Monthly Cyber Briefing

February 2024





Logistics

- All attendees in "Listen Only Mode"
- Please ask content related questions in Q&A
- Recording and final slides shared within 48 hours
- Please take a few minutes to provide feedback via survey prompt at the end of this session



Agenda

- Cyber update
 - Healthcare breaches
 - Ransomware
 - HHS Cybersecurity Strategy and Performance Goals
 - OCR Enforcement Focus
 - Regulatory Changes
- Evolving guidance for medical device cyber-risk and the strategic management approaches for tackling legacy devices



Speakers



Steve Cagle
CEO
Clearwater



Jon Benedict

Director, Consulting Services,
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Clearwater



Cyber Update

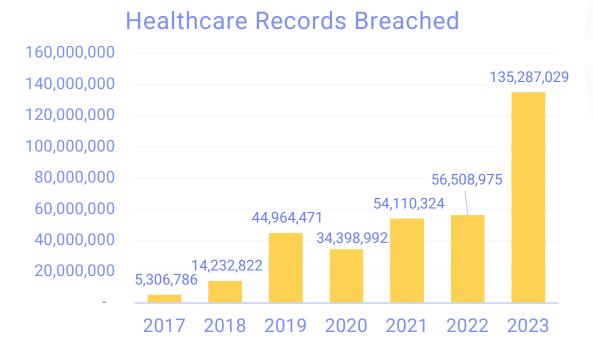
Steve Cagle

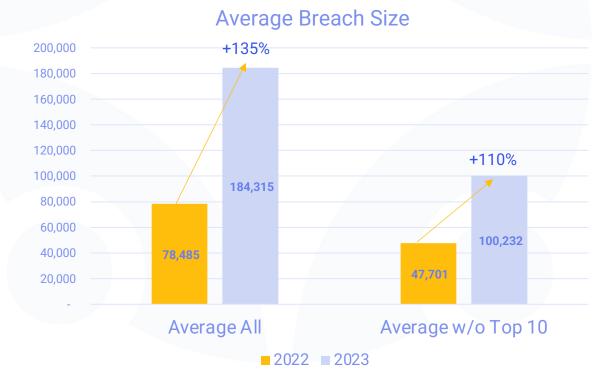




Recap of 2023 (Updated Data as of 1/31/24)

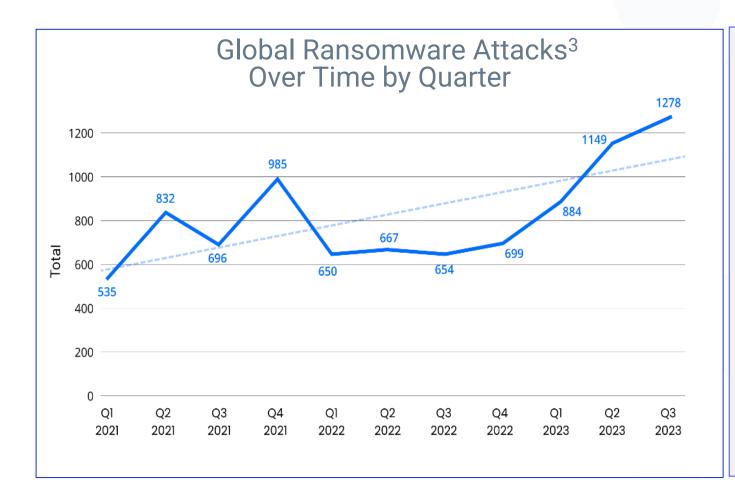
- 135.3M records reported breached in 2023, and increase of 139% vs 56.5 million in 2022¹
- 734 breaches reported in 2023 vs 720 in 2022, a slight increase
- Average breach size has increased 135%, and 110% if removing top 10 breaches each year
- As of 1/31/24 5.6M records reported as breached in month of January, however, the majority are related to PJ&A (business associate) breach reported in November







Ransomware Attacks Spiked in 2023



2023 ransomware attacks up more than 95% over 2022¹.

