Open attachment***
- ***Click on link***
- ***Input info***

E-mail Phishing Attacks

Practices to consider:

- Be suspicious of e-mails from unknown senders, re sensitive info, or call to action that stresses urgency or importance.
- Be suspicious of e-mails that appear to be from known senders that ask you to do something out of context or unexpected.
- Train staff to recognize suspicious e-mails and where to forward them.
- Never open attachments from unknown senders.
- Hover over links to identify URL.
- Tag external e-mails to make them recognizable to staff.
- Implement security measures to identify and limit phishing attacks.

2. Ransomware Attacks

Wana Decrypt0r 2.0

Ooops, your files have been encrypted! English

What Happened to My Computer?
Your important files are encrypted. Many of your documents, photos, videos, databases and other files are no longer accessible because they have been encrypted. Maybe you are busy looking for a way to recover your files, but do not waste your time. Nobody can recover your files without our decryption service.

Can I Recover My Files?
Sure. We guarantee that you can recover all your files safely and easily. But you have not so enough time. You can decrypt some of your files for free. Try now by clicking <Decrypt>. But if you want to decrypt all your files, you need to pay. You only have 3 days to submit the payment. After that the price will be doubled. Also, if you don't pay in 7 days, you won't be able to recover your files forever. We will have free events for users who are so poor that they couldn't pay in 6 months.

How Do I Pay?
Payment is accepted in Bitcoin only. For more information, click <About bitcoin>. Please check the current price of Bitcoin and buy some bitcoins. For more information, click <How to buy bitcoins>. And send the correct amount to the address specified in this window. After your payment, click <Check Payment>. Best time to check: 9:00am - 11:00am GMT from Monday to Friday.

Payment will be raised on
5/16/2017 00:47:55
Time Left
02:23:57:37

Your files will be lost on
5/20/2017 00:47:55
Time Left
06:23:57:37

[About bitcoin](#)
[How to buy bitcoins?](#)
Contact Us

 **bitcoin**
ACCEPTED HERE

Send \$300 worth of bitcoin to this address:
12t9YDPgwueZ9NyMgw519p7AA8isjr6SMw

Ransomware Attacks

- **Cybercriminal infects system with malware through phishing or other attacks.**
- **Malware:**
 - **Encrypts data, thereby denying access until ransom is paid;**
 - **Destroys data; or**
 - **Exfiltrates data.**
- **No guarantee that paying ransom will allow you to recover data.**

Health Information Technology

Hospitals are hit with 88% of all ransomware attacks

Written by Max Green | July 27, 2016 | [Print](#) | [Email](#)

189
[in Share](#)
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 36

Hospitals and health systems have more to lose than organizations in other sectors when it comes to hacks. Patient data sells for more money than any other kind of information on the black market. Adding insult to injury, a new report suggests that the healthcare industry is hit significantly harder by ransomware than in any other — 88 percent of attacks hit hospitals.



BREAKING: Early movers: PCLN, GRMN, BLMN, KMI, CPB, AZN, TMUS & more

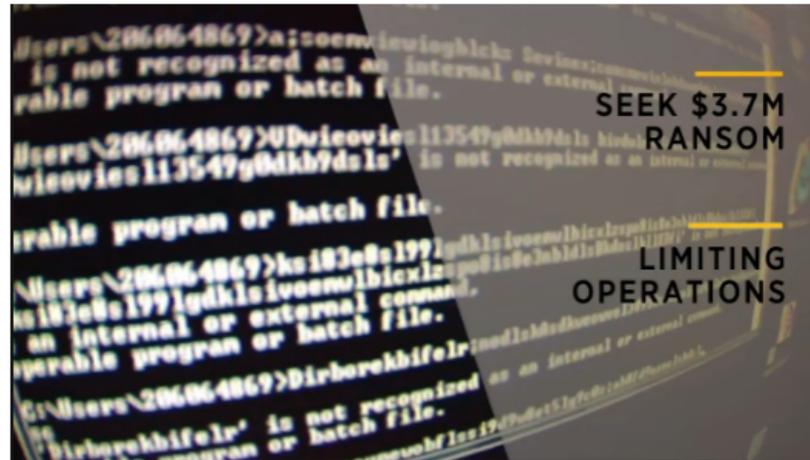


CYBERSECURITY

TECHNOLOGY | RE/CODE | MOBILE | SOCIAL MEDIA | ENTERPRISE | GAMING | CYBERSECURITY

The hospital held hostage by hackers

Anita Balakrishnan
15 Hours Ago

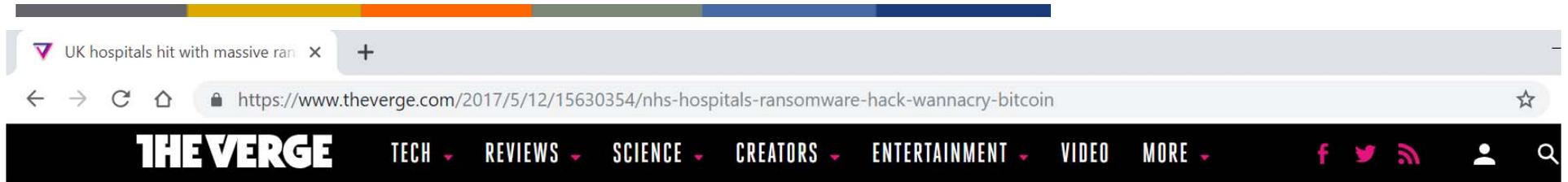


Los Angeles medical workers are dealing with an internal emergency straight out of science fiction, one that cybersecurity experts say is increasingly common.

CNBC (February 17, 2016)

- Hollywood Presbyterian Hospital hit by ransomware.
- Medical record system shut down.
- Hackers demand \$3.7M in bitcoin.
- Hospital pays \$17K.

Ransomware Attacks



In 2017, UK healthcare system subjected to WannaCry ransomware.

- 16 hospitals shut down
- 45,000 computers across 74 countries

TECH \ CYBERSECURITY \

UK hospitals hit with massive ransomware attack

52

Sixteen hospitals shut down as a result of the attack

By [Russell Brandom](#) | May 12, 2017, 11:36am EDT

f SHARE



Add more to your escape

	from \$180/night ★★★★★ Palm Springs Rendezvous
	from \$495/night ★★★★★

Ransomware Attacks

Practices to consider

- Train staff to recognize phishing and other security concerns.
- Warn staff of external e-mails.
- Establish a strong firewall.
- Deploy anti-malware detection and remediation tools.
- Patch software per authorized procedures.
- Use strong username and passwords with multi-facet authentication.
- Limit users who can log in from remote desktops.
- Limit rate of allowed authentication attempts.
- Separate critical and vulnerable systems.
- Determine which computers may access and store critical data.
- Maintain and protect data backups and recovery processes.
- Implement incident response procedures.

<https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf>

According to OCR, ransomware attack is a presumptive HIPAA breach requiring:

- Investigation
- Notice to
 - Individuals
 - HHS
 - Media, if > 500 persons
- Fallout from govt investigation and adverse PR

FACT SHEET: Ransomware and HIPAA

A recent U.S. Government interagency report indicates that, on average, there have been 4,000 daily ransomware attacks since early 2016 (a 300% increase over the 1,000 daily ransomware attacks reported in 2015).¹ Ransomware exploits human and technical weaknesses to gain access to an organization's technical infrastructure in order to deny the organization access to its own data by encrypting that data. However, there are measures known to be effective to prevent the introduction of ransomware and to recover from a ransomware attack. This document describes ransomware attack prevention and recovery from a healthcare sector perspective, including the role the Health Insurance Portability and Accountability Act (HIPAA) has in assisting HIPAA covered entities and business associates to prevent and recover from ransomware attacks, and how HIPAA breach notification processes should be managed in response to a ransomware attack.

1. What is ransomware?

Ransomware is a type of malware (malicious software) distinct from other malware; its defining characteristic is that it attempts to deny access to a user's data, usually by encrypting the data with a key known only to the hacker who deployed the malware, until a ransom is paid. After the user's data is encrypted, the ransomware directs the user to pay the ransom to the hacker (usually in a cryptocurrency, such as Bitcoin) in order to receive a decryption key. However, hackers may deploy ransomware that also destroys or exfiltrates² data, or ransomware in conjunction with other malware that does so.

2. Can HIPAA compliance help covered entities and business associates prevent infections of malware, including ransomware?

