

**WHAT'S NEW FOR HIPAA AND
42 C.F.R. PART 2?**
CURRENT GUIDANCE
AND ENFORCEMENT TRENDS

Jill Jensen, J.D.
NHA Annual Convention

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Breakout Session 11

CLINE WILLIAMS

JILL JENSEN, J.D.

CLINE WILLIAMS
WRIGHT JOHNSON & OLDFATHER

Attorney
jjensen@clinewilliams.com
Direct: 402-479-7116
Fax: 402-474-5393




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TSW OR "WHAT'S IN IT FOR YOU?"

- Describe how 42 C.F.R. Part 2 differs from the HIPAA Privacy and Security Rules and how best to analyze issues that involve both HIPAA and Part 2 facts.
- Identify the top three areas of recent enforcement focus for the Office of Civil Rights for data privacy and security.
- Compare and analyze their own HIPAA privacy and security compliance programs to best practices identified in the presentation.

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ROAD MAP



Part 2 and HIPAA – What's the Difference?

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What's latest the on the HIPAA enforcement front?

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What are the OCR's top areas of enforcement focus?

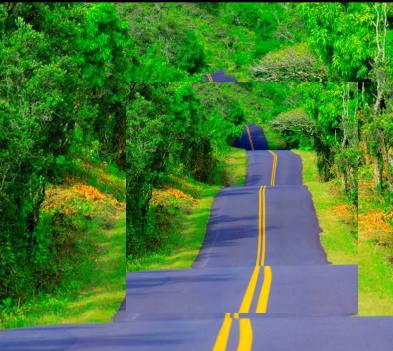
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What best practices should you follow now?

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WHAT'S THE DIFFERENCE?

HIPAA & 42 C.F.R. Part 2



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SO WHY TALK ABOUT PART 2?

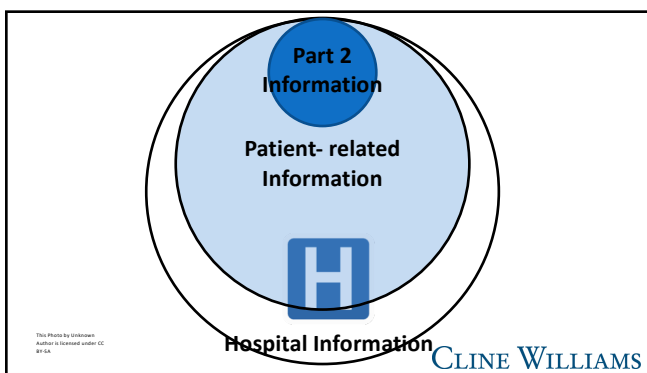
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PART 2 AND HIPAA: THE DIFFERENCES

- To whom and to what do they apply
- How they apply
- The language they use
- What they allow
- How they are enforced

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SOME BACKGROUND

Which came first?
HIPAA or Part 2?



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TRUDGING THE ROAD OF HAPPY DESTINY

- 42 U.S.C. § 290dd-2(a) (1974)
- Part 2 Regs - 1975
- Revised 1987
- Jan. 2017 (eff. March 21, 2017)
- Jan. 2018 (eff. Feb. 2, 2018)



HIPAA

- HIPAA "the statute," 1996
- HIPAA Admin. Simplification Regulations – early 2000s
- HITECH, 2009
- Omnibus Rule, 2013



FROM THIS

- Oldsmobile Convertible Delta 88 "Land Yacht"
- Circa 1975
- Passes everything except the gas station



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TO THIS

- Toyota Prius 2018
- Sips -- does not "guzzle"



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TIME FLIES

- Massive changes in society
- Massive changes in healthcare



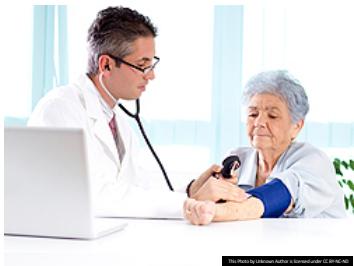
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FROM THIS

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TO THIS



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WHAT IS PART 2?

