

Industry leading Education Today's Webinar

- **2017's HIPAA Onsite Audits: What to Expect and How to Pass**

Webinars

- Upcoming & past webinars:
<http://compliance-group.com/webinar/>



HIPAA Compliance Simplified

Agenda

- HIPAA Overview
- Common misunderstandings
- HIPAA Enforcement
- What causes a Audit?
- Real World Stories
- How do I protect my practice?





HHS Wall of Shame

| | Name of Covered Entity | State | Covered Entity Type | Individuals Affected | Breach Submission Date | Type of Breach | Location of Breached Information |
|---|---|-------|---------------------|----------------------|------------------------|--------------------------------|---|
| 6 | St. Joseph's Hospital and Medical Center | AZ | Healthcare Provider | 623 | 02/13/2017 | Unauthorized Access/Disclosure | Electronic Medical Record |
| 6 | Benesch, Friedlander, Coplan & Aronoff LLP | OH | Business Associate | 1134 | 02/10/2017 | Theft | Paper/Films |
| 6 | Family Medicine East, Chartered | KS | Healthcare Provider | 6800 | 02/03/2017 | Theft | Desktop Computer |
| 6 | Catalina Post-Acute Care and Rehabilitation | AZ | Healthcare Provider | 2953 | 02/02/2017 | Improper Disposal | Paper/Films |
| 6 | Jeffrey D. Rice, O.D., L.L.C. | OH | Healthcare Provider | 1586 | 02/02/2017 | Theft | Paper/Films |
| 6 | Veriv Co. Health & Welfare Plan | OH | Health Plan | 965 | 01/31/2017 | Unauthorized Access/Disclosure | Paper/Films |
| 6 | WellCare Health Plans, Inc. | FL | Health Plan | 24809 | 01/27/2017 | Hacking/IT Incident | Network Server |
| 6 | Shiel Sexton | IN | Health Plan | 710 | 01/27/2017 | Unauthorized Access/Disclosure | Other |
| 6 | Synergy Specialists Medical Group, Inc / Jay S. Benenter, DPM | CA | Healthcare Provider | 569 | 01/27/2017 | Hacking/IT Incident | Email |
| 6 | Princeton Pain Management | NJ | Healthcare Provider | 4666 | 01/27/2017 | Hacking/IT Incident | Desktop Computer, Electronic Medical Record |
| 6 | THE R.O.A.D.S. Foundation Inc. DBA R.O.A.D.S. Community Care Clinic | CA | Healthcare Provider | 670 | 01/26/2017 | Loss | Paper/Films |
| 6 | MultiCare Health System | WA | Healthcare Provider | 1249 | 01/26/2017 | Hacking/IT Incident | Email |
| 6 | Roper St. Francis Healthcare | SC | Healthcare Provider | 576 | 01/24/2017 | Loss | Other Portable Electronic Device |
| 6 | Stephenville Medical & Surgical Clinic | TX | Healthcare Provider | 75006 | 01/23/2017 | Unauthorized Access/Disclosure | Desktop Computer |
| 6 | Multnomah County | OR | Healthcare Provider | 1700 | 01/20/2017 | Unauthorized Access/Disclosure | Email |
| 6 | Wonderful Center For Health Innovation | CA | Healthcare Provider | 3356 | 01/20/2017 | Theft | Laptop |
| 6 | Covenant Medical Center, Inc. | MI | Healthcare Provider | 6197 | 01/20/2017 | Unauthorized Access/Disclosure | Electronic Medical Record |
| 6 | Associated Catholic Charities Incorporated | MD | Healthcare Provider | 1145 | 01/20/2017 | Unauthorized Access/Disclosure | Email |
| 6 | TriHealth, Inc. | OH | Healthcare Provider | 1126 | 01/19/2017 | Unauthorized Access/Disclosure | Network Server, Paper/Films |

Based on HHS Breach Portal: Breaches Affecting 500 or More Individuals, "Type of Breach" https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf



