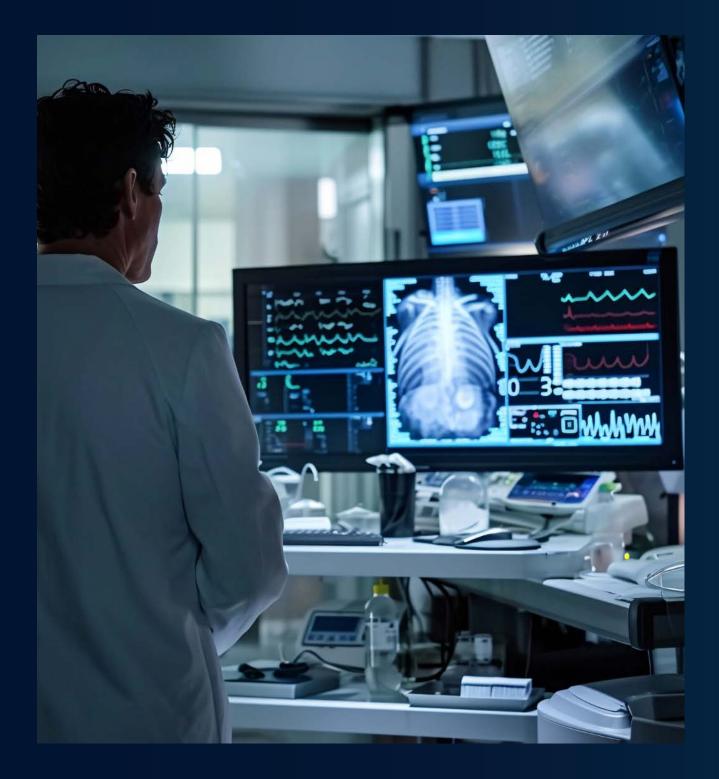
HealthSec USA Summit 2024 Annual Report_

"Enhancing Cybersecurity to Protect Patient Safety"





Issued May 2024

Executive Summary

Welcome to the HealthSec 2024 Annual Report. For each summit, we produce a report like this one to set the tone for the conference, in which we explore the themes and topics of each region covered by its respective annual in person event. This report looks in-depth at several key topics and trends relevant to senior cybersecurity professionals within US Healthcare & Life Sciences in the run up to HealthSec, Including exclusive interviews from the region's leading CISOs participating at this year's event.

The theme for this year's event is 'Enhancing Cybersecurity to Protect Patient Safety'. This is particularly pertinent amidst the current swathe of cyber attacks over the last year, undoubtedly the worst in recent history, often disrupting patient care and putting their safety at risk. In particular, the ongoing attack on Change Healthcare will undoubtedly be remembered for years to come for its lasting impact on the US Healthcare Industry and regulatory landscape.

Overall, it is easy to have a gloomy outlook this year, rising geopolitical tensions have spurred more sophisticated attacks, accentuating the existing lack of talent and resources, especially within smaller Healthcare Delivery Organizations (HDOs). Meanwhile, government action has been focused on increasing regulatory standards as opposed to access to resources. Uptake of AI and Machine Learning capabilities seem to be better amongst cybercriminals than HDOs. All the while, irremediable legacy systems, too costly to replace, are standard.

However, the circumstances are not entirely dire. The US healthcare cybersecurity community, both private and public, have shown their awareness and appreciation of the circumstances, understanding why



cybersecurity concerns need to be taken more seriously, as well as demonstrating the requisite passion to face these challenges head-on. Correspondingly, AI and Machine Learning tools and Zero-Trust, among other innovations, continue to uncover new use-cases, while investment cybersecurity increases. into Moving forward the focus of CISOs and cybersecurity departments needs to be on the full range of NIST's 5 Pillars, with a focus on improving cyber resiliency. This is so that organizations are prepared when the attacks come, able to keep business operations and healthcare delivery as unaffected as possible.

At HealthSec 2024 we will discuss these challenges and opportunities through stimulating debate. We hope the content sparks thought and excitement. Feel free to get in touch with us at info@qgmedia.io if you have any questions or would like further elaboration on anything discussed in the report.

Author: Brodie Neilson HealthSec 2024 Research Lead

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Cybersecurity Snapshot_



Approximately **93%** of healthcare organizations have experienced a data breach in the last **3 years**, most avoidable with basic cybersecurity practices



88% of organizations
 experienced an average of 40
 attacks in the past 12 months



64% of organizations suffered a supply chain attack in the past two years, 77% of which impacted patient care



H-ISAC, Finite State & Securin in a joint research product discovered close to 1,000 vulnerabilities across 966 medical products



Cyber Attacks on Healthcare are 25% more costly than in other industries



The total number of reported cyber attacks on Healthcare in 2023 was **463** as of August 31st (**58.2 a month**)

COST OF A DATA BREACH

According to an IBM's Cost of a Data Breach Report, the Average cost of a healthcare data breach in 2022 was

\$10.1 million •

+40% increase in the last two years •

ranked as the costliest sector for a data breach

Biggest Cyber Attacks on US Healthcare of 2023/24

Change Healthcare Biggest Attack of the Year

- When: February 2024
- **Type:** Ransomware
- Did They Pay? Unconfirmed

Known Business Impacts:

Systems shut down, including more than 100 applications across pharmacy, medical record, clinical, dental, patient, engagement and payment services. Healthcare providers unable to submit or receive payments, causing cash-flow shortages surpassing \$1 billion. Impact ranges from minimal negative operational consequences to long-term financial damage depending on the hospital's relationship with Change Healthcare.

Significant disruption to patient care, with some patients unable to fill prescriptions, risking an influx of health crises and emergency room visits.

