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Agenda

- Security traps demonstrated by recent OCR settlements
- Performing and documenting a risk assessment
- Required safeguards: what you really need to address
- To encrypt or not to encrypt: mobile devices, emails, texts and other communications
- OCR guidance concerning cloud computing, ransomware, and other items



Recent OCR Actions





- February 2, 2017: \$3.2 Million Fine
- Lost Blackberry in 2010 (3,800 ePHI records)
- Lost laptop in 2013 (2,462 ePHI records)
- "impermissible disclosure of unsecured (ePHI) and non-compliance over many years with multiple standards of the HIPAA Security Rule."
 - Lack of risk management plans
 - No encryption on mobile devices
 - Ineffective physical access controls



Children's Medical Center of Dallas

- Notice of Proposed Determination
 - No Request for Hearing
 - "opportunity to provide written evidence of mitigating factors or affirmative defenses and/or written evidence in support of a waiver of a [civil monetary penalty]"
- Aggravating Factors
 - continued use of unencrypted devices from 2008 to 2013
 - prior history of non-compliance
 - losses of laptop, blackberry put them on notice of active risk of compromise of ePHI and non-compliance
 - Reportable incidents in 2008, 2009, 2010, 2013



MAPFRE Life Insurance of Puerto Rico

- January 18, 2017: \$2.2 Million Fine
- "With this resolution amount, OCR balanced potential violations of the HIPAA Rules with evidence provided by MAPFRE with regard to its present financial standing."
- Stolen USB memory stick, 2011 (2,209 ePHI records)



MAPFRE Life Insurance of Puerto Rico

- "Failure to conduct its risk analysis and implement risk management plans, contrary to its prior representations, and a failure to deploy encryption or an equivalent alternative measure on its laptops and removable storage media until September 1, 2014.
- "MAPFRE also failed to implement or delayed implementing other corrective measures it informed OCR it would undertake."



Other OCR Actions

- \$475,000 for lack of timely breach notification (Presence Health)
- \$400,000 for failure to update BAA for over ten years (CARE New England Health System)
 - "WIH failed to renew or modify its existing written business associate agreement with Care New England Health System, its business associate, to include the applicable implementation specifications required by the Privacy and Security Rules."
- \$2.75 Million (University of Mississippi Med Center)
 - breach of ePHI of "10,000 individuals. During the investigation,
 OCR determined that UMMC was aware of risks and vulnerabilities
 to its systems as far back as April 2005, yet no significant risk
 management activity occurred until after the breach, due largely
 to organizational deficiencies and insufficient institutional
 oversight."

Sources:



Other OCR Actions

- \$2.7 Million
 - lost laptop (4,022 ePHI records)
 - lack of BAA with third-party cloud storage provider who suffered a breach (3,044 ePHI records)
- How many improvement could you make with \$2.7 million?
 - "We made significant data security enhancements at the time of the incidents and now are investing at an unprecedented level in proactive measures to further safeguard patient information," Barnes continued. "In the face of these challenges, OHSU is proactively working to ensure the creation of a sustainable gold standard for protected health information security and HIPAA compliance."

Sources:



Summary of Recent Issues

- Missing or outdated BAAs
- Missing or inadequate risk assessment
- Failure to act in the face of known risks
 - failure to encrypt
 - failure to restrict access (physical & logical)
- Failure to perform timely breach notification
- Failure to respond to OCR Notice of Determination



Performing & Documenting the Risk Assessment



HIPAA Security Rule

- 45 CFR 164.302-318
- 164.306 (General Requirements)
 - (a)(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.
 - (a)(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
 - (a)(3) Protect against any reasonably
 anticipated uses or disclosures of such information



HIPAA Security Rule

- 164.308 (Administrative Safeguards)
 - (a)(1)(i) Standard: Security Management Process
 - Implement policies and procedures to prevent, detect, contain, and correct security violations.
 - (a)(1)(ii) Implementation Specifications:
 - (ii)(A) Risk Analysis: Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of electronic protected health information.
 - (ii)(B) Risk Management: Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