- “Pursuant to 42 U.S.C. 290dd-2(g), the regulations in this part impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of any part 2 program. . . .”
- 42 C.F.R. 2.2(a)

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42 C.F.R. § 2.31

“(a) *General.* The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure.”

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SUBSTANCE USE DISORDER

- “Substance use disorder means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.”
- 42 C.F.R. § 2.11.

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WHAT IS A “PROGRAM”?

“Part 2 program means a federally assisted program”

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WHAT IS A PROGRAM? THREE ALTERNATIVES

- ☐ **Individual or entity** (other than general medical facility) **who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or**

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WHAT IS A "PROGRAM"?

- ☐ An **identified unit** of a general medical facility **that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or**

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WHAT IS A "PROGRAM"?

- Medical **personnel or staff** in a general medical facility **whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.**

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WHAT IS "FEDERALLY ASSISTED"?

- Licensed, certified, registered, or otherwise authorized by any department or agency of the United States, including, but not limited, to:
 - Participating in Medicare;
 - Authorization to conduct maintenance treatment or withdrawal management; or
 - Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;

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OTHERS "FEDERALLY ASSISTED"

- Supported by funds provided by any U.S. department or agency:
 - Receives federal financial assistance in any form
 - Conducted by a state or local government unit which, receives federal funds which could be (but are not necessarily) spent for the substance use disorder program; or
- Assisted through tax exempt status

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HOW THEY APPLY

HIPAA

- "Covered Entity"
 - Providers
 - Clearinghouses
 - Plans
 - Standard electronic transactions
 - "Protected health information"
- Generally permits disclosures/uses if an exception applies --

Part 2

- "Part 2 Program"
 - "Federally-assisted"
 - Nonprofit status
 - Medicare/Medicaid
 - Other
 - Individual
 - Institution
 - "Patient identifying information"
- Permits uses/disclosures under certain circs
- Does not compel use or disclosure

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LANGUAGE USED

- HIPAA**
- "Authorizations"
 - "Individual"
 - "Protected Health Information"
 - "Business Associate"
 - OCR enforcement

- Part 2**
- "Consents"
 - "Patient"
 - "Patient identifying information"
 - "Qualified Service Organization"
 - SAMHSA non-enforcement
 - DOJ might enforce criminal violations

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QUALIFIED SERVICE ORGANIZATION (QSO)

- Provides services to Part 2 Program
 - Data processing
 - Bill collecting
 - Laboratory analyses
 - Dosage preparation
 - Legal
 - Accounting
 - Population health management
- Other professional services
- Also,
 - Child abuse, neglect prevention services
 - Nutrition training
 - Child care
 - Individual
 - Group therapy

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QSO AGREEMENT

- In writing
- QSO acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and
- If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

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CAN A BA AGREEMENT SERVE AS A QSOA?

- Yes, if
 - It the BAA has the required QSOA provisions which
 - Acknowledges being bound by Part 2 regulations; and
 - Agrees to resist in judicial proceedings efforts to obtain access to Part 2 program patient records.

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THE BIG DIFFERENCES

- HIPAA**
- Many exceptions
 - Treatment
 - Payment
 - Health Care Operations
 - Required by Law
 - BAA
 - Facility Directories
 - Marketing
 - Personal reps
 - Research
 - Etc.

- Part 2**
- Few exceptions
 - Internal – Need to know basis
 - Parent organization
 - Court order + subpoena post hearing
 - QSO as needed for services
 - Research
 - Bona fide Medical Emergencies
 - Audits/evals
 - Child abuse/neglect
 - Crime on premises or against program personnel

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"PATIENT"

- Current and former
- One who has applied for, been given diagnosis, treatment, or referral for treatment for a substance use disorder at a Part 2 program
- Including a person, after arrest on a criminal charge, is identified as having a substance use disorder to determine that individual's eligibility to participate in a Part 2 program.

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PATIENT IDENTIFYING INFORMATION

- ✓ Name,
 - ✓ Address,
 - ✓ Social security number,
 - ✓ Fingerprints,
 - ✓ Photograph, or similar information
- by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information.

