

Annual Report Workgroup

Aaron Miri, Co-Chair Carolyn Petersen, Co-Chair

November 9, 2018



Agenda

- Call to Order/Roll Call
- Opening Remarks and Workgroup Schedule
- Deeper Dive in Privacy and Security Priority Target Area
 - » Presentations
 - » Workgroup Discussion
- Planning for Workgroup Update at HITAC Meeting on 11/14/18
- Public Comment
- Next Steps and Adjourn

Meeting Schedule for Workgroup

Month	Deliverables to Review
June 20, 2018	Workgroup scope for FY18 Annual Report announced
August 2, 2018	Discuss plans for FY18 Annual Report
August 24, 2018	Landscape Analysis Outline Gap Analysis Outline
September 20, 2018	Landscape Analysis and Gap Analysis Discussion
October 18, 2018	Landscape Analysis and Gap Analysis Discussion Outline of HITAC Progress in FY18
November 9, 2018	Privacy and Security Priority Target Area
December 2018 (TBD)	FY18 Annual Report Draft
January 10, 2019	FY18 Annual Report Draft
Winter/Spring 2019	FY18 Annual Report Completed as Needed
Spring 2019	Work begins on FY19 Annual Report



Review Schedule for Full Committee

Meeting Date	Action Items/Deliverables
June 20, 2018	Subcommittee Charge Presented
September 5, 2018	Workgroup Update
October 17, 2018	Landscape Analysis and Gap Analysis Update
November 14, 2018	Description of HITAC's Work in FY18 Reviewed
January 23, 2019	FY18 Annual Report Reviewed by HITAC
February 20, 2019	FY18 Annual Report Reviewed/Approved by HITAC
Winter/Spring 2019	FY18 Annual Report Submitted to HHS Secretary FY18 Annual Report Submitted to Congress

HITAC Annual Report Workgroup

Presentations about Privacy and Security Priority Target Area



'Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges"

Linda Kloss, Chair Privacy, Confidentiality and Security Subcommittee

November 9, 2018

Outline



- 1. Highlight findings from NCVHS's "Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges"
- 2. Describe the Committee's "Beyond HIPAA" initiative
- Suggest how this work might inform ONC's Annual Report

NCVHS Mandate



- Assist and advise the HHS Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues.
- Assist and advise the Department in the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA).*
- Inform decision-making about data policy by HHS, states, local governments and the private sector.

-- NCVHS Charter, approved January 2018

^{*} Reiterated in Section 1104 of the ACA (2010)

'Beyond HIPAA' Initiative Goals



- Identify and describe the changing environment and the risks to privacy and security of confidential health information; highlight promising policies, practices and technology;
- Lay out integrative models for how best to protect individuals' privacy and secure health data uses outside of HIPAA protections while enabling useful uses, services and research;
- 3. Formulate recommendations for the Secretary on actions that HHS and other federal Departments might take; and
- 4. Prepare a report for health data stewards.

"Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges"



- 1. Big data and expanding uses and users
- 2. Personal devices and Internet of Things
- 3. Laws in other domains (e.g., Fair Credit Reporting restricting uses of consumer data)
- 4. Evolving technologies for privacy and security
- 5. Evolving consumer attitude