Yes. The HIPAA Security Rule requires implementation of security measures that can help prevent the introduction of malware, including ransomware. Some of these required security measures include:

- implementing a security management process, which includes conducting a risk analysis to

3. Loss or Theft of Equipment or Data



MISSING

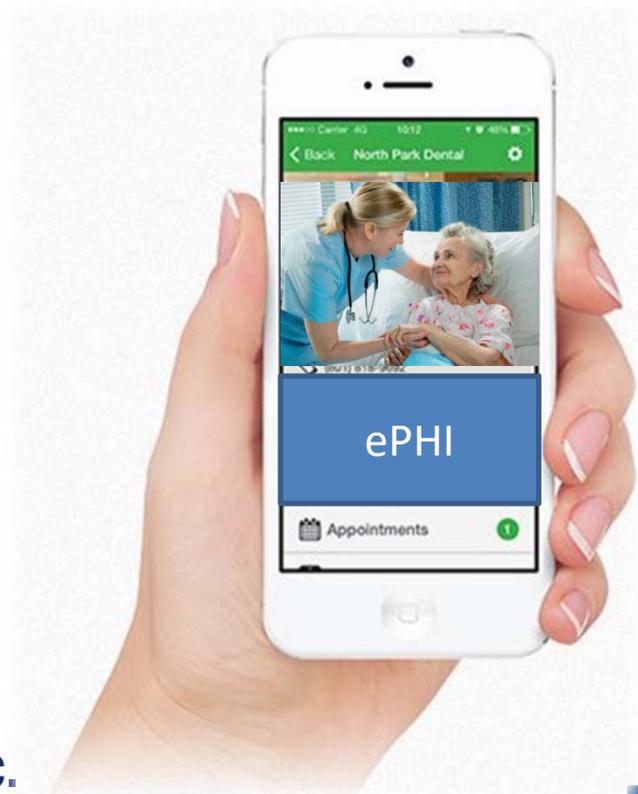


HAVE YOU SEEN ME?



Loss or Theft of Equipment or Data

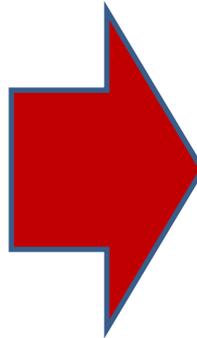
- Beware unsecured or unencrypted equipment, e.g.,
 - Equipment (e.g., desktop, copier, fax, medical device, etc.)
 - Laptops, tablets, smart phones
 - USBs/thumb drives
- May contain e-PHI, e.g.,
 - Medical records
 - E-mails or texts
 - Photos or images
 - Videos
 - Voice messages
 - Other?
- May allow access to system, e.g.,
 - Passwords, connections, emails, etc.



Loss or Theft of Equipment or Data

“[I]n cases where a lost laptop [,USB, phone, or other device containing e-PHI] is recovered, the fact that a forensic analysis of the computer shows that its information was not accessed is a relevant consideration for the risk assessment, and entities in such situations may be able to demonstrate a low probability that the information has been compromised.... [I]f a computer is lost or stolen, we do not consider it reasonable to delay breach notification based on the hope that the computer will be recovered.”

(HHS commentary to the HIPAA omnibus rule, 78 FR 5646)



The corollary:

Loss of unencrypted device containing e-PHI is presumptively a reportable HIPAA breach.



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FOR IMMEDIATE RELEASE

April 24, 2017

Contact: HHS Press Office

202-690-6343

media@hhs.gov

\$2.5 million settlement shows that not understanding HIPAA requirements creates risk

The U.S. Department of Health and Human Services, Office for Civil Rights (OCR), has announced a Health Insurance Portability and Accountability Act of 1996 (HIPAA) settlement based on the impermissible disclosure of unsecured electronic protected health information (ePHI). CardioNet has agreed to settle potential noncompliance with the HIPAA Privacy and Security Rules by paying \$2.5 million and implementing a corrective action plan. This settlement is the first involving a wireless health services provider, as CardioNet provides remote mobile monitoring of and rapid response to patients at risk for cardiac arrhythmias.

In January 2012, CardioNet reported to the HHS Office for Civil Rights (OCR) that a workforce member's laptop was stolen from a parked vehicle outside of the employee's home. The laptop contained the ePHI of 1,391 individuals. OCR's investigation into the impermissible disclosure revealed that CardioNet had an insufficient risk analysis and risk management processes in place at the time of the theft. Additionally, CardioNet's policies and procedures implementing the standards of the HIPAA Security Rule were in draft form and had not been implemented. Further, the Pennsylvania –based organization was unable to produce any final policies or procedures regarding the implementation of safeguards for ePHI, including those for mobile devices.

"Mobile devices in the health care sector remain particularly vulnerable to theft and loss," said Roger Severino, OCR Director. "Failure to implement mobile device security by Covered Entities and Business Associates puts individuals' sensitive health information at risk. This disregard for security can result in a serious breach, which affects each individual whose information is left unprotected."

Unencrypted laptop containing ePHI of 1,391 individuals stolen from employee's car.

- **Insufficient risk analysis**
- **Insufficient safeguards**
- **No policies re mobile devices**

Loss or Theft of Equipment or Data

HHS Examples

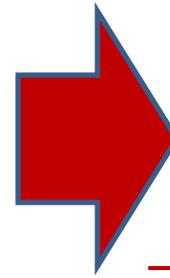
“A covered entity disposed of several hard drives containing electronic protected health information in an unsecured dumpster, in violation of [HIPAA]. HHS’s investigation reveals that the covered entity had failed to implement any policies and procedures to reasonably and appropriately safeguard protected health information during the disposal process.”

“A covered entity’s employee lost an unencrypted laptop that contained unsecured protected health information. HHS’s investigation reveals the covered entity feared its reputation would be harmed if information about the incident became public and, therefore, decided not to provide notification as required by § 164.400 et seq.”

(HHS commentary to breach notification rule, 75 FR 40879)

Consequences

- Willful neglect.
- Mandatory penalties of:
 - If correct w/in 30 days:
 - \$11,182 to \$57,051 per violation
 - Max \$114,102 per type per year.
 - At least \$57,051 per violation if don’t correct w/in 30 days
 - \$57,051 per violation
 - Max \$1,711,533 per type per year



Loss or Theft of Equipment or Data

- **Practices to consider:**
 - Train personnel.
 - Encrypt sensitive data.
 - Use secure server.
 - Implement proven backup and restoration processes.
 - Acquire and use data loss prevention tools.
 - Implement safeguard policy for mobile devices.
 - Maintain accurate asset inventory.
 - Implement process to remove sensitive info from all devices before retired.

Beware Mobile Devices

The screenshot shows a web browser window with the URL <https://www.healthit.gov/resource/your-mobile-device-and-health-information-privacy-and-security>. The page header includes the HealthIT.gov logo, the text "Official Website of The Office of the National Coordinator for Health Information Technology (ONC)", and navigation links for "CONTACT" and "EMAIL UPDATES". A search bar is located in the top right. The main content area features a sidebar on the left with a "Home" section and a "Topics" menu. The main content is titled "Your Mobile Device and Health Information Privacy and Security" and includes a paragraph of text, a "Disclaimer" section, a "Resource Link" section, and an "Audience" section. The Windows taskbar is visible at the bottom of the screen.

HealthIT.gov

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

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Your Mobile Device and Health Information Privacy and Security

Physicians, health care providers and other health care professionals are using smartphones, laptops and tablets in their work. The U.S. Department of Health and Human Services has gathered these tips and information to help you protect and secure health information patients entrust to you when using mobile devices.

Disclaimer

The material in these guides and tools was developed from the experiences of Regional Extension Center staff in the performance of technical support and EHR implementation assistance to primary care providers. The information contained in this guide is not intended to serve as legal advice nor should it substitute for legal counsel. The guide is not exhaustive, and readers are encouraged to seek additional detailed technical guidance to supplement the information contained herein.

Reference in this web site to any specific resources, tools, products, process, service, manufacturer, or company does not constitute its endorsement or recommendation by the U.S. Government or the U.S. Department of Health and Human Services.

Resource Link

Your Mobile Device and Health Information Privacy and Security

Audience

Providers & Professionals

1:41 PM
3/9/2019

Mobile Devices: Tips to Protect and Secure Health Information



Use a password or other user authentication.