46 U.S. hospital systems suffered ransomware attacks in 2023, up from 25 in 2022 and 27 in 2021.²

New Trends

- Dwell time from 4.5 days -> < 1 day⁴
- "New" ransomware groups targeting healthcare: Hunters International, Inc. Ransom, Money Message
- Contacting patients directly (swatting)



HHS Cybersecurity Strategy





¹ National-Cybersecurity-Strategy-2023.pdf (whitehouse.gov)

² National-Cybersecurity-Strategy-Implementation-Plan-WH.gov_.pdf (whitehouse.gov)

³ Healthcare Sector Cybersecurity (hhs.gov)

⁴ HPH Cybersecurity Gateway (hhs.gov)

⁵ Healthcare and Public Health Sector-Special: Cybersecurity Performance Goals (hhs.gov)

HHS Releases Voluntary Healthcare Specific Cybersecurity Performance Goals (CPGs)^{1,2}

- Mapped to 405(d) health industry cybersecurity practices (HICP), NIST CSF v1.1, NIST 800-53 Rev5, and CISA CPGs
- Appears to seek to more clearly define what is required to achieve a desired outcome
- May ultimately just create more confusion?

ID	Goals	Desired Outcomes (NIST CSF V1.1)	HICP Practices	HICP Sub-Practices	NIST 800-53 REV5 Controls	Threats Mitigated
1	Mitigate Known Vulnerabilities: Reduce the likelihood of threat actors exploiting known vulnerabilities to breach organizational networks that are directly accessible from the Internet	ID.RA-1: Asset vulnerabilities are identified and documented PR.IP-12: A vulnerability management plan is developed and implemented DE.CM-8: Vulnerability scans are performed RS.MI-3: Newly identified vulnerabilities are mitigated or documented as accepted risks RS.AN-5: Processes are established to receive, analyze and respond to vulnerabilities disclosed to the organization from internal and external sources (e.g. internal testing, security bulletins, or security researchers) ID.RA-6: Risk responses are identified and prioritized PR.AC-3: Remote access is managed	Vulnerability Management Endpoint Protection	Host/Server-Based Scanning 7.M.A Web Application Scanning 7.M.B Basic Endpoint Protection Controls 2.M.A	CA-2, CA-5, CA-7, CA-8, PM-4, PM-15, RA-3, RA-5, SA-5, SA-11, SI-2, SI-4, SI-5 RA-1, RA-3, RA-5, SI-2 CA-5, PM-4, PM-9, PM-28, RA-7 CA-1, CA-2, RA-1, PM-4, PM-15, RA-7, SI-5, SR-6 AC-1, AC-17, AC-19, AC-20, SC-15	Ransomware Social engineering Insider threat Attacks on network connected devices







HHS CPGS - Our View & Recommendation

- The establishment of well-defined, healthcare-specific cybersecurity performance goals is a positive step forward in helping less mature organizations prioritize important security practices.
- We are glad to see that the CPGs provide references to specific outcomes from existing frameworks, control sets, and practice guides already used in healthcare, such as the 405(d) HICP, NIST CSF v1.1, and NIST Special Publication 800-53 rev5.
- The CPGs reflect intended outcomes of a very basic subset of security practices. We at Clearwater are concerned that this might create further confusion and lure some organizations into a false sense of security.
- Our recommendation does not change leverage the NIST CSF using 405(d) HICP and continue to perform on going risk analysis of all information systems with ePHI.



How Is Clearwater Addressing?

- HPH CPGs are mapped to the NIST CSF and 405(d) HICP, and therefore understanding an organization's status relative to the CPGs is achievable by analyzing outcomes from our existing NIST CSF and 405(d) HICP evaluations, and we can provide this output from our existing assessments.
- Clearwater uses NIST CSF and 405(d) HICP for its ClearAdvantage® Program, or to help organizations create their strategy roadmaps. As such, clients who subscribe to the ClearAdvantage program, and implement our recommendations, are, by definition, achieving and exceeding these goals.



We Expect OCR to Continue Enforcement Focus in These Areas in 2024

Enforcement related to

- Phishing attacks
- Ransomware attacks
- Failure to conduct OCR Quality
 Risk Analysis
- Right of Access
- Embedded Tracking Technologies



HHS' Office for Civil Rights Settles Ransomware Cyber-Attack Investigation

OCR Settles with Business Associate in attack affecting over 200K individuals

HHS' Office for Civil Rights Settles First Ever Phishing Cyber-Attack Investigation

Louisiana Medical Group settles after investigation reveals large cybersecurity breach affecting nearly 35,000 patients

HHS' Office for Civil Rights Settles Multiple HIPAA Complaints With Optum Medical Care Over Patient Access to Records

This Settlement with Optum marks the 46th Enforcement Action in the OCR Right of Access Initiative

HHS Office for Civil Rights Settles with L.A. Care Health Plan Over Potential HIPAA Security Rule Violations

\$1.3M settlement after failure to conduct OCR Quality Risk Analysis

HHS Office for Civil Rights and the Federal Trade Commission Warn Hospital Systems and Telehealth Providers about Privacy and Security Risks from Online Tracking Technologies