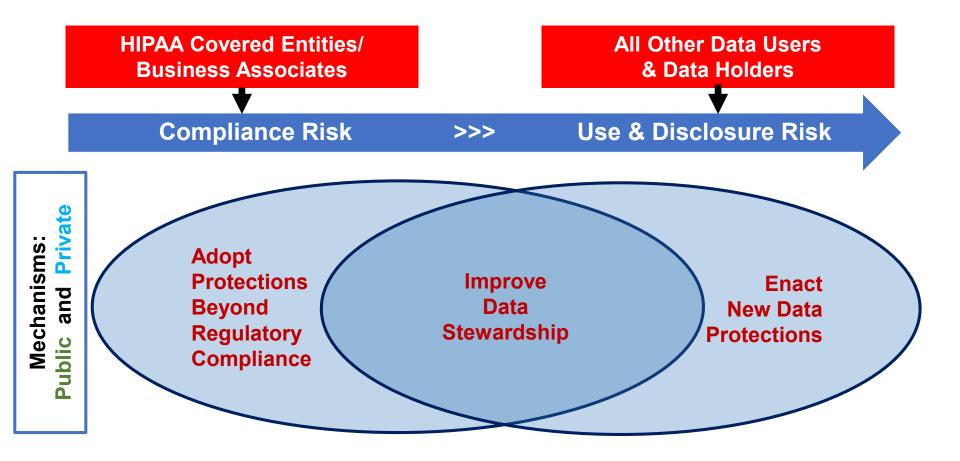
Key Themes



- 1. The Regulated (subject to HIPAA) and Unregulated Worlds (not subject to HIPAA).
- 2. Data in the unregulated category are for the most part, not subject to any specific statutory regulation for privacy.
- 3. Growing challenge of defining health information, its ownership, control and consent.
- 4. Selected stories of the world beyond HIPAA illustrating potential risks and harms pertaining to Big data, personal health devices, and the Internet of Things.
- 5. Opportunity to increase protections and choice for consumers and at the same time reduce burden.
- 6. Framing legislative issues and approaches such as general data protection.

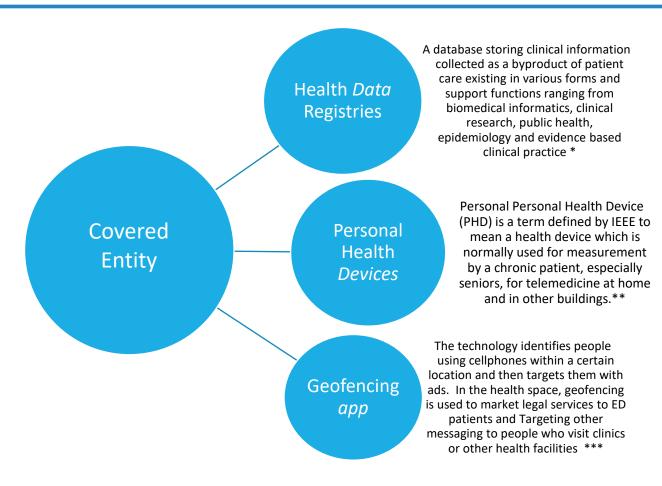
Beyond HIPAA: Health Information Stewardship Continuum





Applying the Draft Model to Use Cases Operating at the intersection of the HIPAA-covered and unregulated health data world





Drolet, BC and Johnson, KB. Categorizing the world of registries. Journal of Biomedical Informatics 41 (2008) 1009-1020: https://www.sciencedirect.com/science/article/pii/S1532046408000018X?via%3Dihub

^{**} ISO/IEEE, 11073-20601: health informatics—personal health device communication, application profile optimized exchange protocol, http://www.iso.org.

^{***}https://www.npr.org/sections/health-shots/2018/05/25/613127311/digital-ambulance-chasers-law-firms-send-ads-to-patients-phones-inside-ers

Use Case: Health Data Registries



	Leverage current mechanisms	Improve data stewardship	Enact new protections
	 Covered entities require data use agreements which include prohibitions against reidentification and redisclosure. Covered entities offer patients opportunity to opt out of registries. CEs strengthen management of de-identified data sets 	Voluntary certification of registry sponsors	
2	Office for Civil Rights issues guidance for registering Business Associates and Data Use Agreements	Mechanism for accreditation of registries for funding streams	Registries become covered entities

Beyond HIPAA Progress



Project Scoping 2016 & initial Hearings 2017

Environmental Scan 2017/18 Explore
"exemplars" at
the intersection
of regulated and
unregulated

Model Framing: Agreement on approach • 13th Report to Congress

Hearing

Letter to HHS Secretary







Questions for NCVHS?







NIST Cybersecurity and Privacy Update

Kevin Stine
Chief, Applied Cybersecurity Division
Information Technology Laboratory
National Institute of Standards and Technology
November 9, 2018





Cultivating Trust in Information and Technology Through Cybersecurity And Privacy

Adoption of technologies



Standards

Best practices



We seek to...