Install and enable encryption.



Install and activate wiping and/or remote disabling.



Disable and do not install file-sharing applications.



Install and enable a firewall.



Install and enable security software.



Keep security software up to date.



Research mobile applications (apps) before downloading.



Maintain physical control of your mobile device.



Use adequate security to send or receive health information over public Wi-Fi networks.



Delete all stored health information before discarding or reusing the mobile device.

Loss or Theft of Equipment or Data

Questions to consider:

- Does my equipment contain confidential or sensitive information?
- Is the device secured through, e.g., strong password protection?
- Is the information encrypted?
- May I or do I need to take the equipment with me?
- Is there a secure virtual private network (VPN) that I can use?

4. Insider Accidental or Intentional Data Loss



Insider Accidental or Intentional Data Loss

Common vulnerabilities

- Files e-mailed to wrong address
- Inadequate monitoring, tracking and auditing
 - Access to e-mail and file storage
 - E-mailing and uploading data outside organization
- Inadequate physical access control
- Inadequate training

Practices to consider

- Train personnel
- Workforce access limits and audits
- Implement privileged access management tools
- Implement and use data loss prevention tools.
- Backup

5. Attacks Against Connected Medical Devices



Malware Alters CT Scans and Creates and Removes Tumors

Home

Healthcare Cybersecurity

Malware Alters CT Scans and Creates and Removes Tumors

Search

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Posted By HIPAA Journal on Apr 5, 2019



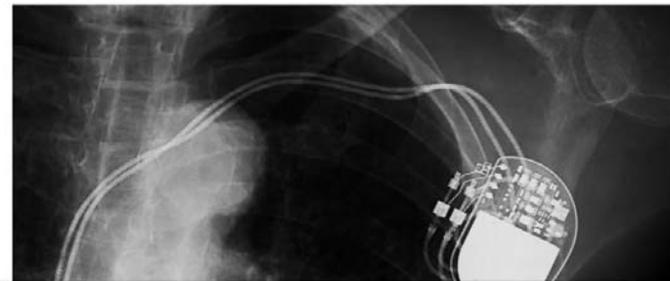
WIRED

A New Pacemaker Hack Puts Malware Directly on the Device

LILY HAY NEWMAN SECURITY 08.09.18 12:30 PM

A NEW PACEMAKER HACK PUTS MALWARE DIRECTLY ON THE DEVICE

SHARE



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- Heart monitors
- Pacemakers
- Insulin pumps
- Imaging scans
- Others?

Attacks Against Connected Medical Devices

Common vulnerabilities

- Patches not implemented
- Outdated equipment
- Most devices cannot be monitored by intrusion detection system
- Cybersecurity profile info may be unavailable
- Wide variance in devices

Practices to consider

- Communicate with device mfr
- Follow mfr instructions
- Patch devices after patch has been validated and tested
- Assess security on networked devices
- Assess devices risks
- Contract carefully
- Access controls for outsiders

<https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf>

Recommended Practices

1. E-mail protection system
2. Endpoint protection system
3. Access management
4. Data protection and loss prevention
5. Network management
6. Vulnerability management
7. Incident response
8. Medical device security
9. Cybersecurity policies

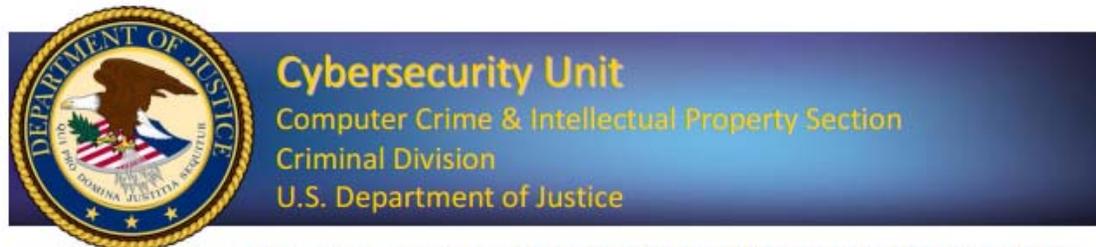
- Sample Forms
- Resources

ov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf

Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients



Healthcare & Public Health
Sector Coordinating Councils
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1301 New York Avenue, N.W., 6th Floor, Washington, D.C. 20530 - CYBERSECURITY.CCIPS@USDOJ.GOV - (202)514-1026

Best Practices for Victim Response and Reporting of Cyber Incidents

Version 1.0 (April 2015)

Any Internet-connected organization can fall prey to a disruptive network intrusion or costly cyber attack. A quick, effective response to cyber incidents can prove critical to minimizing the resulting harm and expediting recovery. The best time to plan such a response is now, *before* an incident occurs.

This “best practices” document was drafted by the Cybersecurity Unit to assist organizations in preparing a cyber incident response plan and, more generally, in preparing to respond to a cyber incident. It reflects lessons learned by federal prosecutors while handling cyber investigations and prosecutions, including information about how cyber criminals’ tactics and tradecraft can thwart recovery. It also incorporates input from private sector companies that have managed cyber incidents. It was drafted with smaller, less well-resourced organizations in mind; however, even larger organizations with more experience in handling cyber incidents may

Health Insurance Portability and Accountability Act (“HIPAA”)

- 45 CFR 164
 - .500: Privacy Rule
 - .300: Security Rule
 - .400: Breach
Notification Rule
- HITECH Act
 - Modified HIPAA
 - Implemented by HIPAA Omnibus Rule



HIPAA Criminal Penalties

Applies if employees or others obtain or disclose protected health info from a covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of law	<ul style="list-style-type: none">• \$50,000 fine• 1 year in prison
Committed under false pretenses	<ul style="list-style-type: none">• \$100,000 fine• 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	<ul style="list-style-type: none">• \$250,000 fine• 10 years in prison

(42 USC 1320d-6(a))

HIPAA Civil Penalties

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none"> • \$114 to \$57,051 per violation • Up to \$28,525 per type per year • No penalty if correct w/in 30 days • OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none"> • \$1,141 to 57,051 per violation • Up to \$114,102 per type per year • No penalty if correct w/in 30 days • OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none"> • \$11,182 to \$57,051 per violation • Up to \$285,255 per type per year • Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none"> • At least \$57,051 per violation • Up to \$1,711,533 per type per year • Penalty is mandatory

(45 CFR 160.404; see also 74 FR 56127)

HIPAA: Avoiding Civil Penalties

You can likely avoid HIPAA civil penalties if you:

- Have required policies and safeguards in place
- Train personnel and document training.
- Respond immediately to mitigate and correct any violation.
- Timely report breaches if required.

*No “willful neglect” =
No penalties if correct
within 30 days.*

HIPAA: Additional Consequences

- State attorney general can bring lawsuit.
 - \$25,000 fine per violation + fees and costs.
- Under HITECH, patients may recover % of fines.
 - Waiting for final rules.
- Patients can probably bring lawsuit.
 - No private cause of action under HIPAA, but HIPAA may represent standard of care.
- Must impose employee sanctions.
- HHS is conducting audits.
- Must self-report breach of unsecured PHI.

It's better to comply.

HIPAA Privacy Rule

- **May not use or disclose protected health info (“PHI”) without patient’s authorization except in limited circumstances.**
- **Must give patients certain rights concerning their PHI.**
- **Must implement reasonable safeguards to protect PHI.**
- **Must execute business associate agreements.**

(45 CFR 164.502-.514)

HIPAA Security Rule

- Risk assessment
- Implement safeguards.
 - Administrative
 - Technical, including encryption
 - Physical
- Execute business associate agreements.

(45 CFR 164.301 et seq.; *see* WSA 35-2-615)



Protect ePHI:

- Confidentiality
- Integrity
- Availability

OCR Settlements in 2018 (record \$28.7 million)

12/18	Hospital allowed access to 62,500 patient records via internet. No risk analysis, inadequate security systems, no BAA.	\$3,000,000
12/18	Hospital failed to terminate former employees access to eHI, allowing access to ePHI. No BAA.	\$111,400
12/18	Hospital's PHI was viewable on vendor's Website. Failed to conduct risk assessment, implement security policies, or execute BAA.	\$500,000
10/18	Anthem cyberattack exposed PHI of 79,000,000 people. Resulted from spear phishing e-mails. Failed to conduct risk assessment, review system activity, or implement adequate security.	\$16,000,000 (largest ever)
6/18	Theft of unencrypted laptop from home of hospital employee. Failure to encrypt devices despite identifying that as a risk.	\$4,348,000
2/18	Fresenius allowed unauthorized access to ePHI. Failed to conduct appropriate risk assessment, protect hardware containing ePHI when left facility, encrypt data.	\$3,500,000
12/17	Cancer center failed to implement safeguards to protect ePHI despite prior warnings that its information had been hacked.	\$2,300,000
4/17	Monitoring company's laptop containing 1,390 patients' info stolen from car; insufficient risk analysis and no finalized security policies.	\$2,500,000
4/17	FQHC's info hacked; no risk analysis and insufficient security rule safeguards.	\$400,000

Risk Assessment

Requirement

- Must conduct and document an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI.