HHS Wall of Shame

| Name of Covered Entity | State | Covered Entity Type | Individuals Affected | Breach Submission Date | Type of Breach | Location of Breached Information |
|--|-------|---------------------|----------------------|------------------------|---|--|
| Massachusetts Eye and Ear Infirmary | MA | Healthcare Provider | 1076 | 01/08/2013 | Theft | Other |
| Children's Eyewear Sight | CA | Healthcare Provider | 1090 | 01/13/2015 | Theft | Desktop Computer |
| Eye Institute of Corpus Christi | TX | Healthcare Provider | 43963 | 03/26/2016 | Theft | Electronic Medical Record |
| EyeCare of Bartlesville | OK | Healthcare Provider | 4000 | 03/13/2015 | Hacking/IT Incident | Desktop Computer, Network Server |
| Massachusetts Eye and Ear Infirmary | MA | Healthcare Provider | 3584 | 04/20/2013 | Theft | Laptop |
| Oakland Vision Services, PC | MI | Healthcare Provider | 3080 | 05/03/2012 | Hacking/IT Incident | Network Server |
| Southeast Eye Institute, P.A. dba eye Associates of Pinellas | FL | Healthcare Provider | 87314 | 05/09/2016 | Hacking/IT Incident | Network Server |
| University of Houston for UN College of Optometry | TX | Healthcare Provider | 7000 | 05/08/2012 | Hacking/IT Incident, Unauthorized Access/Disclosure | Network Server |
| Silicon Valley Eyecare Optometry and Contact Lenses | CA | Healthcare Provider | 40000 | 05/13/2013 | Theft | Network Server |
| Associates in EyeCare, P.S.C. | KY | Healthcare Provider | 971 | 05/16/2016 | Theft | Laptop, Other Portable Electronic Device |
| Gulf Breeze Family Eyecare, Inc | FL | Healthcare Provider | 9626 | 06/17/2013 | Theft, Unauthorized Access/Disclosure | Desktop Computer, Electronic Medical Record, Email, Network Server, Paper/Titles |
| Cybele Eye-Tech of Green, Inc. | OH | Healthcare Provider | 850 | 07/14/2016 | Unauthorized Access/Disclosure | Electronic Medical Record |
| Penn State University - MI College of Optometry | MI | Healthcare Provider | 3947 | 10/11/2013 | Hacking/IT Incident | Network Server |
| EnvisionRx | OH | Business Associate | 540 | 10/23/2015 | Unauthorized Access/Disclosure | Paper/Titles |
| Indiana University School of Optometry | IN | Healthcare Provider | 757 | 10/26/2011 | Theft | Network Server |
| Visionworks Inc. | TX | Health Plan | 74844 | 11/10/2014 | Loss | Network Server |
| REVEE-HOODS EYE CENTER | CA | Healthcare Provider | 30000 | 11/15/2014 | Theft | Network Server |
| Visionworks Inc. | TX | Health Plan | 47683 | 11/21/2014 | Theft | Network Server |
| True Vision Eyecare | OH | Healthcare Provider | 542 | 11/21/2014 | Theft | Laptop |
| Babblers Eye Center PC | CT | Healthcare Provider | 1789 | 11/28/2012 | Theft | Desktop Computer |

Based on HHS Breach Portal: Breaches Affecting 500 or More Individuals, "Type of Breach" https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf

Are YOU HIPAA Compliant?



We are HIPAA compliant...

Risk Assessments

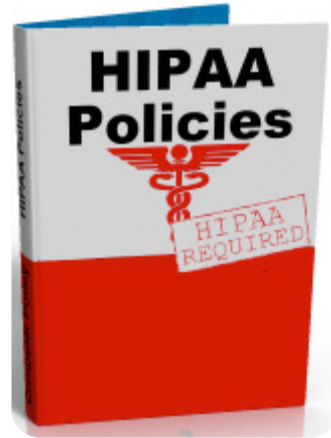
- I had an expensive Security Risk Assessment done
- Am I HIPAA compliant?



| Payment Summary | |
|---|------------|
| Please review the following details for this transaction. | |
| Description | Item Price |
| Remote Risk Assessment \$4000 | \$4,000.00 |
| Total | \$4,000.00 |

Policies & Procedures

- I have a Manual, I am compliant “right”?



Workforce Training

- I paid for my employees HIPAA training, I am compliant.