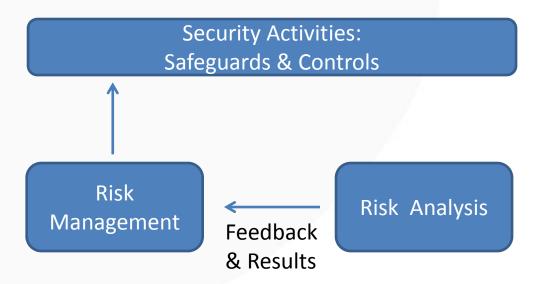
HIPAA Security Rule - Documentation

 164.316(B)(1)(ii): If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

D		Risk Assessment Project	
1	1	System Documentation Phase	
2		1.0 Set boundary for selected system	-
3		1.1 Record system identification information	
4		1.2 Document system purpose and desc.	
5		1.3 Document the system security level	
6	2	System Risk Determination Phase	—
7		2.1 Identify threats and vulnerabilities	_
8		2.2 Describe risks	
9		2.3 Identify existing controls	
10		2.4 Determine likelihood of occurrence	_
11		2.5 Determine severity of impact	
12		2.6 Determine risk levels	J
13	3	Safeguard Determination Phase	—
14		3.1 Recommend controls and safeguards) -
15		3.2 Determine residual likelihood of occurrence	
16		3.3 Determine residual severity of impact	
17		3.4 Determine residual risk level	
18	4	Report presentation, archiving and sign-off	_



Risk Management & Analysis





NIST Standards

"Covered entities may use any of the NIST documents to the extent that they provide relevant guidance to that organization's implementation activities. While NIST documents were referenced in the preamble to the Security Rule, this does not make them required. In fact, some of the documents may not be relevant to small organizations, as they were intended more for large, governmental **organizations."** – Source: CMS FAQ on Security Rule.



NIST Standards

- 800-39: Managing Information Security Risk
- 800-37: Risk Management Framework
- 800-30: Risk Assessment



Risk Management & Analysis



- 1. Develop and implement a risk management plan.
- 2. Implement security measures.
- 3. Evaluate and maintain security measures.

- 1. Identify the scope of the analysis.
- 2. Gather data.
- 3. Identify and document potential threats and vulnerabilities.
- 4. Assess current security measures.
- 5. Determine the likelihood of threat occurrence.
- 6. Determine the potential impact of threat occurrence.
- 7. Determine the level of risk.
- 8. Identify security measures and finalize documentation



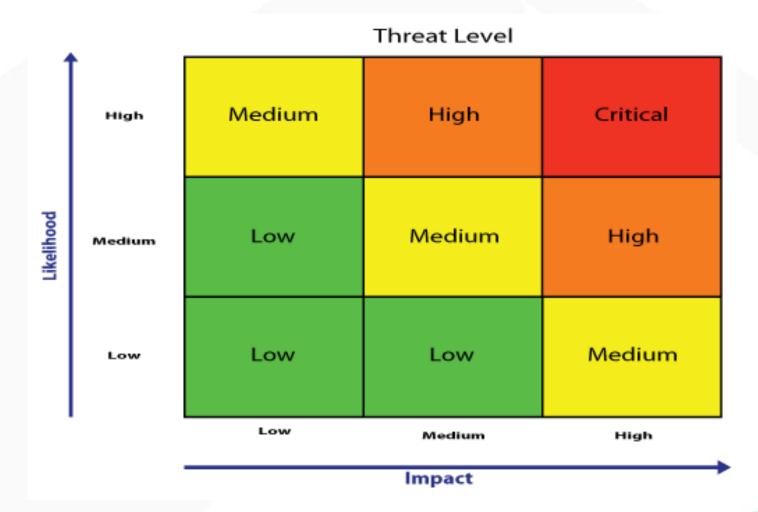
Risk Analysis Steps

Risk Analysis

- 1. Identify the scope of the analysis
- 2. Gather data
- 3. Identify and document potential threats and vulnerabilities
- 4. Assess current security measures
- 5. Determine the likelihood of threat occurrence
- 6. Determine the potential impact of threat occurrence
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- 8. Identify security measures and finalize documentation



Risk Level





Source: http://the-outsourcing.com/subpage.php?pn=region®id=1&aid=274

Risk Assessment

- What is <u>not</u> considered a risk assessment:
 - Gap Assessment against the implementation specifications
 - A list of threats and corresponding safeguards
 - follow all the steps
 - show deliberation in:
 - identifying all ePHI
 - completing inventories
 - threat identification, likelihood and impact analysis



Risk Assessment

Common Mistakes:

- Failure to account for Third-Party Risk
 - SAAS, Cloud, Business Associates
 - Right to audit, over-reliance in absence of SOC 2
 - Misunderstanding of SOC 1 vs. SOC 2 reports
- Failure to complete and inventory of ePHI and systems
- Not conducting a risk assessment as defined, opting for gap analysis
- No risk assessment at all!
- No minutes of board deliberations, management action



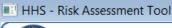
Risk Assessment Guidance

- Risk Assessment Guidance
- Security Risk Assessment Tool
 - HealthIT.gov
 - Windows and iPad version
 - Paper versions
 - User guide
 - No guarantee of compliant results

Source:

https://www.healthit.gov/providers-professionals/security-risk-assessment https://www.healthit.gov/providers-professionals/security-risk-assessment-tool









Security Risk Assessment Tool

Current User: none | Logout | www.HealthIT.gov



Security Risk Assessments

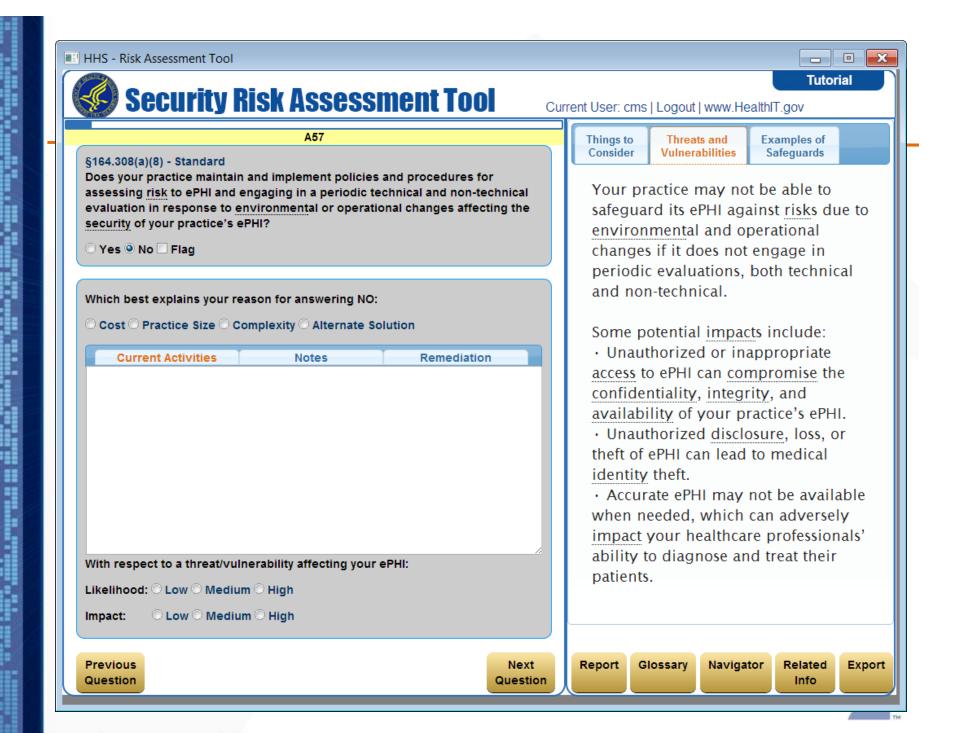
The HIPAA Security Rule requires covered entities to conduct a risk assessment to identify risks and vulnerabilities to electronic protected health information (e-PHI). Risk assessment is the first step in an organization's Security Rule compliance efforts. Following HIPAA risk assessment guidelines will help you establish the safeguards you need to implement based on the unique circumstances of your health care practice.

Risk assessment is an ongoing process that should provide your medical practice with a detailed understanding of the risks to the confidentiality, integrity, and availability of e-PHI. HIPAA requires that covered entities "implement policies and procedures to prevent, detect, contain, and correct security violations" by conducting "an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI held by the [organization]." Performing a security risk assessment and mitigating the findings is also a requirement for providers attesting to "Meaningful Use" under the CMS EHR Incentive Program.

Providers should develop a risk assessment that addresses these criteria by evaluating the impact and likelihood of potential breaches, implementing security features, cataloguing security features, and maintaining security protections.

Users About Your Business Asset Inventory

First Name Last Name Initials



Required & Addressable Safeguards



Required vs. Addressable

Required

the implementation specification must be implemented

Addressable

 The concept of "addressable implementation specifications" was developed to provide covered entities additional flexibility with respect to compliance with the security standards.