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PART 2

- Restricts disclosure of PII whether recorded or not
 - If it would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person; and
 - It is created or maintained by a Part 2 Program
- Restricts use of such PII to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient

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TO WHOM DOES PART 2'S PROHIBITION APPLY?

- Part 2 Programs
- Their QSOs
- Recipients of Part 2 patient identifying information
 - Payers
 - Part 2 Program Parent entities
 - Individuals or entities informed of prohibition on redisclosure

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WHAT'S (FAIRLY) NEW FOR PART 2?

- The Part 2 Regs were modernized in 2017 to make them more compatible with the goals of health care reform
 - Facilitate information exchange within new health care models
 - Continue to address legitimate privacy concerns of patients
 - Clarified the regulations
 - Amended requirements for consent

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CONSENTS

- Paper or electronic
- Patient name
- The specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure ("From whom")
- How much and what kind of information is to be disclosed, SUD information that may be disclosed.
- Treating providers by name
- If not at treating provider:
 - If to a payer, payer's name
 - If not a payer, like a HIE, the name of the HIE and
 - Names of individual participants in HIE;
 - The name(s) of entity participant(s) that have a treating provider relationship with the patient; OR
 - "General designation" of treating providers of patient.

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CONSENTS AND GENERAL DESIGNATIONS

When using a general designation,

- ☐ Must include a statement on the consent form
- ☐ That confirms patient's understanding that, upon request and consistent with Part 2, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation.

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OTHER CONSENT REQUIREMENTS

- The purpose of the disclosure limited to the information required for the stated purpose;
- A statement that the consent is subject to revocation at any time except if to the extent it has been relied upon already.
- The date, event, or condition upon which the consent will expire if not revoked before but the consent must last no longer than reasonably necessary to serve the purpose for which it is provided.
- The signature of the patient or authorized individual
 - Electronic signatures are permitted if not prohibited by any applicable law.
- The date the consent is signed.

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WHAT'S (FAIRLY) NEW FOR PART 2?

- Additional changes in 2018: Permits disclosures
 - With patient consent, to facilitate payment and healthcare operations such as claims management, quality assessment, and patient safety activities.
 - To certain contractors, subcontractors, and legal representatives for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation.
- The final rule allows use of an abbreviated notice of prohibition on re-disclosure for EHRs

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"This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65."

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FOR EHRS

"42 CFR part 2 prohibits unauthorized disclosure of these records."



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SAMHSA GUIDANCE

- FAQs – Part 2 and HIE
- FAQs -- How Part 2 Applies now

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OTHER THINGS TO WATCH FOR

- More efforts to further align Part 2 with HIPAA
- Likely will not occur without action by Congress, however.
 - Attempted in the House version of the SUPPORT Act which was not in the final bill sent to President Trump for signature

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HOW PART 2 IS ENFORCED?

- SAMHSA has no authority to enforce Part 2
- DOJ may bring criminal charges
 - Hasn't happened yet



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HIPAA ENFORCEMENT



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ENFORCEMENT TRENDS

- OCR still is the "kinder and gentler" part of HHS
- 95% of its activities are oriented toward fixing problems and providing technical assistance



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PHASE 2 AUDITS

- Desk audits
 - 166 Covered Entities – Completed Sept. 2017
 - Security Rule -- Risk analysis and risk management, and Breach Notification Rule, content and timeliness of notice
 - OR
 - Privacy Rule: NPP and individual access
 - 41 Business Associates – Completed Dec. 2017
 - Security Rule: Risk analysis and risk management and Breach Notification Rule: report of breach to covered entity

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TOP OCR CONCERNS

- Preserve patient access
- Maintain privacy and security
- Secure portable and other devices
- Do an ongoing assessment of your situation
- Adopt a solution that is reasonable and appropriate for your circumstances

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WHAT'S NEXT IN HIPAA AUDITS

- Summary of findings will be shared by OCR in 2018
- Enforcement audits likely the next step per Roger Severino, Director of Office of Civil Rights at NIST/OCR seminar, October 18, 2018.
- Severino: "Top to bottom" audit warranted if breach report not submitted