Other Regulatory Updates

- OCR Initiaitives¹
 - NPRM on April 12, 2023 to prohibit the use or disclosure of PHI to identify, investigate, prosecute, or sue patients, providers, and others involved in the provision of legal reproductive health, including abortion
 - Update to HIPAA Privacy Rule expected this year
 - Updates to HIPAA and Part 2 related to disclosures and penalties for substance use disorder (SUD) patients
 - Update to HIPAA Security Rule per cybersecurity strategy
- CMMC rules released for comment in December 2023, and regulation expected to be in effect in 2024²
- The Federal Acquisition Regulatory (FAR) Council on Oct. 3, 2023, issued two proposed rules for incident reporting and new cybersecurity requirements^{3,4}
- SEC Cybersecurity incident reporting regulation in effect since December 18th for SEC registered companies⁵
- CIRCIA Notice of Proposed Rulemaking, which is required to be published no later than March 20246



² Cybersecurity Maturity Model Certification Program Proposed Rule Published > U.S. Department of Defense > Release

^{3 &}lt;u>2023-21328.pdf (govinto.gov)</u>

^{4 2023-21327} pdf (govinfo gov)

Tighter SEC Cybersecurity Incident Disclosure Requirements Go into Effect Today | Locke Lord LLP - JDSupra

⁷ Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA) | CISA

Other Regulatory Updates – State Level

- NY State proposed cybersecurity regulation and \$500m in grant money for hospitals in November 2023¹
 - Rules are out for public comment period ends 2/5/24
 - Grant money in the budget for 2024 applications due March 13^{th2}
- The Florida Cybersecurity Incident Liability Act (H.B 473) has been introduced in the Florida legislature
 - Aims to introduce a "safe harbor" that limits liability for all businesses that implement reasonable and appropriate cybersecurity measures that meet industry standards and cybersecurity frameworks



Recommendations Based on Current Threat & Regulatory Enforcement Environment

Areas where you may want to "turn up the dial":

- Increase cadence of vulnerability scanning, and prioritize remediation of high-risk vulnerabilities
- Ramp sophistication of social engineering tests to reflect more current TTPs
- Scrutinize your capabilities to detect and respond to attacks orchestration of end point detection, log management, and vulnerabilities, coverage, incident response process and timelines
- Execute security controls validation assessments that are aligned to current attack scenarios taking place in healthcare
- Update and exercise incident response and test recovery plans
- Conduct on on-going risk analysis at the information system level
- Prioritize security projects based on YOUR risk NOT someone else's checklist
- Conduct a third-party compliance assessment to ensure you are meeting requirements

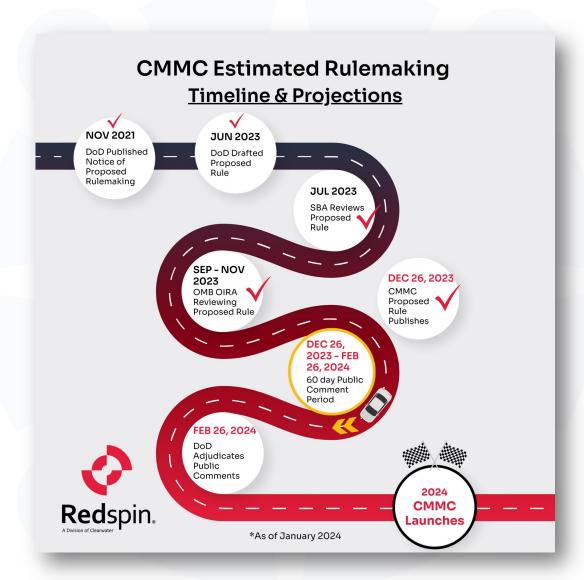


Latest Resources



Healthcare's Incident Response Playbook





A roadmap of CMMC estimated rulemaking timeline projections.

Evolving Guidance for Medical Device Cyber-Risk

Jon Benedict



Guidance Updates for Legacy Medical Device Cybersecurity

Cybersecurity Act of 2015

Should PostM
Cybersecurity Act Organization Medical Science Should PostM

2016

2015

OIG, FDA Guidance
Should Better Address
PostMarket Mgmt. of
Cybersecurity on
Medical Devices

Omnibus Bill, provides
FDA authority in
regulating
cybersecurity on
medical devices



 IMDRF, Principle & Practice of Medical Device Cybersecurity (N60)

FDA/MITRE, Next
Steps Toward
Managing Legacy
Medical Devices
Cybersecurity Risks

Legacy is a Today problem not Tomorrow

- Most Devices would currently be considered Legacy – not meeting the cybersecurity lifecycle guidance.
- Many still have a useful life that lasts beyond the declared "end of support" or "end of life" status by mfg.