- Equip organizations to better manage cybersecurity and privacy risk
- **Help** to build a secure infrastructure
- Energize and promote a robust ecosystem of cybersecurity education, training, and workforce development
- **Ensure** the right *people* and *things* have the right access to the right resources at the right time
- Drive adoption of standards-based cybersecurity





Cybersecurity Framework Charter Improving Critical Infrastructure Cybersecurity

December 18, 2014

Amends the National Institute of Standards and Technology Act (15 U.S.C. 272(c)) to say:

"...on an ongoing basis, facilitate and support the development of a voluntary, consensus-based, **industry-led** set of standards, guidelines, best practices, methodologies, procedures, and processes to cost-effectively reduce cyber risks to critical infrastructure"

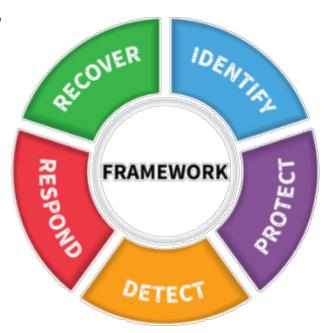


Cybersecurity Enhancement Act of 2014 (P.L. 113-274)



Key Cybersecurity Framework Attributes Principles of Current and Future Versions of the Framework

- Common and accessible language
- It's adaptable to many technologies, lifecycle phases, sectors and uses
- It's risk-based
- It's meant to be paired
- It's a living document
- Guided by many perspectives private sector, academia, public sector





Cybersecurity Framework Components: Core

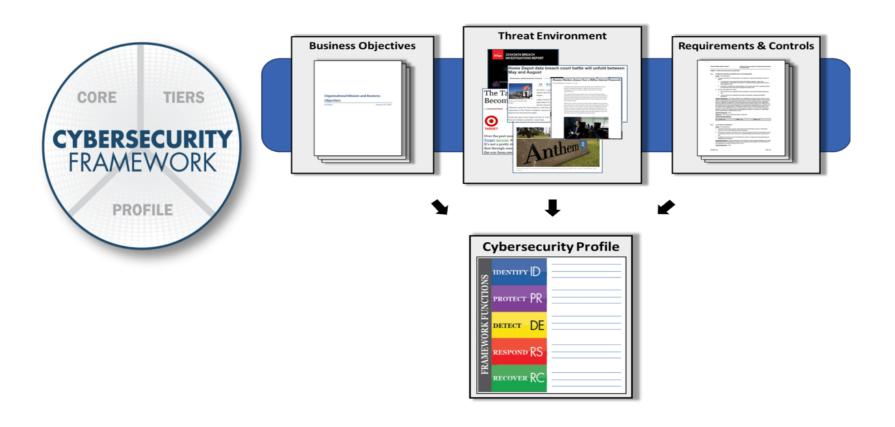


Function	Category	ID	
	Asset Management	ID.AM	
Identify	Business Environment	ID.BE	
	Governance	ID.GV	
	Risk Assessment	ID.RA	
	Risk Management Strategy	ID.RM	
	Supply Chain Risk	ID.SC	
	Management		
	Identity Management and	PR.AC	
	Access Control		
	Awareness and Training	PR.AT	
Protect	Data Security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

Subcategory	Informative References
ID.BE-1: The organization's role in the supply chain is identified and	COBIT 5 APO08.01, APO08.04, APO08.05, APO10.03, APO10.04,
communicated	APO10.05 ISO/IEC 27001:2013 A.15.1.1, A.15.1.2
	A.15.1.3, A.15.2.1, A.15.2.2
ID.BE-2: The organization's place in	NIST SP 800-53 Rev. 4 CP-2, SA-12
critical infrastructure and its industry	COBIT 5 APO02.06, APO03.01
sector is identified and communicated	ISO/IEC 27001:2013 Clause 4.1 NIST SP 800-53 Rev. 4 PM-8
ID.BE-3 : Priorities for organizational mission, objectives, and activities are	COBIT 5 APO02.01, APO02.06, APO03.01
established and communicated	ISA 62443-2-1:2009 4.2.2.1, 4.2.3.6
	NIST SP 800-53 Rev. 4 PM-11, SA-14
ID.BE-4: Dependencies and critical	COBIT 5 APO10.01, BAI04.02, BAI09.02
functions for delivery of critical services are established	ISO/IEC 27001:2013 A.11.2.2, A.11.2.3, A.12.1.3
	NIST SP 800-53 Rev. 4 CP-8, PE-9, PE-11, PM-8, SA-14
ID.BE-5: Resilience requirements to	COBIT 5 DSS04.02
support delivery of critical services are	ISO/IEC 27001:2013 A.11.1.4, A.17.1.1,
established for all operating states	A.17.1.2, A.17.2.1
(e.g. under duress/attack, during recovery, normal operations)	NIST SP 800-53 Rev. 4 CP-2, CP-11, SA-14