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500+ Breaches by Type *

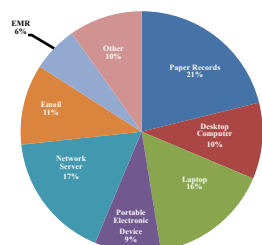
September 23, 2009 through December 31, 2017

January 1, 2018 through September 30, 2018

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500+ Breaches by Location *

September 23, 2009 through December 31, 2017




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RECENT BIG DOLLAR CASES*

2/1/2018	Fresenius Medical Care North America	\$3,500,000
2/13/2018	Filefax	\$100,000
6/18/2018	MD Anderson Cancer Center	\$4,348,000 ALJ Judgment
9/20/2018	ABC Cases	\$999,000
10/15/2018	Anthem	\$16,000,000

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**\$3.5 MM +
COMPREHENSIVE
CORRECTIVE
ACTION PLAN**



**FRESENIUS
MEDICAL CARE**

- 5 breaches (occurred Feb.-July 2012); 5 facilities
- "failed to implement policies and procedures to safeguard its facilities and the equipment therein from unauthorized access, tampering, and theft."
- Unencrypted thumb drive stolen from staff member car (P&P failure)
- Hard drive and missing desktop – not reported up chain
- Unencrypted laptop and case stolen -- included passwords

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**FRESENIUS
MEDICAL CARE**

- ✓ Accurate and thorough risk analysis required
- ✓ Review/revise P&Ps on physical access, device and media controls
- ✓ Training program
- ✓ \$3.5MM settlement amount

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FILEFAX

- Dumpster diver took medical records to recycling facility for money
- Anonymous complaint alerted OCR, and OCR investigated
- Medical records of 2150 individuals had been left
- The records had been left in an unlocked truck outside of Filefax
- \$100,000 Resolution Amount
- CAP with Receiver of Filefax
 - Create records disposition plan
 - Obtain HHS approval
 - Implement plan per court

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- ALJ decision – summary judgment for OCR on all issues
- \$4.3 MM in penalties
- 3 separate data breach reports in 2012 and 2013
 - Theft of unencrypted laptop
 - Loss of 2 unencrypted USB devices
 - Had policies for encryption and risk analysis identified it as a high risk issue
 - Did not adopt an enterprise-wide solution until August 2011
 - EPHI of about 35,000 patients

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer Center~~
 Making Cancer History®




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ABC CASES

- Multiple settlements with OCR
- Three prominent Boston-area providers
 - Massachusetts General Hospital (\$515K)
 - Brigham & Women's Hospital (\$384K)
 - Boston Medical Center (\$100K)
- Invited film crews to film an ABC television network documentary series, without first obtaining patient authorizations
- OCR investigated based upon newspaper article
- \$999,000 among the three

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TAKE-A-WAYS FROM THE ABC CASES

- P&Ps -- prohibit the use or disclosure of PHI for photography, video recording, or audio recording, not otherwise permitted or required by HIPAA before a valid authorization obtained
- Process for reviewing media requests for filming
- Restricting access of media to patient treatment areas -
- ID personnel who handle such requests
- Actively monitor all photography, video recording, and audio recording conducted in facility by the media, in nonpublic areas for purposes not related to medical treatment or a health care operations
- Reporting procedures and Sanctions

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DON'T GO ALL HOLLYWOOD



- Have appropriate P&Ps about media access
- Get Authorizations before access
- Limit and monitor media activity on premises
- Implement and enforce

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- \$16MM settlement – largest ever (Oct. 15, 2018)
- 79 MM people
- Series of cyberattacks
- Vendor vulnerability
- Robust corrective action plan



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- AN EPIC FAIL

•Failed to

- Conduct an enterprise-wide risk analysis,
 - Insufficient procedures to regularly review information system activity
- To identify and respond to suspected or known security incidents
- Implement adequate minimum access controls to prevent the cyber-attackers from accessing ePHI, as early as February 18, 2014.