Certificate of Completion
HIPAA Privacy & Security Compliance Training
This certificate hereby grants
My employee
in recognition of the successful completion of HIPAA compliance training
on **December 13, 2013**
Director of Safety & Privacy Officer

Your Cart

| Item Description | Quantity | Price | SubTotal |
|---|----------|---------|-----------------|
| ✖ HIPAA Security Training | 10 | \$20.00 | \$200.00 |
| HIPAA Privacy Training for Healthcare Providers | 10 | \$24.99 | \$249.90 |
| Total: | | | \$449.90 |

FAIL

* Cost for 10 employee practice

Avoidable Breach

- Who: Anchorage Community Mental Health Services (ACMHS) - **Nonprofit** org. (**Alaska**)
- What: **Malware** caused breach of unsecured ePHI
- Why: “ACMHS had adopted policies and procedures in 2005, but these **policies and procedures were not followed and/or updated.**” ACMHS could have **avoided** the breach (and not be subject to the settlement agreement), if it had followed its own policies and procedures
- Settlement: **\$150,000 & CAP (Corrective Action Plan)** (12/2014)



What is HIPAA Compliance and what is NOT

- **Compliance vs. Security**

- Fines vs. Risk

- **HIPAA/HITECH**

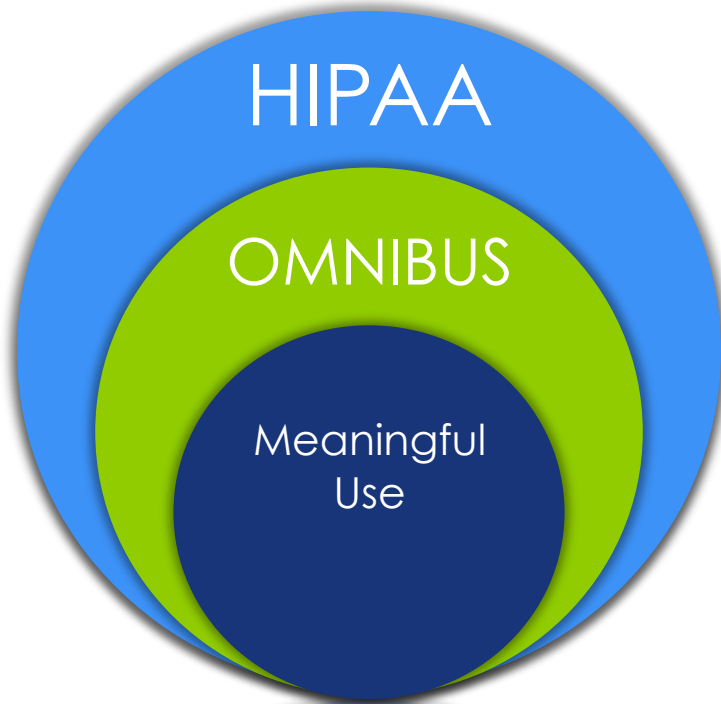
- Protect patient confidentiality while furthering innovation and patient care
- [Privacy Rule and Security Rule](#)

- **Omnibus**

- Business Associates must be HIPAA compliant
- Covered Entities must have BAAs
 - Conduct Due Diligence
- [Breach Notification Rule](#)

- **Meaningful Use**

- Accelerate adoption of EHR (electronic Health records)



Compliance

vs.

Security

- Audits
 - Security, Privacy, and Administrative
- Gap Identification
- Remediation
- Policies & Procedures
- Employee Training & Attestation
- Business Associate Management
 - BA Agreements & Audit
- Incident Management