Addressable

- A covered entity will do one of the following for each addressable specification:
 - (a) implement the addressable implementation specifications; (if it is reasonable and appropriate to do so)
 - (b) implement one or more alternative security measures to accomplish the same purpose; (if the addressable implementation specification is unreasonable and inappropriate, and there is a reasonable and appropriate alternative.)
 - (c) not implement either an addressable implementation specification or an alternative.



Documentation of Decisions

- This decision will depend on a variety of factors such as:
 - the entity's risk analysis,
 - risk mitigation strategy,
 - what security measures are already in place,
 - the cost of implementation.
- The decisions that a covered entity makes regarding addressable specifications must be documented in writing.
- The written documentation should include the factors considered as well as the results of the risk assessment on which the decision was based.



Administrative Safeguards

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable				
Administrative Safeguards						
Security Management Process	164.308(a)(1)	Risk Analysis (R) Risk Management (R)				
ssigned Security Responsibility	164.308(a)(2) 164.308(a)(3)	Sanction Policy (R) Information System Activity Review (R) (R) Authorization and/or Supervision (A) Workforce Clearance Procedure				
nformation Access Management	164.308(a)(4)	Termination Procedures (A) Isolating Health care Clearinghouse Function (R) Access Authorization (A) Access Establishment and Modification (A)				
Security Awareness and Training	164.308(a)(5)	Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A) Password Management (A)				
Security Incident Procedures Contingency Plan	164.308(a)(6) 164.308(a)(7)	Response and Reporting (R) Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A)				
Evaluation Business Associate Contracts and Other Arrangement.	164.308(a)(8) 164.308(b)(1)	Applications and Data Criticality Analysis (A) (R) Written Contract or Other Arrangement (R)				



Physical Safeguards

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable					
Physical Safeguards							
Facility Access Controls	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)					
Workstation Use	164.310(b) 164.310(c) 164.310(d)(1)	(R) (R) Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)					



Technical Safeguards

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable						
Technical Safeguards (see § 164.312)								
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)						
Audit Controls	164.312(b)	(R)						
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)						
Person or Entity Authentication	164.312(d)	(R)						
Transmission Security	164.312(e)(1)	Integrity Controls (A) Encryption (A)						



HIPAA Security Rule

- 164.306 (General Requirements)
 - (b) Flexibility of Approach
 - Choose Security Measures That Are Reasonable & Appropriate
 - How do we know what is Reasonable & Appropriate?
 - size and complexity
 - technical infrastructure, hardware, and security capabilities
 - cost of security measures
 - probability and criticality of potential risks to ePHI
 - (c) Standards
 - (d) Implementation Specifications



Encryption



What to Encrypt?

- Whether you encrypt depends on your risk assessment
- However:
 - Failure to encrypt PHI on mobile devices is asking for big trouble
 - Why is PHI on mobile devices in the first place?
 - Document the business reasons, then the risks (threats and vulnerabilities) including impact and likelihood
 - Then document the chosen safeguard: encryption
- PHI at Rest
 - in database
 - in flat files
- PHI in Transit
 - Email (Why is PHI in email? See above)
 - EMR
 - Third Party Service Provider
 - Text Messages (Why is PHI in text messages? See above)



Mobile Device Guidance

Five Steps

- 1. Decide whether mobile devices will access, transmit or store PHI or function as part of EMR system
- 2. Assess the risks (threats and vulnerabilities)
- Identify mobile device risk management strategy, including safeguards
- 4. Develop, Document, Implement
- 5. Train: Security awareness

Source:

https://www.healthit.gov/providers-professionals/your-mobile-device-and-health-information-privacy-and-security https://www.healthit.gov/providers-professionals/five-steps-organizations-can-take-manage-mobile-devices-used-health-care-pro



Hot Topics



Ransomware

- "Ransomware infections are security incident under the Security Rule"
- "Once detected the covered entity must initiate its security incident and response and reporting procedures."
- "Part of a deeper analysis should involve assessing whether or not there was a breach of PHI as a result of the security incident."
- "The presence of ransomware (or any malware) is a security incident under HIPAA that may also result in an impermissible disclosure of PHI in violation of the Privacy Rule and a breach, depending on the facts and circumstances of the attack."