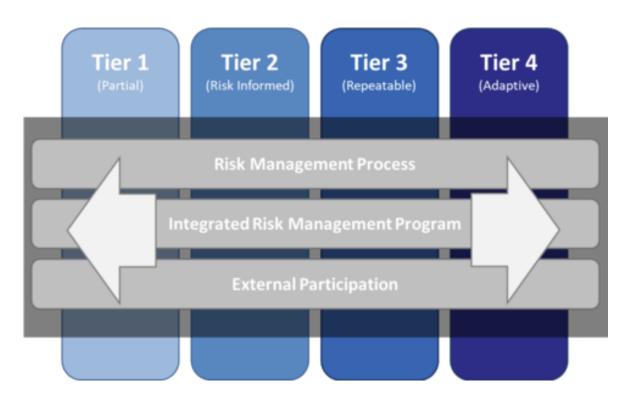
Cybersecurity Framework Components: Profile





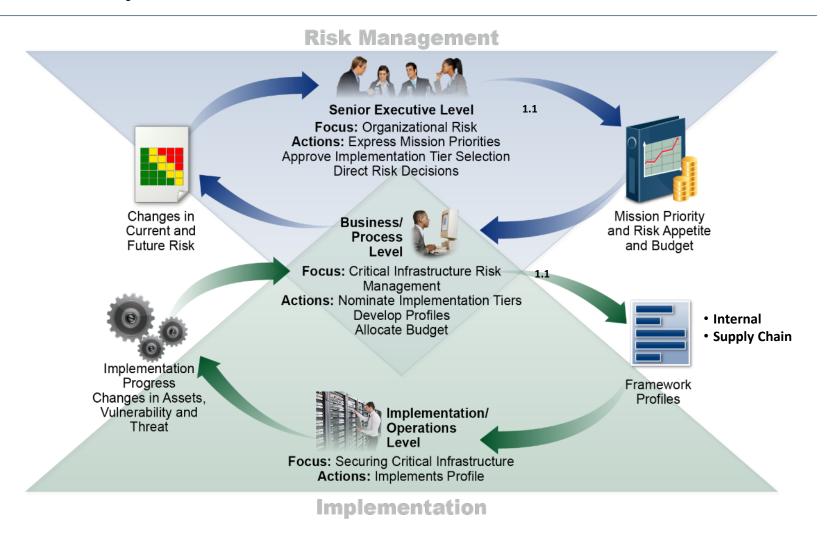
Cybersecurity Framework Components: Tiers







Supporting Risk Management with the Cybersecurity Framework Cybersecurity Framework Version 1.1





Sample Resources

www.nist.gov/cyberframework/industry-resources





Italy's National Framework for Cybersecurity

American Water Works Association's

<u>Process Control System Security</u>

<u>Guidance for the Water Sector</u>





Financial Services Sector Specific Cybersecurity "Profile"

Cybersecurity Risk Management and Best Practices Working Group 4: Final Report





Sample Resources (Healthcare and Public Health Sector) www.nist.gov/cyberframework/framework-resources

HHS's HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework

Symantec's Implementing the NIST Cybersecurity Framework in Healthcare

The Joint HPH Cybersecurity Working Group's <u>Healthcare Sector Cybersecurity</u> <u>Framework Implementation Guide</u>

HITRUST's Common Security Framework to NIST Cybersecurity Framework mapping

Clearwater Compliance's <u>Harnessing the Power of the NIST Framework: Your Guide</u> to Effective Information Risk Management White Paper



NIST's National Cybersecurity Center of Excellence





NIST's National Cybersecurity Center of Excellence Healthcare Portfolio

Securing Electronic Health Records on Mobile Devices

A platform for healthcare providers to securely document, maintain, and exchange electronic patient information among mobile devices.

Securing Wireless Infusion Pumps

Helping Healthcare Delivery Organizations secure wireless infusion pumps on an enterprise network.

Securing Picture Archiving and Communication System

Providing guidance for securing the PACS ecosystem in healthcare sector organizations.





NIST Cybersecurity Risk Management Conference



Learn about the NIST Cybersecurity Risk Management Conference and register at

https://www.nist.gov/newsevents/events/2018/11/nist-cybersecurity-riskmanagement-conference



Questions & Opportunities to Engage



National Cybersecurity Center of Excellence:

https://www.nccoe.nist.gov

Cybersecurity Framework:

https://www.nist.gov/cyberframework

Privacy Framework: https://www.nist.gov/privacy-

<u>framework</u>

Follow us on Twitter: @NISTcyber

Contact: Kevin Stine, kevin.stine@nist.gov







Questions for NIST?