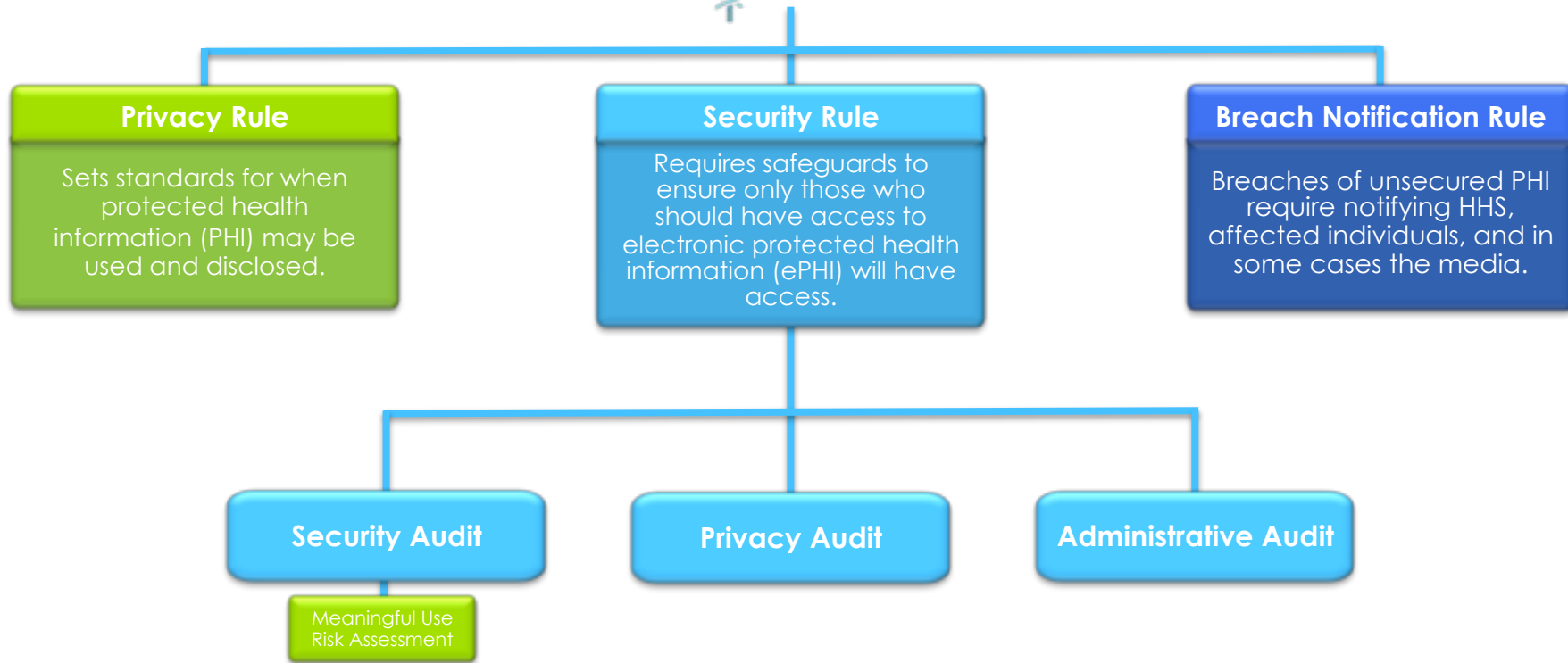
- Security Risk Analysis
 - Penetration Testing
 - Vulnerability Scan
- Network Security
- Managed Services
- IT Consulting
- Cloud Services

Security Risk Assessment

FINES

RISK

REPUTATION



What Information Does HIPAA Protect?

PHI may include any of the following:

- Names
- Addresses
- Dates of Service
- Telephone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle identifiers/Serial Numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers;
- Biometric identifiers
- Full Face Photos or Videos
- Any other unique identifying number, characteristic, or code



Omnibus Rule

- Business Associates:
 - Direct liability by function
 - Directly liable for violations
 - Must be HIPAA Compliant (Security Rule)
 - **Technical, Administrative, & Physical** Safeguards
- Covered Entities:
 - Compliance with Privacy Rule
 - Must have BAAs (Business Associate Agreements)
 - Conduct **Due Diligence**
 - for the CE
- Contracting with subcontractors
 - BA liability flows to all subcontractors



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"I heard the new HIPAA Omnibus Rules are a whole lot tougher on business associates."