Source:

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



Cloud Computing

- Business Associate Agreements
 - Right to audit
 - Attestation Requirements
 - Incident Procedures; Notification Requirements
- Third-Party Risk Management
 - Risk Assessment
 - **–** SOC 2
 - Regular Vulnerability Assessments



NIST Cybersecurity Framework

- Barack Obama, Exec Order 13636 (Feb. 2013)
 - Improving Critical Infrastructure Cybersecurity
 - Partnership between government and owners and operators of critical infrastructure
 - Improve cybersecurity information sharing
 - ISAOs & ISACs (See EO 13691)
 - Collaboratively develop and implement risk-based standards
 - NIST had one year to:
 - work with private sector
 - identify existing voluntary consensus standards and industry best practices
 - build them into a Cybersecurity Framework



PPD 21: Critical Infrastructure Security

- Chemical
- Commercial Facilities
- Communications
 - Critical Manufacturing
- Dams
 - Defense Industrial Base
 - **Emergency Services**

- Energy
- Financial Services
- Food and Agriculture
- Govt. Facilities
- Healthcare & Public Health
- Nuclear Reactors, Materials, Waste
- Transportation
- Water and Wastewater



NIST Cybersecurity Framework

- NIST CSF (Feb. 2014)
- Goal: Using the Framework's structure will drive companies to ask the right questions and begin to implement the right solutions for their particular company and industry



NIST CSF

- Not one-size-fits-all
- Complements, and does not replace, an organization's risk management process and cybersecurity program (assuming one exists)
- Three Parts:
 - Core
 - Profile
 - Implementation Tiers
- Contains a methodology to protect:
 - individual privacy
 - civil liberties



NIST CSF

- Building from those standards, guidelines, and practices, the Framework provides a common taxonomy and mechanism for organizations to:
 - Describe their current cybersecurity posture;
 - Describe their target state for cybersecurity;
 - Identify and prioritize opportunities for improvement within the context of a continuous and repeatable process;
 - Assess progress toward the target state;
 - Communicate among internal and external stakeholders about cybersecurity risk.



NIST CSF: CORE

Functions	Categories	Subcategories	Informative References
IDENTIFY			
PROTECT			
DETECT			
RESPOND			
RECOVER			



ID.AM Asset Management ID.BE Business Environment ID.GV Governance ID.RA Risk Assessment ID.RM Risk Management Strategy PR.AC Access Control PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology DE.AE Anomalies and Events	
ID Identify ID.GV Governance ID.RA Risk Assessment ID.RM Risk Management Strategy PR.AC Access Control PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
ID.RA Risk Assessment ID.RM Risk Management Strategy PR.AC Access Control PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR.AC Access Control PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR.AC Access Control PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR.AT Awareness and Training PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR.DS Data Security PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR Protect PR.IP Information Protection Processes and Procedures PR.MA Maintenance PR.PT Protective Technology	
PR.MA Maintenance PR.PT Protective Technology	
PR.PT Protective Technology	
DE AE Annualis and France	
DE.AE Anomalies and Events	
DE Detect DE.CM Security Continuous Monitoring	
DE.DP Detection Processes	
RS.RP Response Planning	
RS.CO Communications	
RS Respond RS.AN Analysis	
RS.MI Mitigation	
RS.IM Improvements	
RC.RP Recovery Planning	
RC Recover RC.IM Improvements	
RC.CO Communications	



Function	Category	Subcategory	Informative References
		PR.DS-1: Data-at-rest is protected	 CCS CSC 17 COBIT 5 APO01.06, BAI02.01, BAI06.01, DSS06.06 ISA 62443-3-3:2013 SR 3.4, SR 4.1 ISO/IEC 27001:2013 A.8.2.3 NIST SP 800-53 Rev. 4 SC-28
	Data Security (PR.DS): Information and records (data) are managed consistent with the organization's risk strategy to protect the confidentiality,	PR.DS-2: Data-in-transit is protected	 CCS CSC 17 COBIT 5 APO01.06, DSS06.06 ISA 62443-3-3:2013 SR 3.1, SR 3.8, SR 4.3 SR 4.2 ISO/IEC 27001:2013 A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3 NIST SP 800-53 Rev. 4 SC-8
integrity, and availability of information.	PR.DS-3: Assets are formally managed throughout removal, transfers, and disposition	 COBIT 5 BAI09.03 ISA 62443-2-1:2009 4. 4.3.3.3.9, 4.3.4.4.1 ISA 62443-3-3:2013 SR 4.2 ISO/IEC 27001:2013 A.8.2.3, A.8.3.1, A.8 A.8.3.3, A.11.2.7 NIST SP 800-53 Rev. 4 CM-8, MP-6, PE-1 	
	PR.DS-4: Adequate capacity to ensure availability is maintained	 COBIT 5 APO13.01 ISA 62443-3-3:2013 SR 7.1, SR 7.2 ISO/IEC 27001:2013 A.12.3.1 	