HHS Office for Civil Rights Cybersecurity Resources

Nicholas P. Heesters, Jr., MEng, JD, CIPP Health Information Privacy Security Specialist, HHS Office for Civil Rights (OCR)

November 9, 2018



OCR Cybersecurity Resources: Agenda

- HIPAA Security Rule to NIST Cyber Security Framework (CSF) Crosswalk
- HHS Office for Civil Rights Cybersecurity Guidance
- HHS ONC/OCR Security Risk Assessment Tool 3.0

HIPAA Security Rule to NIST Cybersecurity Framework Crosswalk

- The crosswalk is a response to <u>Executive Order 13636</u>, Improving Critical Infrastructure Cybersecurity (Cybersecurity Framework) and to help organizations in various industries understand, communicate, and manage cybersecurity risks. In the health care space, HIPAA covered entities and business associates must comply with the HIPAA Security Rule to ensure the confidentiality, integrity, and availability of electronic protected health information (ePHI) that they create, receive, maintain, or transmit.
- The crosswalk is not guidance but a voluntary tool to assist organizations in assessing and managing security risks, while also assuring critical operations and service delivery. The crosswalk could also help entities prioritize investments and maximize the impact of each dollar spent on cybersecurity. By mapping the provisions of the different security frameworks, the crosswalk provides a common language that can improve communications, awareness, and understanding about cybersecurity between and among IT, planning, and operating units, as well as senior executives of organizations.

HIPAA Security Rule to NIST Cybersecurity Framework Crosswalk

- The HHS Office for Civil Rights released the crosswalk in February 2016. It
 was developed in cooperation with the National Institute for Standards and
 Technology (NIST) and the HHS Office of the National Coordinator for Health
 Information Technology (ONC).
- Organizations that have already aligned their security programs to either
 the NIST Cybersecurity Framework or the HIPAA Security Rule may find this
 crosswalk helpful for identifying potential gaps in their programs. For
 example, if a covered entity has an existing security program aligned to the
 HIPAA Security Rule, they can use this mapping document to identify which
 pieces of the NIST Cybersecurity Framework they are already meeting and
 which represent new practices to incorporate into its risk management
 program.

HIPAA Security Rule to NIST Cybersecurity Framework Crosswalk

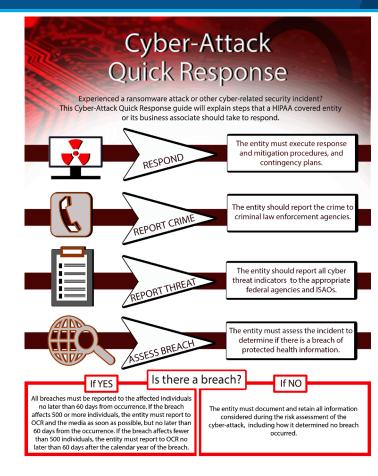
	Risk Management Strategy (ID.RM): The organization's priorities, constraints, risk tolerances, and assumptions are established and used to support operational risk decisions.	ID.RM-1: Risk management processes are established, managed, and agreed to by organizational stakeholders	• COBIT 5 APO12.04, APO12.05, APO13.02, BAI02.03, BAI04.02 • ISA 62443-2-1:2009 4.3.4.2 • NIST SP 800-53 Rev. 4 PM-9 • HIPAA Security Rule 45 C.F.R. § 164.308(a)(1)(ii)(B)
		ID.RM-2: Organizational risk tolerance is determined and clearly expressed	 COBIT 5 APO12.06 ISA 62443-2-1:2009 4.3.2.6.5 NIST SP 800-53 Rev. 4 PM-9 HIPAA Security Rule 45 C.F.R. § 164.308(a)(1)(ii)(B)

OCR Cybersecurity Guidance

- Ransomware Guidance
- Cybersecurity Checklist and Infographic
- Cybersecurity Newsletters
 - » April 2018: Risk Analysis vs. Gap Analysis
 - » 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
- » October 2018: National Cybersecurity Awareness Month



Security Risk Assessment (SRA) Tool

- The HHS Office of the National Coordinator for Health Information Technology (ONC) and the HHS Office for Civil Rights (OCR) have updated the popular Security Risk Assessment (SRA) Tool to make it easier to use and apply more broadly to the risks to health information.
- The tool is designed for use by small to medium sized health care practices covered entities, and business associates to help them identify risks and vulnerabilities to ePHI.
- The updated tool provides enhanced functionality to document how such organizations can implement or plan to implement appropriate security measures to protect ePHI.
- Windows operating system- Download the Windows version of the tool at http://www.HealthIT.gov/security-risk-assessment.
- The iOS iPad version was not updated, but the previous version is available at the <u>Apple App Store</u> (search under "HHS SRA Tool").