(45 CFR 164.308(a)(1))

- Ongoing process.

Elements

- Scope includes all ePHI in any format, including hard drives, portable media, mobile devices, servers, transmission, storage, networks, etc.
- Track flow of ePHI
- Identify threats and vulnerabilities
- Assess current security measures
- Assess likelihood of threat
- Determine level of risk
- Confirm and implement plan

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html>

The screenshot shows a web browser window with the URL <https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html>. The page features a navigation sidebar on the left with categories: HIPAA for Professionals, Regulatory Initiatives, Privacy (+), Security (-), Breach Notification (+), Compliance & Enforcement (+), Special Topics (+), Patient Safety (+), and Covered Entities & Business (+). The main content area has a title "Guidance on Risk Analysis" and three paragraphs of text. The first paragraph discusses the NIST HIPAA Security Toolkit Application. The second paragraph mentions the HIPAA Security Risk Assessment (SRA) Tool. The third paragraph states that the OCR is responsible for issuing periodic guidance on the HIPAA Security Rule. At the bottom, there is a link to download a PDF copy of the guidance and a "top" button.

Text Resize **A A A** Print Share

Guidance on Risk Analysis

The [NIST HIPAA Security Toolkit Application](#), developed by the National Institute of Standards and Technology (NIST), is intended to help organizations better understand the requirements of the HIPAA Security Rule, implement those requirements, and assess those implementations in their operational environment. Target users include, but are not limited to, HIPAA covered entities, business associates, and other organizations such as those providing HIPAA Security Rule implementation, assessment, and compliance services.

The Office of the National Coordinator for Health Information Technology (ONC) and the HHS Office for Civil Rights (OCR) have jointly launched a [HIPAA Security Risk Assessment \(SRA\) Tool](#). The tool's features make it useful in assisting small and medium-sized health care practices and business associates in complying with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule.

The Office for Civil Rights (OCR) is responsible for issuing periodic guidance on the provisions in the HIPAA Security Rule. (45 C.F.R. §§ 164.302 – 318.) This series of guidance documents will assist organizations in identifying and implementing the most effective and appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The materials will be updated annually, as appropriate.

For additional information, please review our other [Security Rule Guidance Material and our Frequently Asked Questions](#) about the Security Rule.

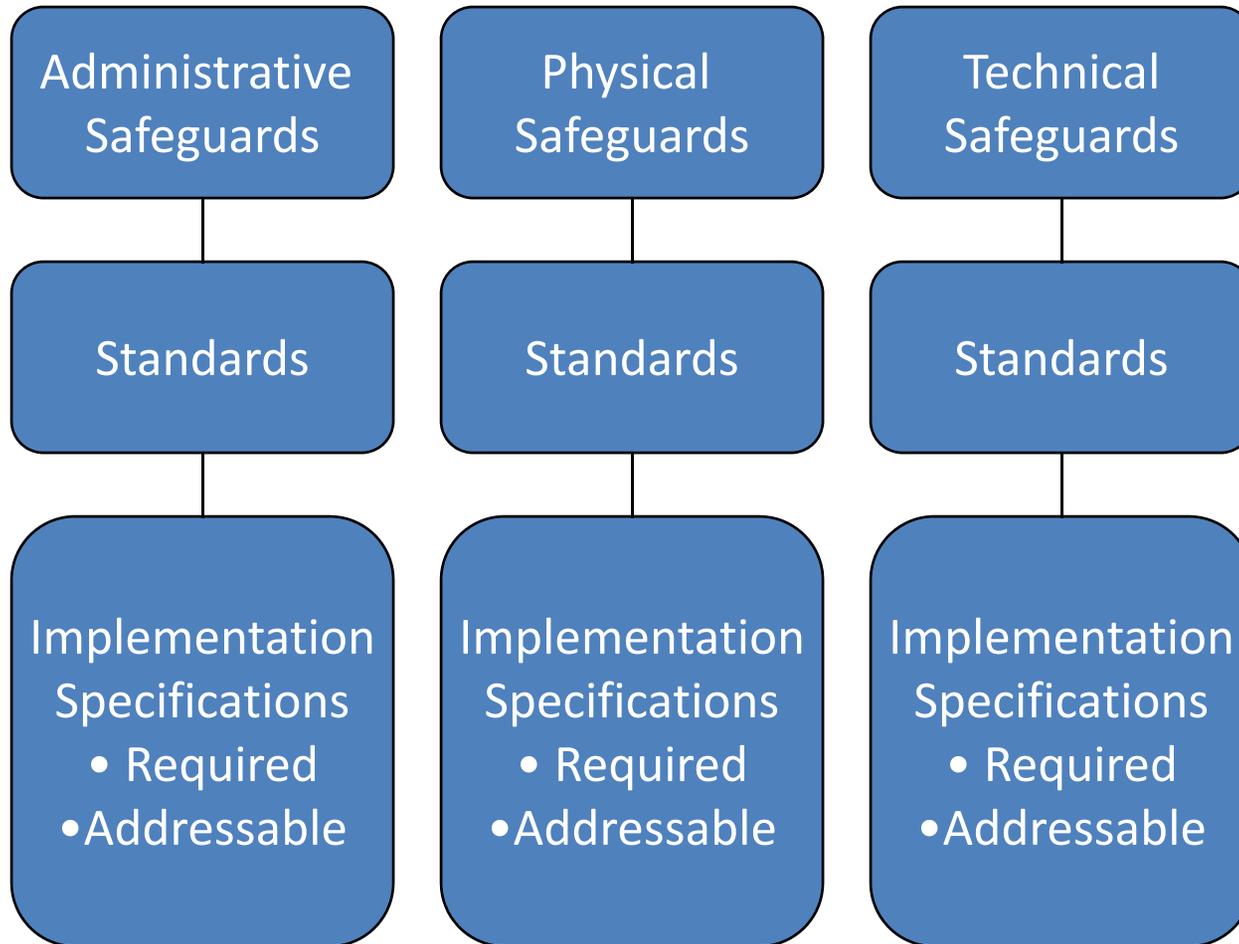
[Download a copy of the guidance in PDF. - PDF](#)

top

<https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>

The screenshot shows the HealthIT.gov website. The browser address bar displays the URL: <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>. The page header includes the HealthIT.gov logo, the text "Official Website of The Office of the National Coordinator for Health Information Technology (ONC)", and a "Connect with us" link. A navigation menu contains "TOPICS", "HOW DO I?", "BLOG", "NEWS", and "ABOUT ONC". A search bar is located on the right. The breadcrumb trail reads: Home > Topics > Privacy, Security, and HIPAA > Security Risk Assessment Tool. On the left sidebar, under "Privacy, Security, and HIPAA", the "Security Risk Assessment Tool" is highlighted. The main content area features the title "Security Risk Assessment Tool" and a paragraph explaining that the Health Insurance Portability and Accountability Act (HIPAA) Security Rule requires covered entities to conduct risk assessments. A large orange arrow points from the right side of the page towards the title, with the text "Updated Tool 2018" inside it. On the far right, a partial sidebar contains the text "Need Please comm SRA To Feedb troubl proble itself. any su impro You m our He 4717".

Safeguards



Security Rule: Administrative Safeguards

- Assign security officer.
- Implement policies, procedures and safeguards to minimize risks.
- Sanction workforce members who violate policies.
- Process for authorizing or terminating access to e-PHI.
- Train workforce members on security requirements.
- Process for responding to security incidents.
- Review or audit information system activity.
- Establish backup plans, disaster recovery plans, etc.
- Periodically evaluate security measures.