Function	Category	Subcategory	Relevant Control Mappings ²
	Data Security (PR.DS): Information and records (data) are managed consistent with the organization's risk strategy to protect the confidentiality, integrity, and availability of information.	PR.DS-1: Data-at-rest is protected	• CCS CSC 17 • COBIT 5 APO01.06, BAI02.01, BAI06.01, DSS06.06 • ISA 62443-3-3:2013 SR 3.4, SR 4.1 • ISO/IEC 27001:2013 A.8.2.3 • NIST SP 800-53 Rev. 4 SC-28 • HIPAA Security Rule 45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(b)(1), 164.310(d), 164.312(a)(1), 164.312(a)(2)(iii), 164.312(a)(2)(iv), 164.312(b), 164.312(c), 164.314(b)(2)(i), 164.312(d)

Source:



Function	Category	Subcategory	Relevant Control Mappings ²
		PR.DS-2: Data-in- transit is protected	• CCS CSC 17 • COBIT 5 APO01.06, DSS06.06 • ISA 62443-3-3:2013 SR 3.1, SR 3.8, SR 4.1, SR 4.2 • ISO/IEC 27001:2013 A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3 • NIST SP 800 53 Rev. 4 SC 8 • HIPAA Security Rule 45 C.F.R. §§ 164.308(b)(1), 164.308(b)(2), 164.312(e)(1), 164.312(e)(2)(i), 164.312(e)(2)(ii), 164.314(b)(2)(i)
		PR.DS-3: Assets are formally managed throughout removal, transfers, and disposition	 COBIT 5 BAI09.03 ISA 62443-2-1:2009 4. 4.3.3.3.9, 4.3.4.4.1 ISA 62443-3-3:2013 SR 4.2 ISO/IEC 27001:2013 A.8.2.3, A.8.3.1, A.8.3.2, A.8.3.3, A.11.2.7 NIST 3P 800-53 Rev. 4 CM-8, MP-6, PE-16 HIPAA Security Rule 45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.310(a)(2)(ii), 164.310(a)(2)(iii), 164.310(d)(1), 164.310(d)(2)
		PR.DS-4: Adequate capacity to ensure availability is maintained	 COBIT 5 APO13.01 ISA 62443-3-3:2013 SR 7.1, SR 7.2 ISO/IEC 27001:2013 A.12.3.1 NIST SP 800-53 Rev. 4 AU-4, CP-2, S6 5 HIPAA Security Rule 45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.308(a)(1)(ii)(B), 164.308(a)(7), 164.310(a)(2)(i), 164.310(d)(2)(iv), 164.312(a)(2)(ii)

Implementation Tiers

Factors

- Risk Management Process
 - ad hoc, reactive, formal?
- Integrated Risk Management Program
 - information sharing internally, executive support, funding, measurement
- External Participation
 - ability to interact and share information externally

Tiers

- Partial
- Risk Informed
- Repeatable
- Adaptive



How To Use NIST CSF

- Basic review of cybersecurity practices
 - Functions, categories, subcategories
- Communicate cybersecurity requirements with stakeholders
- Identify opportunities for new or revised informative references



How To Use NIST CSF (cont.)

- Establish or Improve A Cybersecurity Program
 - Step 1: Prioritize and Scope
 - Step 2: Orient
 - systems, information, assets, regulatory
 - Step 3: Create a Current Profile
 - which categories/subcategories are working
 - Step 4: Conduct a Risk Assessment
 - discern likelihood and impact (more next time)
 - incorporate threat and vulnerability information
 - Step 5: Create a Target Profile
 - which categories/subcategories are needed
 - Step 6: Determine, Analyze, Prioritize Gaps
 - Compare current to target profile
 - Step 7: Implement Action Plan