SRA Tool New Features and Functionality

- Enhanced User Interface
- Modular Workflow with Question Branching Logic
- Custom Assessment Logic
- Progress Tracker
- Improved Threats & Vulnerabilities Rating
- Detailed Reports
- Business Associate and Asset Tracking
- Overall Improvement of the User Experience

SRA Tool Development Approach

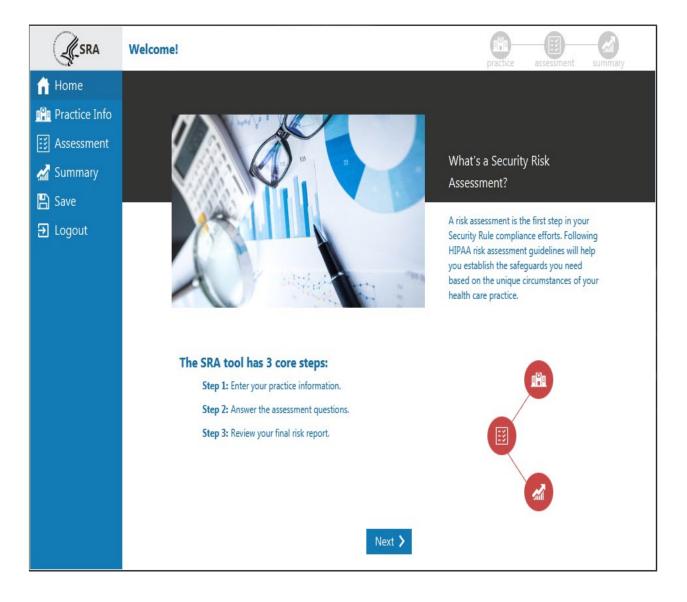
- ONC and OCR conducted comprehensive usability testing of the SRA tool (version 2.0) with health care practice managers.
- Analysis of the findings across the user base informed the development of the content and the requirements for the SRA Tool 3.0.
- ONC and OCR then conducted testing of the SRA tool 3.0 to compare the user experience in completing the same tasks presented in the first round of testing.
- Over the next year, ONC and OCR will continue to gather feedback on the tool to inform future SRA tool modifications and updates. You can give feedback or request help by emailing PrivacyAndSecurity@hhs.gov

SRA Tool Brief Overview of Content

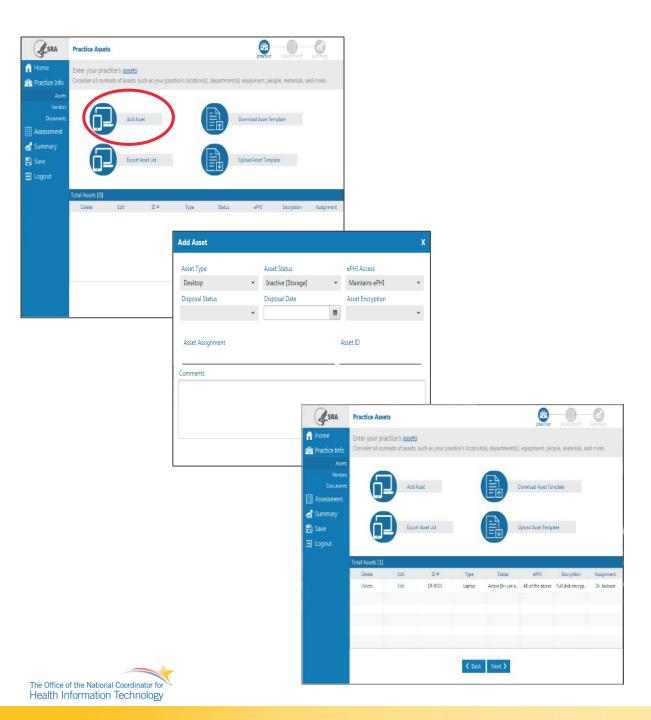
- Section 1: Security Risk Assessment (SRA) Basics (security management process)
- Section 2: Security Policies, Procedures, & Documentation (defining policies & procedures)
- Section 3: Security & Your Workforce (defining/managing access to systems and workforce training)
- Section 4: Security & Your Data (technical security procedures)
- Section 5: Security & Your Practice (physical security procedures)
- Section 6: Security & Your Vendors (business associate agreements and vendor access to PHI)
- Section 7: Contingency Planning (backups and data recovery plans)