The Need For BAAs

- Who: Raleigh Orthopaedic (North Carolina)
- What/Why: 17,300 patients affected
 - Handed over PHI to potential business partner without first executing a **business associate agreement**.
- Settlement: **\$750,000 & CAP** (4/20/16)



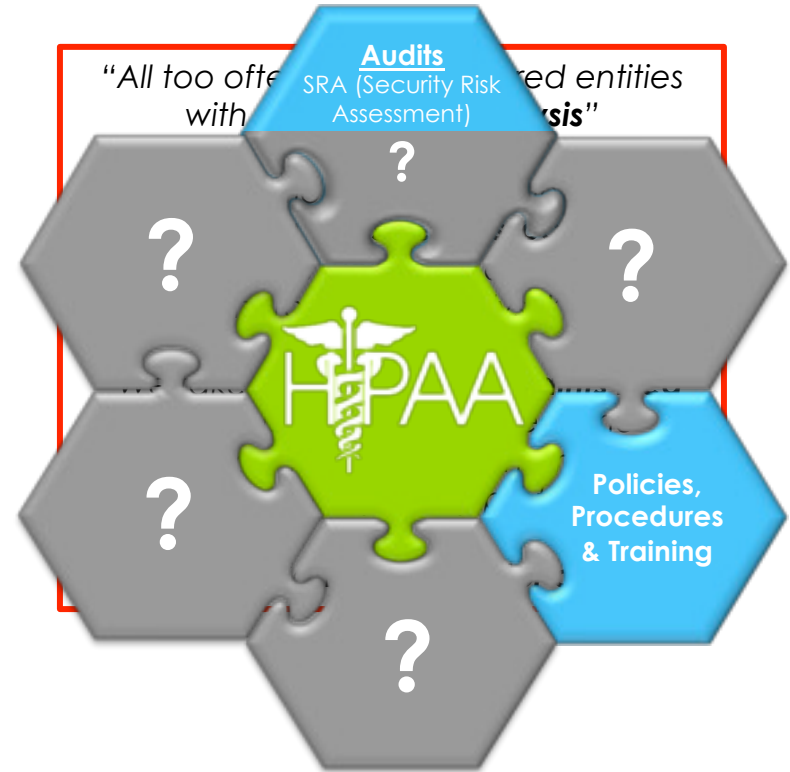
“HIPAA’s obligation on covered entities to obtain **business associate agreements** is more than a mere check-the-box paperwork exercise,” said **Jocelyn Samuels, Director of OCR**. “It is critical for entities to know to whom they are handing PHI and to obtain assurances that the information will be protected.”

<http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/raleigh-orthopaedic-clinic-bulletin/index.html>

Why Should I Worry About HIPAA?

HIPAA is the Law

- Current market solutions often only address pieces of compliance
- Enforcement is on the rise ↑
 - Record fines levied: **400% increase**
 - **\$6.2 Million** in 2015
 - **\$24 Million** in 2016
 - **\$11.4 Million** so far in 2017*
 - Three prison sentences
 - Medical license revoked
 - State Attorney General levying fines



<http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>

HIPAA Enforcement

Who is being fined?



- **\$24 Million** in 2016 – 400% increase
- **\$11.4 Million** so far in 2017

“All too often we see covered entities with a **limited risk analysis**”

“Organizations must have in place compliant **business associate agreements** as well as an accurate and thorough risk analysis”

“We take seriously **all complaints filed by individuals**, and will seek the necessary remedies to ensure that patients' privacy is fully protected.”

- **Jocelyn Samuels, Director of OCR**

- **Three** Prison Sentences
- Medical License **Revoked**
- **State Attorney General** levying fines

The Seven Fundamental Elements of an Effective Compliance Program

Compliance according to HHS:

1. *Implementing written policies, procedures and standards of conduct.*
2. *Designating a compliance officer and compliance committee.*
3. *Conducting effective training and education.*
4. *Developing effective lines of communication.*
5. *Conducting internal monitoring and auditing.*
6. *Enforcing standards through well-publicized disciplinary guidelines.*
7. *Responding promptly to detected offenses and undertaking corrective action.*