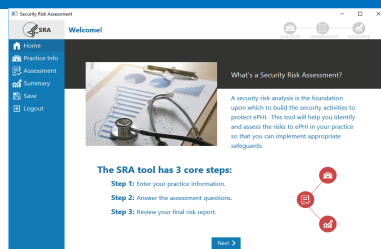
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OTHER RECENT DEVELOPMENTS



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ONC/OCR SECURITY RISK ASSESSMENT TOOL V3*



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PROPOSED HIPAA POLICY ACTIVITY*

- Notice of Proposed Rulemaking on Good Faith Disclosures by Health Care Providers to Address Opioid Crisis
- Request for Information: Improving Care Coordination and Reducing Regulatory Burden
 - Notice of Privacy Practices
 - Timely Provider Information Sharing
 - Accounting of Disclosures

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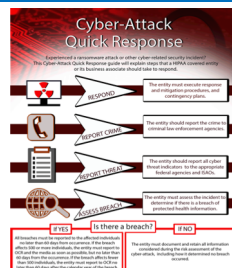
PROPOSED HIPAA POLICY ACTIVITY*

- Request for Information on Civil Monetary Penalties or Monetary Settlements to Harmed Individuals
- HIPAA/FERPA Updated Guidance

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OCR CYBERSECURITY GUIDANCE

- Ransomware Guidance
- Cyber Security Checklist and Infographic



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CYBERSECURITY GUIDANCE*

- **Monthly Cybersecurity Newsletters**

- April 2018: Risk Analyses vs. Gap Analyses
- May 2018: Workstation Security
- June 2018: Software Vulnerabilities and Patching
- July 2018: Guidance on Disposing of Electronic Devices and Media
- August 2018: Securing Electronic Media and Devices

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

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ADDITIONAL RESOURCES

- <https://list.nih.gov/cgi-bin/wa.exe?A0=OCR-PRIVACY-LIST>
- <https://www.hhs.gov/hipaa/for-professionals/index.html>

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BEST PRACTICES

"Compliance does not mean security."

BEST PRACTICES

- Map where your PHI/EPHI resides – data mapping
 - Collaborative effort between clinicians and IT
 - Ongoing
 - Include hardware, software, in-flow, internal movement, and out-flow of data
 - Include your vendors
- If you don't know where your information is, how can you protect it?

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MORE BEST PRACTICES

- Do ongoing Risk Analysis
- Manage your risk
- Monitor activity
- Take corrective action





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

LEVERAGE AVAILABLE TOOLS

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**MAKE SURE
ONE HAND
KNOWS
WHAT THE
OTHER IS
DOING**

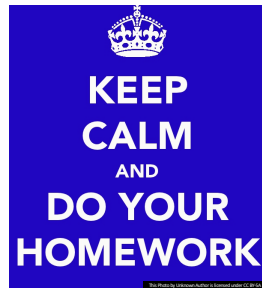


**Does IT know what
happens on the floors?**

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**BEST PRACTICES
IN RISK
MANAGEMENT**

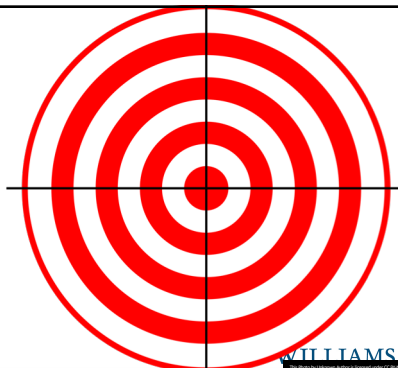
- Plan and schedule tasks with deadlines
- Assign tasks
- Hold team accountable



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**BE A "HARD"
TARGET**

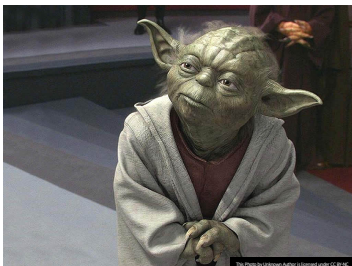
- Patch, Patch, Patch!
- Encrypt, Encrypt, Encrypt!
- Make sure the doors are locked! (including the backdoor)(i.e., your vendors)



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A word to the wise is sufficient.

"DO OR
DO NOT.
THERE IS
NO TRY."



THANK YOU!

Jill Jensen, J.D.
jjensen@clnewilliams.com
 Direct: 402-479-7116
 Fax: 402-474-5393