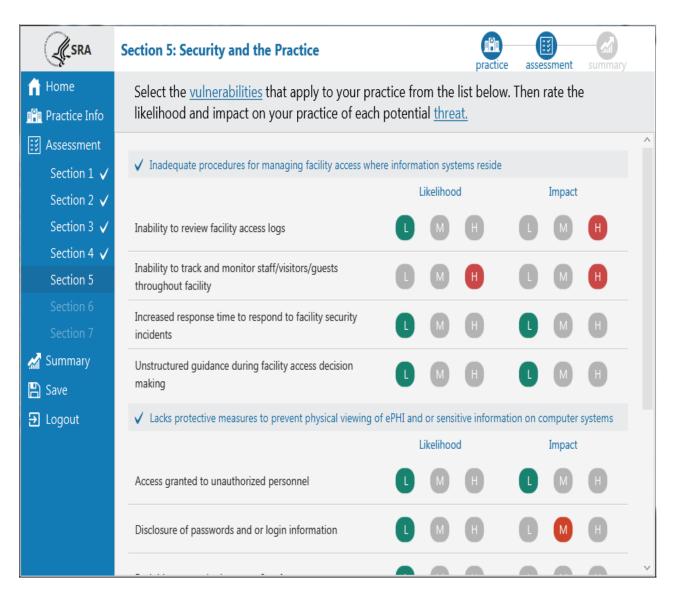
- Enter your name
- Pick a place to save your SRA
- Name your SRA
- Review the Disclaimer
- Begin your SRA



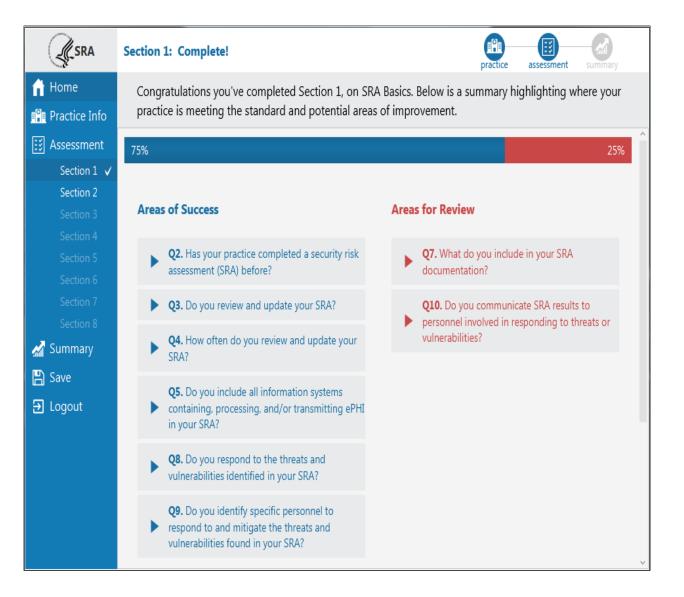
- Enter your name
- Pick a place to save your SRA
- Name your SRA
- Review the Disclaimer
- Begin your SRA



- PracticeInformation
 - » Track Asset Inventory
 - » Track BAA & Vendors
 - » Track
 Documentation



- Likelihood & Impact Rating
 - Color coded rating system
 - Guided Risk Framework
- Guidance within ToolTips