(45 CFR 164.308)

Security Rule: Physical Safeguards

- **Limit access to physical facilities and devices containing e-PHI.**
- **Document repairs and modifications to facilities.**
- **Secure workstations.**
- **Implement policies concerning proper use of workstations.**
- **Implement policies concerning the flow of e-PHI into and out of the facility.**
- **Implement policies for disposal of e-PHI.**
- **Create a backup copy of e-PHI.**

(45 CFR 164.310)

Security Rule: Technical Safeguards

- Assign unique names or numbers to track users.
- Implement automatic logoff process.
- Use encryption and decryption, where appropriate.
- Implement systems to audit use of e-PHI.
- Implement safeguards to protect e-PHI from alteration or destruction.
- Implement methods to ensure e-PHI has not been altered or destroyed.
- Implement verification process.
- Protect data during transmission.

(45 CFR 164.312)

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html>

hipaa/for-professionals/security/guidance/index.html

HHS.gov Health Information Privacy U.S. Department of Health & Human Services

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HIPAA for Professionals

Privacy +

Security -

- Summary of the Security Rule
- Guidance
- Combined Text of All Rules

Breach Notification +

Compliance & Enforcement +

Special Topics +

Patient Safety +

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Security Rule Guidance Material

In this section, you will find educational materials to help you learn more about the HIPAA Security Rule and other sources of standards for safeguarding electronic protected health information (e-PHI).

[Security Risks to Electronic Health Information from Peer-to-Peer File Sharing Applications](#)-The Federal Trade Commission (FTC) has developed a guide to Peer-to-Peer (P2P) security issues for businesses that collect and store sensitive information.

[Safeguarding Electronic Protected Health Information on Digital Copiers](#)-The Federal Trade Commission (FTC) has tips on how to safeguard sensitive data stored on the hard drives of digital copiers.

Security Rule Educational Paper Series

The HIPAA Security Information Series is a group of educational papers which are designed to give HIPAA covered entities insight into the Security Rule and assistance with implementation of the security standards.

[Security 101 for Covered Entities](#)

<https://www.healthit.gov/topic/privacy-security-and-hipaa/health-it-privacy-and-security-resources-providers>

The screenshot shows a web browser window displaying the HealthIT.gov website. The page title is "Health IT Privacy and Security Resources for Providers". The navigation bar includes "TOPICS", "HOW DO I?", "BLOG", "NEWS", and "ABOUT ONC". The main content area features a sidebar with categories like "Privacy, Security, and HIPAA", "Educational Videos", "Security Risk Assessment Tool", "HIPAA Basics", "Privacy & Security Resources & Tools", "Resources and Tools for Consumers", "Resources and Tools for Providers", "Security Risk Assessment Tool", "Privacy & Security Training Games", and "Model Privacy Notice (MPN)". The main content area has a section titled "Health IT Privacy and Security Resources for Providers" with a description of the resources and a list of "Tools and Templates" including "Sync for Science (S4S) API Privacy and Security", "Guide to Privacy and Security of Electronic Health Information", "Security Risk Assessment (SRA) Tool", "Security Risk Analysis Guidance", and "HIPAA Security Toolkit Application".

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Search

Home > Topics > Privacy, Security, and HIPAA > Privacy & Security Resources & Tools > Resources and Tools for Providers

Health IT Privacy and Security Resources for Providers

The Office of the National Coordinator for Health Information Technology (ONC), U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), and other HHS agencies have developed a number of resources for you. These tools, guidance documents, and educational materials are intended to help you better integrate HIPAA and other federal health information privacy and security into your practice.

Tools and Templates

- Sync for Science (S4S) API Privacy and Security [PDF - 939 KB]. Led an independent privacy and security technical and administrative testing, analysis, and assessment of a voluntary subset of S4S pilot organizations' implementations of the S4S API.
- Guide to Privacy and Security of Electronic Health Information [PDF - 1.3 MB]. ONC tool to help small health care practices in particular succeed in their privacy and security responsibilities. The Guide includes a sample seven-step approach for implementing a security management process.
- Security Risk Assessment (SRA) Tool. HHS downloadable tool to help providers from small practices navigate the security risk analysis process.
- Security Risk Analysis Guidance . OCR's expectations for how providers can meet the risk analysis requirements of the HIPAA Security Rule.
- HIPAA Security Toolkit Application. National Institute of Standards and Technology (NIST) toolkit to help organizations better understand the requirements of the HIPAA Security Rule, implement those requirements, and assess those implementations in their operational environment.

1:33 PM
3/9/2019

Encryption

- Encryption is an addressable standard per 45 CFR 164.312:
 - (e)(1) *Standard: Transmission security*. Implement technical security measures to guard against unauthorized access to [ePHI] that is being transmitted over an electronic communications network.
 - (2)(ii) *Encryption (Addressable)*. Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.
- ePHI that is properly encrypted is “secured”.
 - Not subject to breach reporting.
- OCR presumes that loss of unencrypted laptop, USB, mobile device is reportable “breach.”

Encryption

Theft of unencrypted laptop from employee's home.

This judgment “underscores the risks entities take if they fail to implement effective safeguards, such as data encryption, when required to protect sensitive patient information.”
--OCR Director Roger Severino

5/18/judge-rules-in-favor-of-ocr-and-requires-texas-cancer-center-to-pay-4.3-million-in-penalties-for-hipaa-... ☆

FOR IMMEDIATE RELEASE
June 18, 2018

Contact: HHS Press Office
202-690-6343
media@hhs.gov

Judge rules in favor of OCR and requires a Texas cancer center to pay \$4.3 million in penalties for HIPAA violations

A U.S. Department of Health and Human Services Administrative Law Judge (ALJ) has ruled that The University of Texas MD Anderson Cancer Center (MD Anderson) violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules and granted summary judgment to the Office for Civil Rights (OCR) on all issues, requiring MD Anderson to pay \$4,348,000 in civil money penalties to OCR. This is the second summary judgment victory in OCR's history of HIPAA enforcement and the \$4.3 million is the fourth largest amount ever awarded to OCR by an ALJ or secured in a settlement for HIPAA violations.

MD Anderson is both a degree-granting academic institution and a comprehensive cancer treatment and research center located at the Texas Medical Center in Houston. OCR investigated MD Anderson following three separate data breach reports in 2012 and 2013 involving the theft of an unencrypted laptop from the residence of an MD Anderson employee and the loss of two unencrypted universal serial bus (USB) thumb drives containing the unencrypted electronic protected health information (ePHI) of over 33,500 individuals. OCR's investigation found that MD Anderson had written encryption policies going as far back as 2006 and that MD Anderson's own risk analyses had found that the lack of device-level encryption posed a high risk to the security of ePHI. Despite the encryption policies and high risk findings, MD Anderson did not begin to adopt an enterprise-wide solution to implement encryption of ePHI until 2011, and even then it failed to encrypt its inventory of electronic devices containing ePHI between March 24, 2011 and January 25, 2013. The ALJ agreed with OCR's

Encryption

Is the use of encryption mandatory in the Security Rule?

Answer: No. The final Security Rule made the use of encryption an addressable implementation specification. See 45 CFR § 164.312(a)(2)(iv) and (e)(2)(ii).

The encryption implementation specification is addressable, and must therefore be implemented if, after a risk assessment, the entity has determined that the specification is a reasonable and appropriate safeguard in its risk management of the confidentiality, integrity and availability of e-PHI.

If the entity decides that the addressable implementation specification is not reasonable and appropriate, it must document that determination and implement an equivalent alternative measure, presuming that the alternative is reasonable and appropriate. If the standard can otherwise be met, the covered entity may choose to not implement the implementation specification or any equivalent alternative measure and document the rationale for this decision.

(OCR FAQ at <https://www.hhs.gov/hipaa/for-professionals/faq/2001/is-the-use-of-encryption-mandatory-in-the-security-rule/index.html>).

Communicating by E-mail or Text

- **General rule: must be secure, i.e., encrypted.**
- **To patients:** may communicate via unsecure e-mail or text if warned patient and they choose to receive unsecure.
(45 CFR 164.522(b); 78 FR 5634)
- **To providers, staff or other third parties:** must use secure platform.
(45 CFR 164.312; CMS letter dated 12/28/17)
- **Orders:** Medicare Conditions of Participation and Conditions for Coverage generally prohibit texting orders.
(CMS letter dated 12/28/17)



Business Associates

- **May disclose PHI to business associates if have valid business associate agreement (“BAA”).**

(45 CFR 164.314 and .504(e))

- **Business associates =**
 - Entities that create, receive, maintain, or transmit PHI on behalf of a covered entity.
 - Covered entities acting as business associates.
 - Subcontractors of business associates.