Definition of Legacy

A legacy medical device is any device that cannot be reasonably protected against cybersecurity threats.



How do we address?

- Recommendations to address legacy medical device challenges:
 - Shared responsibility of all stakeholders, including MDMs, HCPs, users, regulators, and software vendors throughout the medical device lifecycle
 - Vulnerability Management
 - Workforce Development





The Risk-Informed Challenge

- Data is needed to inform strategic decisions for your MDS Program
- SBOM
 - Understand the risks associated with all components of a medical device
 - Required for all new FDA submissions after 10/1/2023
- Vulnerability Management
 - Must be a shared responsibility
- Workforce Management
 - Templates for Roles and Responsibilities



Medical Device Vulnerability Management

- The current vulnerability management process is resource intensive and time consuming for HDOs & MDMs
- Focus on streamlining and improving the process
- Ensuring information is actionable and is directed to the appropriate individuals within the affected organizations.
- Identifying areas for automation
- Leveraging SBOMs and other databases



Workforce Management / Competency Models

- Managing the risks of legacy devices and minimizing the impact of devices becoming unsupported requires a skilled workforce
- Competency Models can be used to determine what skills and knowledge are required for different roles supporting critical functions that manage legacy risk
- HDO Competency Model Template
 - Cybersecurity core competencies
 - Critical areas and functions
- Resources for workforce development
 - CISA provides a collection of cybersecurity training resources
 - https://www.cisa.gov/cybersecurity-training-exercises
 - The Federal Virtual Training Environment
 - https://fedvte.usalearning.gov/public_fedvte.php



The Practical Outcome of Risk Management

One size does not fit all:

- What a large hospital system did:
 - Deep tech stack, discovery tools integrated with CMDB and ticketing system

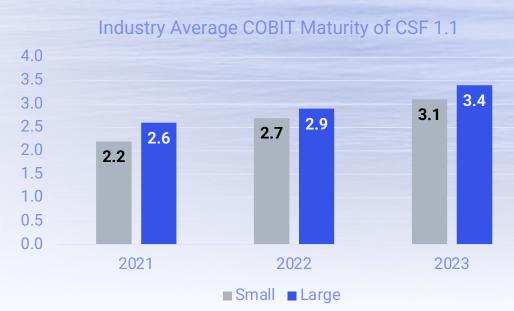
- What a small hospital did:
 - Not as mature tech stack, well thought out policies and procedures with a well-trained staff that understands and executes the program



Maturity Score – 3 Year Comparison









Staying Resilient to Medical Device Attacks

- Have a current, accurate inventory of all medical devices connected to your network
- Know who is responsible for working with manufacturers and vendors to confirm security settings and approved patches
- Ensure software updates are properly and timely maintained on each device.
- Segmentation is one of the most scalable and effective defenses
- Document and know what your plan is when medical devices are compromised.
 - Communicate how patients should notify you if they suspect a compromise.
- Regularly practice your organization's protocols in case of a potential shutdown or attack against medical devices.









We are here to help.

Moving healthcare organizations to a more secure, compliant, and resilient state so they can achieve their mission.

Upcoming Events

ViVE | February 25-28, 2024 Booth #1549, Cybersecurity Pavilion

HIPAA Summit | February 27-March 1 Cybersecurity Roundtable on Feb. 28

HIMSS | March 11-15 Booth #1618, Cybersecurity Command Center

HCCA | April 14-17 **Andrew Mahler presenting** "How Safe Is 'Safe Harbor'?

Balancing De-identification, Anonymization, and Pseudonymization of Health Data with Privacy Risks" on April 15





March 11-15, 2024

A VIRTUAL ONLINE VIDEO - LIVE AND ARCHIVED

The Virtual Forty-First National HIPAA Summit

VIRTUAL ONLINE VIDEO LIVE AND ARCHIVED January 31, 2024: Certified Cyber Security Architectsm (CCSAsm) Professional Certification Training & Exam February 7, 2024: HIPAA Summit Workforce Privacy Training February 14, 2024: HIPAA Summit Workforce Security/Breach Training February 21, 2024: HIPAA Summit Workforce Training: HIPAA Transactions, Operating Rules, and Critical

Tuesday, February 27 - Friday, March 1, 2024: Virtual National HIPAA Summit 41





April 14-17, 2024 • Nashville or Virtual



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