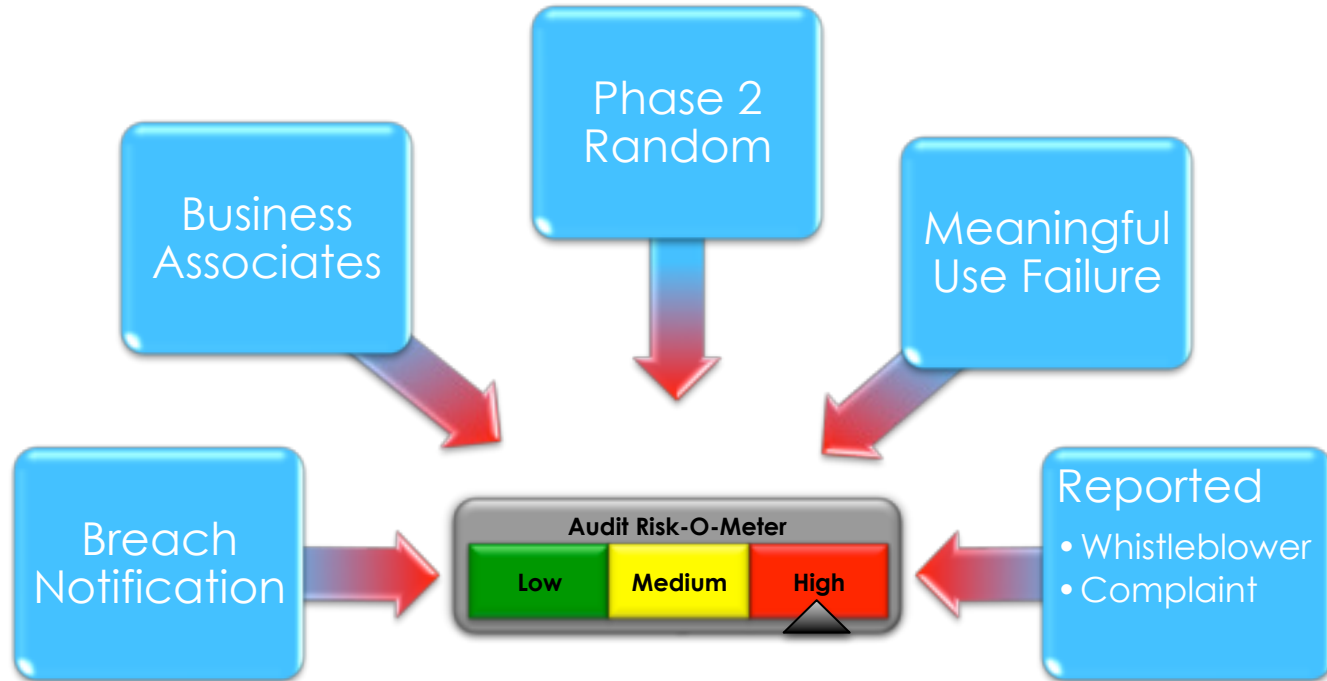
*Source HHS & OIG

Random odds

- Winning Lotto 1 in 175 Million
- Attacked by a shark 1 in 11.5 Million
- Hit by Lightning 1 in 960,000
- Hole in One 1 in 12,500
- Random HIPAA Audit 1 in 10,000
- Meaningful use Audit 1 in 10
- Breach-Related Audit 1 in ?



Causes Of A HIPAA Audit



The Process Of An Audit

Desk Audit

Request for Gap and Remediation Report



On Site Audit

Review of all 7 Elements of Effective Compliance



Results

Corrective Action Plan

Fines

Risk Analysis is NOT Enough

- Who: OHSU (Oregon Health & Science University)
- What: Reports of **unencrypted laptops, stolen unencrypted thumb drive**, 1,361 patient records
- Why: Conducted **SIX** risk analysis in (2003, 2005, 2006, 2008, 2010, 2013) but did not address the widespread vulnerabilities. Also, lacked **policies & procedures**. Lack of **BAA**.
- Settlement: **\$2.7 Million & CAP** (7/18/16)



*“From well-publicized large scale breaches and findings in their own risk analyses, OHSU **had every opportunity to address security** management processes that were insufficient. Furthermore, OHSU should have addressed the lack of a business associate agreement before allowing a vendor to store ePHI,” said OCR Director Jocelyn Samuels. “This settlement underscores the importance of leadership engagement and why it is so critical for the C-suite to **take HIPAA compliance seriously.**”*

<http://www.hhs.gov/about/news/2016/07/18/widespread-hipaa-vulnerabilities-result-in-settlement-with-oregon-health-science-university.html>