(45 CFR 160.103)

Business Associates

Common Business Associates

- External IT support
- Software vendors
- Data storage, processing, and destruction companies
- Billing and coding
- Consultants
- Management companies
- Auditors
- Accountants
- Lawyers
- Others?

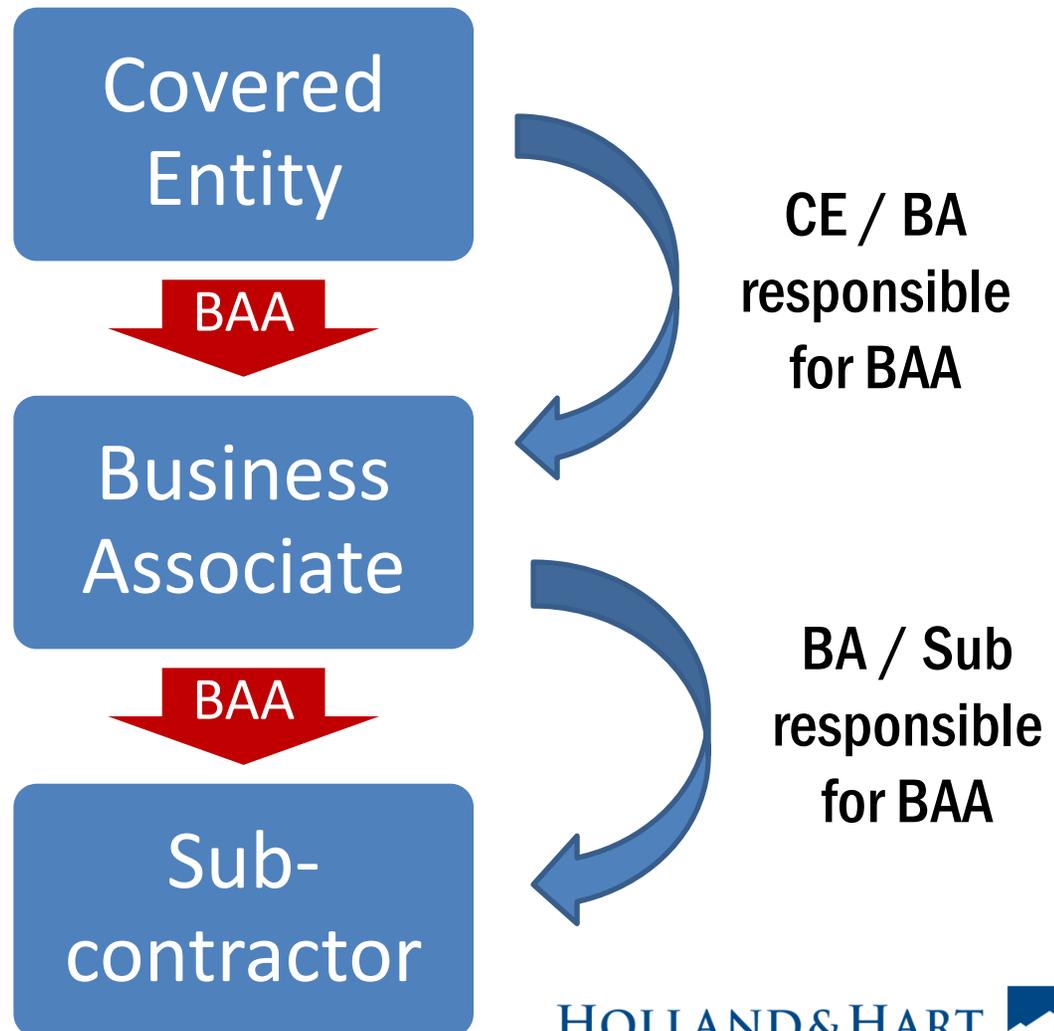
Not Business Associates

- Entities who are not receiving PHI to perform function for a covered entity or the covered entity's business associate.
- Employees
- Workforce members
- Persons whose access is incidental only, e.g., janitor, plumber, etc.

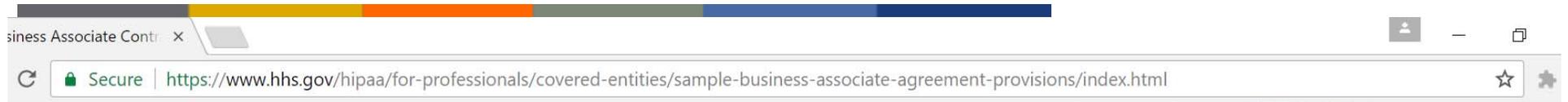
Business Associate Agreements

Must contain required terms, e.g.,

- Permitted uses
- Must comply with Security Rule
- Must report breaches
- Must get BAAs with subcontractors
- Must assist covered entity in responding to patient rights
- Termination.



<https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>



- HIPAA for Professionals
- Privacy +
- Security +
- Breach Notification +
- Compliance & Enforcement +
- Special Topics +
- Patient Safety +
- Covered Entities & Business Associates -
 - Business Associates
 - Business Associate Contracts
- Training & Resources

Business Associate Contracts

SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS

(Published January 25, 2013)

Introduction

A "business associate" is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate. A business associate may use or disclose protected health information only as permitted or required by its business associate contract or as required by law. A business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule.

A written contract between a covered entity and a business associate must: (1) establish the permitted and required uses and disclosures of protected health information by the business associate; (2) provide that the business associate will not use or further disclose the information other than as permitted or required by the contract or as required by law; (3) require the business associate to



Recent OCR settlements based in whole or part on failure to have BAA

Date	Conduct	Penalty
12/18	Health system failed to have BAA with contractor that maintained ePHI	\$3,000,000
12/18	Hospital failed to have BAA with web-based vendor	\$111,400
12/18	Hospitalist group failed to enter BAA with billing company	\$500,000
12/17	Cancer care center failed to enter BAAs with vendors	\$2,300,000
4/17	Pediatric clinics failed to enter BAAs with file storage company	\$31,000
8/16	Health network failed to enter BAAs	\$5,500,000
7/16	Medical university failed to obtain BAA with cloud-based storage vendor	\$2,700,000
4/16	Radiology group failed to have BAA; x-rays left by vendor	\$750,000
3/16	Health system failed to have BAA; laptop stolen from care of BA's employee	\$1,550,000

Breach Reporting (45 CFR 164.400)



Breach Notification

- If there is “breach” of “unsecured PHI”,
 - Covered entity must notify:
 - Each individual whose unsecured PHI has been or reasonably believed to have been accessed, acquired, used, or disclosed.
 - HHS.
 - Local media, if breach involves > 500 persons in a state.
 - Business associate must notify covered entity.

(45 CFR 164.400 et seq.)

“Breach” of Unsecured PHI

- Acquisition, access, use or disclosure of PHI in violation of privacy rules is presumed to be a breach unless the covered entity or business associate demonstrates that there is a low probability that the info has been compromised based on a risk assessment of the following factors:
 - nature and extent of PHI involved;
 - unauthorized person who used or received the PHI;
 - whether PHI was actually acquired or viewed; and
 - extent to which the risk to the PHI has been mitigated,unless an exception applies.

(45 CFR 164.402)

“Breach” of Unsecured PHI

- **“Breach” defined to exclude the following:**
 - Unintentional acquisition, access or use by workforce member if made in good faith, within scope of authority, and PHI not further disclosed in violation of HIPAA privacy rule.
 - Inadvertent disclosure by authorized person to another authorized person at same covered entity, business associate, or organized health care arrangement, and PHI not further used or disclosed in violation of privacy rule.
 - Disclosure of PHI where covered entity or business associate have good faith belief that unauthorized person receiving info would not reasonably be able to retain info

(45 CFR 164.402)

Notice to Individual

- Without unreasonable delay but no more than 60 days of discovery.
 - When known by anyone other than person who committed breach.
- Written notice to individual.
 - By mail.
 - Must contain elements, including:
 - Description of breach
 - Actions taken in response
 - Suggested action individual should take to protect themselves.