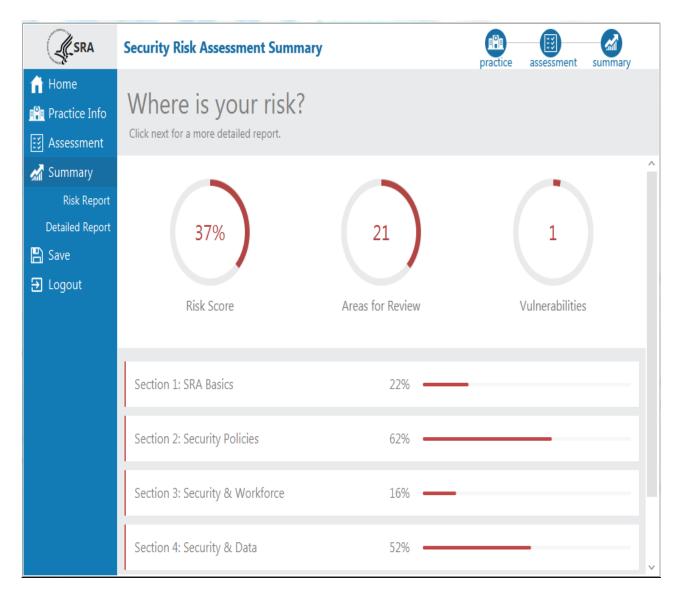


Section Summary

- Areas of Success
- » Areas for Review
- » Score
- » Comments & Documents

Final SRA Summary

- » Dashboard
- » Detailed Report



Summary Dashboard

- » Cumulative Risk score
- » Risk score by section
- » Total Areas for Review
- » Total # of Vulnerabilities







Questions for OCR?

Nicholas.Heesters@hhs.gov

https://www.hhs.gov/hipaa/forprofessionals/security/guidance/cybersecurity/index.html

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



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HITAC Annual Report Workgroup

Workgroup Discussion: Privacy and Security Priority Target Area



Privacy and Security Priority Target Area

- Potential HITAC Activities Identified by Workgroup to Date
 - » Opportunity: Increased uniformity of information sharing policies across states. For example, address implications of the California Consumer Privacy Act of 2018.
 - Suggested HITAC Activity: Consider federal role in setting guidelines for exchange of data across states
 - » Opportunity: Support for widespread adoption of cybersecurity framework(s)
 - Suggested HITAC Activity: Consider whether a nationwide cybersecurity framework should be adopted
 - Suggested HITAC Activity: Delineate cybersecurity accountability for data by role



Privacy and Security Priority Target Area

- Other Opportunities Identified for Further Consideration
 - » Education about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
 - » Granular levels of consent to share and disclose information
 - » Address implications of European Union's General Data Protection Regulation (GDPR) and Privacy Shield
 - » Education of technology users about privacy and security settings, especially for social media
 - » Consider what to regulate about the Internet of Things (IoT)
 - » Continue to improve patient matching when sharing data

HITAC Annual Report Workgroup

Workgroup Discussion:

Update Presentation for HITAC Meeting on 11/14/18



Planning for Update at HITAC Meeting on 11/14/18

- Summarize Workgroup Discussion from Workgroup Meetings on 10/18/18 and 11/9/18:
 - » Outline of Section on HITAC Progress in FY18
 - » Deeper dive in Privacy and Security Priority Target Area

Public Comment

To make a comment please call:

Dial: 1-877-407-7192

(once connected, press "*1" to speak)

All public comments will be limited to three minutes.

You may enter a comment in the "Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.







Health IT Advisory Committee



Meeting Adjourned

Next Annual Report Workgroup meeting scheduled for 12/6/18, 11:00-12:30 p.m. ET



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HITAC Annual Report Workgroup

Additional Slides



Annual Report Workgroup Membership and ONC Staff

Member Name	Organization	Role
Carolyn Petersen	Individual	Co-Chair
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Co-Chair
Christina Caraballo	Audacious Inquiry	HITAC Committee Member
Brett Oliver	Baptist Health	HITAC Committee Member
Chesley Richards	Public Health Scientific Services, CDC	Federal Representative

ONC Staff Name	Title	Role
Donald Rucker	National Coordinator for Health Information Technology	
Elise Sweeney Anthony	Executive Director, Office of Policy	
Seth Pazinski	Division Director, Strategic Planning & Coordination	
Lauren Richie	Branch Chief, Policy Coordination	Designated Federal Officer (DFO)
Michelle Murray	Senior Health Policy Analyst	Workgroup ONC Staff Lead



Workgroup Scope

- Overarching: The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.
- **Detailed:** Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:
 - » Analysis of HITAC progress related to the priority target areas
 - » Assessment of health IT infrastructure and advancements in the priority target areas
 - » Analysis of existing gaps in policies and resources for the priority target areas
 - » Ideas for potential HITAC activities to address the identified gaps

HITAC Priority Target Areas: Defined

HITAC Priority Target Areas noted in Section 4003(e) of the 21st Century Cures Act cover the following areas:

- Interoperability Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information
- Privacy and Security The promotion and protection of privacy and security of health information in health IT
- Patient Access The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information
- Any other target area related to the above target areas that the HITAC identifies as an appropriate target area to be considered on a temporary basis with adequate notice to Congress