Improper Disclosure Of PHI

- Who: Feinstein Institute for **Medical Research**
- What: **Laptop stolen from car contained** (13,000 PHI) of research participants. **Password-protected but not encrypted**
- Why: Failed to reasonably safeguard PHI;
 - **Lacked policies & procedures** for ePHI access
 - **Failed to implement policies and procedures** to safeguard ePHI
- Ruling: **\$3.9 Million & CAP** (3/17/16)



“Research institutions subject to HIPAA must be held to the **same compliance standards as all other HIPAA-covered entities**,” said OCR Director Jocelyn Samuels. “For individuals to trust in the research process and for patients to trust in those institutions, they must have some assurance that their information is kept private and secure.”

Unauthorized Patient Testimonials

- Who: Complete P.T. Pool & Land **Physical Therapy**
- What: **Posted patient testimonials** (including names/photos) on website without authorization.
- Why: Failed to reasonably safeguard PHI;
 - **Impermissibly disclosed PHI without authorization;**
 - **Failed to implement policies and procedures** to comply with HIPAA regarding authorization
- Ruling: **\$25,000 & CAP** (2/16/16)



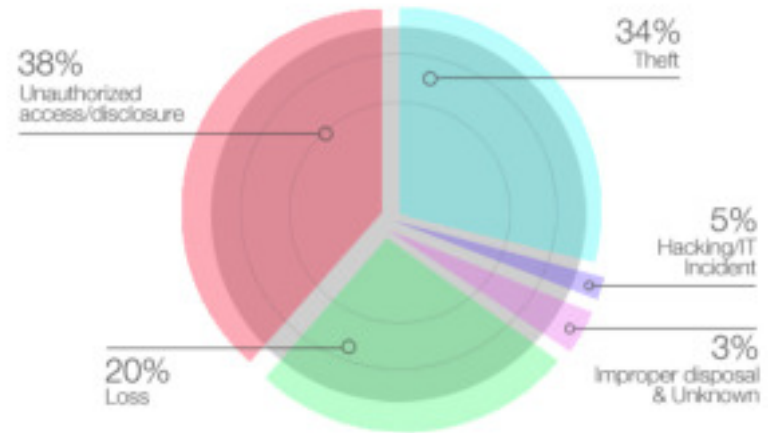
"The **HIPAA Privacy Rule** gives **individuals** important **controls** over whether and how their protected health information is **used and disclosed for marketing** purposes," said OCR Director Jocelyn Samuels. "With limited exceptions, the Rule requires an individual's **written authorization** before a use or disclosure of his or her protected health information can be made for marketing."

<http://www.healthcareitnews.com/news/physical-therapist-pay-25000-over-unauthorized-patient-testimonials>

But...It Probably Won't Happen To Me

- In a recent study, **more than half** of business associates (**59%**) reported a data breach in the last two years that involved the loss or theft of patient data. More than a quarter (**29%**) experienced two breaches or more.
- Of the 345 incidents reported by HHS and listed on their site under Breaches Affecting 500 or More Individuals, 74 involved a business associate (**21%**).

HIPAA Breach by Type
with Business Associate Involvement



Data from HHS.gov

Fifth Annual Benchmark Study on Privacy & Security of Healthcare Data conducted by Ponemon Institute
http://media.scmagazine.com/documents/121/healthcare_privacy_security_be_30019.pdf

Tardy Breach Notification = 1st Fine Of 2017

- Who: Presence Health
- What: **Missing paper schedules** (836 PHI)
- Why: **Failed to notify within 60 days** of discovery:
 - **Media outlets**
 - **OCR**
 - **Individuals affected**
- Settlement: **\$475,000 & CAP** (1/9/17)



*“Covered entities need to have a clear policy and procedures in place to respond to the **Breach Notification Rule’s timeliness requirements**” said OCR Director Jocelyn Samuels. “**Individuals need prompt notice of a breach** of their unsecured PHI so they can take action that could help mitigate any potential harm caused by the breach.”*

<https://www.hhs.gov/about/news/2017/01/09/first-hipaa-enforcement-action-lack-timely-breach-notification-settles-475000.html>

Solving The HIPAA Compliance Puzzle



We simplify compliance so you can confidently focus on your business.



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