(45 CFR 164.404(d))

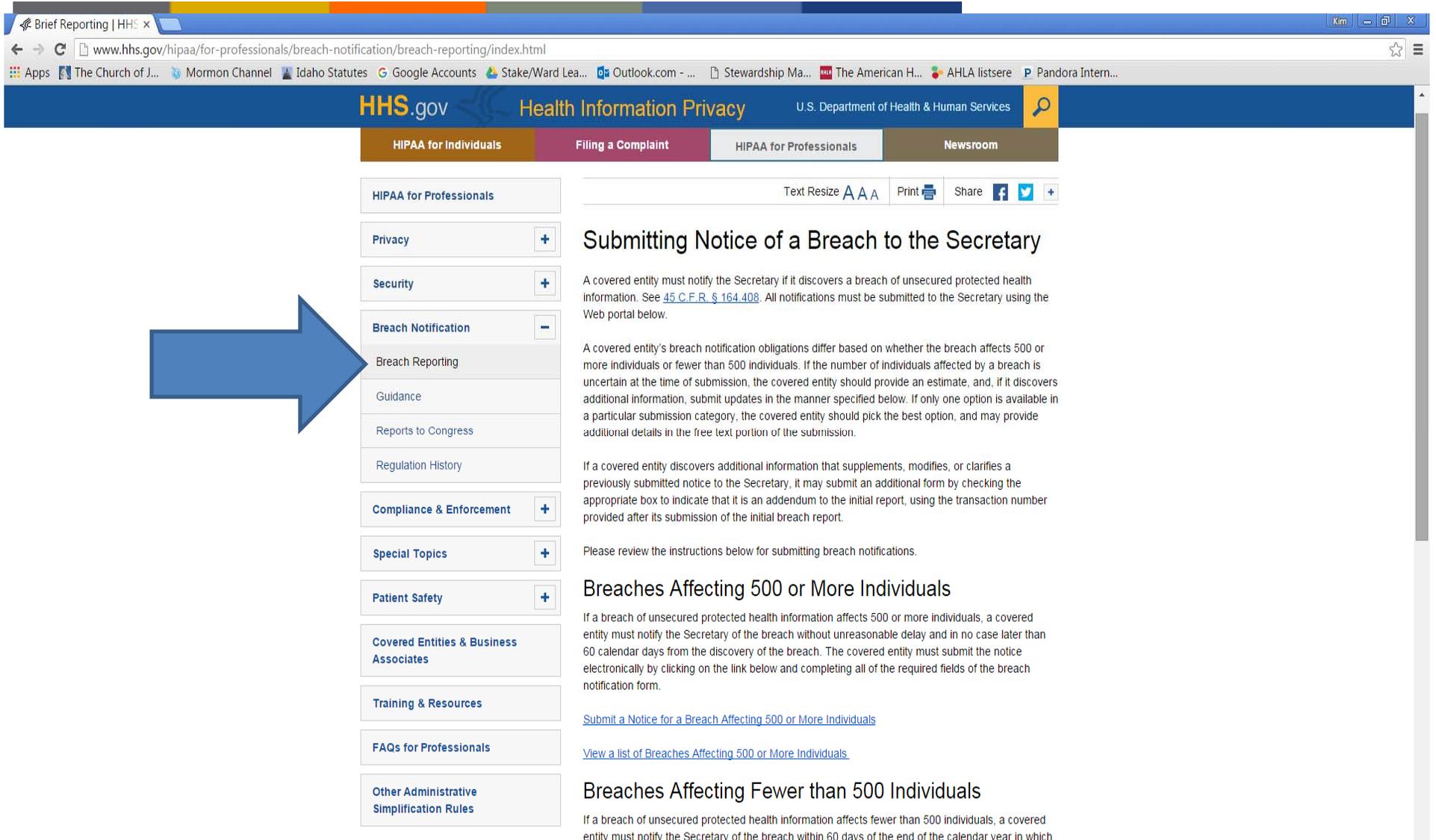
Notice to HHS

- If breach involves fewer than 500 persons:
 - Submit to HHS annually within 60 days after end of calendar year in which breach was discovered (i.e., by March 1).
- If breach involves 500 or more persons:
 - Notify HHS contemporaneously with notice to individual or next of kin, i.e., without unreasonable delay but within 60 days.

(45 CFR 164.408)

- Submit report at <http://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html>.

<https://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html>



The screenshot shows the HHS.gov website with the following elements:

- Header:** HHS.gov Health Information Privacy U.S. Department of Health & Human Services
- Navigation:** HIPAA for Individuals, Filing a Complaint, HIPAA for Professionals, Newsroom
- Left Sidebar (Expanded):** HIPAA for Professionals, Privacy (+), Security (+), Breach Notification (-), Breach Reporting (highlighted by a blue arrow), Guidance, Reports to Congress, Regulation History, Compliance & Enforcement (+), Special Topics (+), Patient Safety (+), Covered Entities & Business Associates, Training & Resources, FAQs for Professionals, Other Administrative Simplification Rules
- Main Content Area:**
 - Text:** Text Resize A A A, Print, Share (Facebook, Twitter, Plus)
 - Section Header:** Submitting Notice of a Breach to the Secretary
 - Text:** A covered entity must notify the Secretary if it discovers a breach of unsecured protected health information. See [45 C.F.R. § 164.408](#). All notifications must be submitted to the Secretary using the Web portal below.
 - Text:** A covered entity's breach notification obligations differ based on whether the breach affects 500 or more individuals or fewer than 500 individuals. If the number of individuals affected by a breach is uncertain at the time of submission, the covered entity should provide an estimate, and, if it discovers additional information, submit updates in the manner specified below. If only one option is available in a particular submission category, the covered entity should pick the best option, and may provide additional details in the free text portion of the submission.
 - Text:** If a covered entity discovers additional information that supplements, modifies, or clarifies a previously submitted notice to the Secretary, it may submit an additional form by checking the appropriate box to indicate that it is an addendum to the initial report, using the transaction number provided after its submission of the initial breach report.
 - Text:** Please review the instructions below for submitting breach notifications.
 - Section Header:** Breaches Affecting 500 or More Individuals
 - Text:** If a breach of unsecured protected health information affects 500 or more individuals, a covered entity must notify the Secretary of the breach without unreasonable delay and in no case later than 60 calendar days from the discovery of the breach. The covered entity must submit the notice electronically by clicking on the link below and completing all of the required fields of the breach notification form.
 - Links:**
 - [Submit a Notice for a Breach Affecting 500 or More Individuals](#)
 - [View a list of Breaches Affecting 500 or More Individuals](#)
 - Section Header:** Breaches Affecting Fewer than 500 Individuals
 - Text:** If a breach of unsecured protected health information affects fewer than 500 individuals, a covered entity must notify the Secretary of the breach within 60 days of the end of the calendar year in which

Notice to HHS

- HHS posts list of those with breaches involving more than 500 at https://ocrportal.hhs.gov/ocr/breach/breach_report.jsfpersons

The screenshot shows a web browser window with the URL https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf. The page header identifies the U.S. Department of Health and Human Services, Office for Civil Rights, and the Breach Portal. The main heading is "Breaches Affecting 500 or More Individuals". Below this, a paragraph explains that the list is required by section 13402(e)(4) of the HITECH Act and is now in a more accessible format. A "Show Advanced Options" link is visible. The main content is a table titled "Breach Report Results" with the following columns: Name of Covered Entity, State, Covered Entity Type, Individuals Affected, Breach Submission Date, Type of Breach, and Location of Breached Information. The table lists 20 breaches, with the most affected being Kern Medical Center (83,000 individuals) and Detroit Department of Health and Wellness Promotion (10,000 individuals).

Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
Brooke Army Medical Center	TX	Healthcare Provider	1000	10/21/2009	Theft	Paper/Films
Mid America Kidney Stone Association, LLC	MO	Healthcare Provider	1000	10/28/2009	Theft	Network Server
Alaska Department of Health and Social Services	AK	Healthcare Provider	501	10/30/2009	Theft	Other, Other Portable Electronic Device
Health Services for Children with Special Needs, Inc.	DC	Health Plan	3800	11/17/2009	Loss	Laptop
Mark D. Lurie, MD	CA	Healthcare Provider	5166	11/20/2009	Theft	Desktop Computer
L. Douglas Carlson, M.D.	CA	Healthcare Provider	5257	11/20/2009	Theft	Desktop Computer
David I. Cohen, MD	CA	Healthcare Provider	857	11/20/2009	Theft	Desktop Computer
Michele Del Vicario, MD	CA	Healthcare Provider	6145	11/20/2009	Theft	Desktop Computer
Joseph F. Lopez, MD	CA	Healthcare Provider	952	11/20/2009	Theft	Desktop Computer
City of Hope National Medical Center	CA	Healthcare Provider	5900	11/23/2009	Theft	Laptop
The Children's Hospital of Philadelphia	PA	Healthcare Provider	943	11/24/2009	Theft	Laptop
Cogent Healthcare, Inc.	TN	Business Associate	6400	11/25/2009	Theft	Laptop
Democracy Data & Communications, LLC (VA	Business Associate	83000	12/08/2009	Other	Paper/Films
Kern Medical Center	CA	Healthcare Provider	596	12/10/2009	Theft	Other
Rick Lawson, Professional Computer Services	NC	Business Associate	2000	12/11/2009	Theft	Desktop Computer, Electronic Medical Record, Network Server
Detroit Department of Health and Wellness Promotion	MI	Healthcare Provider	646	12/15/2009	Theft	Desktop Computer, Laptop
Detroit Department of Health and Wellness Promotion	MI	Healthcare Provider	10000	12/15/2009	Theft	Other Portable Electronic Device

Notice to Media

- If breach involves unsecured PHI of more than 500 residents in a state, covered entity must notify prominent media outlets serving that state (e.g., issue press release).
 - Without unreasonable delay but no more than 60 days from discovery of breach.
 - Include same content as notice to individual.

(45 CFR 164.406)

Notice by Business Associate

- **Business associate must notify covered entity of breach of unsecured PHI:**
 - Without unreasonable delay but no more than 60 days from discovery.
 - Notice shall include to extent possible:
 - Identification of individuals affected, and
 - Other info to enable covered entity to provide required notice to individual.

(45 CFR 164.410)

- **Business associate agreements may impose different deadlines.**

Wyoming Breach Reporting Statute (WSA 40-12-501)



Wyoming Breach Reporting Statute

- Generally requires commercial entities to immediately investigate and notify subject persons if:
 - Unauthorized acquisition of computerized data that materially compromises security, confidentiality, or integrity of data;
 - “personal identifying info”, i.e.,
 - Name + certain other identifiers (e.g., SSN; driver’s license; account #, credit card #, debit card # + code; tribal ID; username or e-mail + password; birth/marriage certificate; health info; individual tax ID);
 - Misuse could cause injury to Wyoming resident; and
 - Misuse is likely to occur.
- AG may bring suit to enforce statute or recover damages.
- Compliance with HIPAA satisfies Wyoming statute.

(WSA 40-12-502)

Additional Resources



<https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf>

Recommended Practices

1. E-mail protection system
2. Endpoint protection system
3. Access management
4. Data protection and loss prevention
5. Network management
6. Vulnerability management
7. Incident response
8. Medical device security
9. Cybersecurity policies

- Sample Forms
- Resources

ov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf

Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients



Healthcare & Public Health
Sector Coordinating Councils
PUBLIC PRIVATE PARTNERSHIP

Appendix F: Resources

Below is a list of free resources with supplemental information for the threats and concepts addressed in this document. This list is not intended to be comprehensive or complete.

U.S Department of Health and Human Services (HHS) Resources

- **Security Risk Assessment Tool**
 - **Link:** <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment>
 - **Description:** Security Risk Assessment Tool is designed to help healthcare providers conduct a security risk assessment as required by the HIPAA Security Rule and the Centers for Medicare and Medicaid Service (CMS) Electronic Health Record (EHR) Incentive Program
 - # of pages: N/A
- **Risk Management Handbook (RMH) Chapter 08: Incident Response**
 - **Link:** <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Downloads/RMH-Chapter-08-Incident-Response.pdf>
 - **Description:** "The intent of this document is to describe standard operating procedures that facilitate the implementation of security controls associated with the Incident Response (IR) family of controls taken from the National Institute of Standards and Technology (NIST) Special Publication 800-53 Revision 4 Security and Privacy Controls for Federal Information Systems and Organizations and tailored to the CMS environment in the CMS ARS."
 - # of pages: 116
- **Incident Report Template**
 - **Link:** <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/RMH-Chapter-08-Incident-Response-Appendix-K-Incident-Report-Template.html?DLPage=4&DLEntries=10&DLSort=0&DLSortDir=ascending>
 - **Description:** Template for reporting a computer security incident
 - # of pages: 7
- **Cybersecurity | FDA General Page**
 - **Link:** <https://www.fda.gov/medicaldevices/digitalhealth/ucm373213.htm>
 - **Description:** FDA's Cybersecurity page
 - # of pages: 2-3
- **Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health**
 - **Link:** <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm604500.htm>
 - **Description:** FDA's Medical Device Safety Action Plan
 - # of pages: 18
- **HHS Office for Civil Rights Cybersecurity Page**
 - **Link:** <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>
 - **Description:** This web page includes most of OCR's general cybersecurity resources (cybersecurity incident checklist, ransomware guidance, cybersecurity newsletters, HIPAA

<https://www.hhs.gov/hipaa/for-professionals/index.html>

HHS.gov
U.S. Department of Health & Human Services
Health Information Privacy

I'm looking for...

HHS A-Z Index

HIPAA for Individuals | Filing a Complaint | HIPAA for Professionals | Newsroom

HHS > [HIPAA Home](#) > HIPAA for Professionals

HIPAA for Professionals

Text Resize **A A A** | Print | Share [f](#) [t](#) +

HIPAA for Professionals

To improve the efficiency and effectiveness of the health care system, the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#), Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

- HHS published a final [Privacy Rule](#) in December 2000, which was later modified in August 2002.

6:33 AM
6/28/2018

[https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-](https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf)

Guide to Privacy and Security of | x +

← → ↻ 🏠 <https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf>

1. Importance of Privacy and Security Matters
2. HIPAA Rules
3. Patient's Rights
4. EHR, HIPAA Security, and Cybersecurity
5. Meaningful Use Rules
6. 7-Step Approach for Security Management
7. Breach Notification Rules

The Office of the National Coordinator for Health Information Technology



Guide to Privacy and Security of Electronic Health Information

Version 2.0
April 2015

The information contained in this Guide is not intended to serve as legal advice nor should it substitute for legal counsel. The Guide is not exhaustive, and readers are encouraged to seek additional detailed technical guidance to supplement the information contained herein.

Putting the I in HealthIT
HealthIT.gov



1301 New York Avenue, N.W., 6th Floor, Washington, D.C. 20530 - CYBERSECURITY.CCIPS@USDOJ.GOV - (202)514-1026

Best Practices for Victim Response and Reporting of Cyber Incidents

Version 1.0 (April 2015)

Any Internet-connected organization can fall prey to a disruptive network intrusion or costly cyber attack. A quick, effective response to cyber incidents can prove critical to minimizing the resulting harm and expediting recovery. The best time to plan such a response is now, *before* an incident occurs.

This “best practices” document was drafted by the Cybersecurity Unit to assist organizations in preparing a cyber incident response plan and, more generally, in preparing to respond to a cyber incident. It reflects lessons learned by federal prosecutors while handling cyber investigations and prosecutions, including information about how cyber criminals’ tactics and tradecraft can thwart recovery. It also incorporates input from private sector companies that have managed cyber incidents. It was drafted with smaller, less well-resourced organizations in mind; however, even larger organizations with more experience in handling cyber incidents may

<https://www.hollandhart.com/healthcare#overview>

The screenshot shows the top of the Holland & Hart website. The header includes the slogan "EXCELLENCE IN LEGAL SERVICES" and the firm's logo, which features a stylized mountain peak and the text "HOLLAND & HART" along with "70 YEARS EST. 1947". A navigation menu is visible on the left. The main content area is titled "OVERVIEW" and includes sections for "PRACTICES/INDUSTRIES", "NEWS & INSIGHTS", and "CONTACTS". Under "CONTACTS", there are two profile cards: one for Kim Stanger, Partner in Boise, and one for Blaine Benard, Partner in Salt Lake City. Below the contact cards is a "HEALTH LAW BLOG" section with a sub-headline "Access to previous webinar recordings, publications, and more." A large orange arrow points from the "HEALTH LAW BLOG" section towards the right side of the image.



Past Webinars
Publications



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