Cybercriminal - BlackCat (aka, ALPHV/Noberus) - a russian-speaking cyber threat actor suspected to be associated with the Russian state. Known for using a ransomware-as-a-service business model (RaaS).

The U.S. Department of Health and Human Services (HHS) has released a statement with the Centers for Medicare & Medicaid Services (CMS) detailing support for impacted organizations and individuals.

UnitedHealth Group set up a temporary financial assistance program for provider organizations impacted.

The HHS have since opened an investigation into the attack



Ardent Health Services

- When: November 2023
- **Type:** Ransomware
- Did they Pay? Unconfirmed

Known Business Impact

Ambulances diverted across multiple states

"Ardent proactively took its network offline, suspending all user access to its IT applications, including corporate servers, Epic Software, internet and clinic programs", according to a December Press Release

Restored functionality to select systems on December 6th

MyChart Patient Portal access restored on December 21st



McLaren Health Care

- When: July November 2023
- **Type:** Ransomware
- Did they Pay? Unconfirmed
- **People Affected:** 2.2 Million Patient Records (Under Investigation)

Known Business Impact

A data breach claimed by Prolific Ransomware-as-a-service (RaaS) Russia-Based Alphv/BlackCat of over six terabytes of data.

Data included personal and health information, potentially including names, Social Security numbers, health insurance information, dates of birth, billing and claims information, medical records and diagnostic and treatment information. Though the breach occurred in July, patients were only notified beginning in November, causing concerns over the potential violation of state and federal laws.

Alphv/BlackCat has since been infiltrated and Seized by the FBI.



HCA Healthcare

- When: July 2023
- **Type:** Third-party storage breach
- **People Affected:** 11 million U.S. healthcare patients

Known Business Impact

Unidentified Hackers in mid-July gained access to an external storage location which formatted emails and calendar reminders sent to patients. Though this doesn't seem to include medical records, the stolen data did include names, email addresses, birth dates and other personally identifiable information.

A class-action lawsuit has since been mounted by affected patients against

HCA seeking monetary damages for a failure to provide adequate protection for their personally identifiable information.

Cerebral

- When: March 2024
- **Type:** Data Breach
- **People Affected:** 3.1 Million people

Known Business Impacts:

After installing tracking pixels from major tech giants on their applications, protected health information (PHI) was exposed to third parties without patient consent, resulting in a major HIPAA violation.

Telehealth organization Cerebral notified HIPPA and patients after it was made aware of the error following a review of its own privacy and logging technology, suggesting they were not fully aware that third-parties had access to patient data.

Exposed data included dates of birth, contact information, self-assessment responses, treatment details and other clinical information.

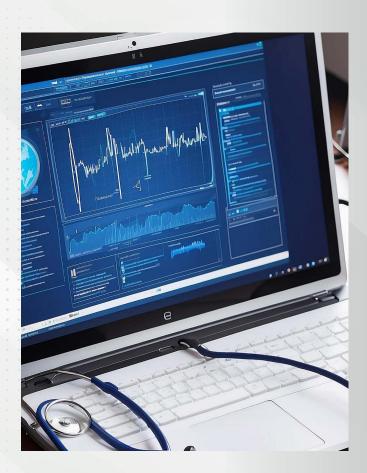


Part 1: Threat Briefing

Overall, 2024 observes an already tense cybersecurity landscape escalate to unprecedented levels. The size and severity of attacks continue to increase year on year, with larger and more prominent healthcare providers falling victim. This notably includes the ransomware attack on Change Healthcare in February 2024, which represents perhaps the most severe cyber attack on US healthcare in history and has since spurred a government investigation. Though as of this time, the short-term and long-term impacts are difficult to assess, the disruptions to service providers' cash flow and payments exceed \$1 billion per day.

Another key attack hit HCA Healthcare, the largest private healthcare provider in the world, who in July 2023 fell victim to a third-party storage breach, compromising the personal information of over 11 million patients. Throughout 2023 and 2024 ransomware has remained the omnipresent threat, while software supply chain insecurity, a data breach epidemic and IoT medical device vulnerabilities, especially within legacy systems, are among the other top security concerns.

Over the reporting period we have seen ransomware actors' businesses mature, with the continued uptake of more including sophisticated operations Ransomware As A Service (RaaS) and new harassment tactics such as double and triple extortion. This has made much of the existing ransomware advice about maintaining backups insufficient. Though rate of ransomware attacks in the healthcare has dropped from 66% to 60% over the last year, it remains considerably more than the 34% reported in 2021. Ransomware incidents involvina negotiations are up from 40% in mid-2021



to 70% in 2023. Combined with the increased implementation of AI tools, this seems to reflect a growing sophistication and costliness of ransomware attacks moving forward.

The increased number and severity of high-profile cyber attacks, as well as growing concern over unreported data breaches, have spurred a new wave of legislation which significantly raises expectations of cyber defenses within US healthcare, particularly within cyber The new 'Ransomware resilience. Vulnerability Warning Pilot' program (RVWP) mandates cyber incidents to be reported within 72 hours of the company becoming aware. This represents a push by CISA for more agile and coordinated incident response procedures. Because of the prominence of ransomware and the swell of recent legislation over the 2023/4 reporting period, 'Ransomware and the Threat Landscape' and 'Compliance' are our first two key themes heading into HealthSec 2024.

Regarding Gen Al and Machine Learning tools, the healthcare industry is undergoing a transformative shift in how medical services are structured, administered and fine-tuned. The continued integration of cutting-edge technologies, Internet of Things (IoT) and Internet of Medical Things (IoMT) within medical devices has significantly expanded the attack surface area of Healthcare Delivery Organizations (HDOs). In this perpetual struggle between cyber defenders and cybercriminals, Artificial Intelligence (AI) emerges as a pivotal force, offering immense potential for both cybercriminals and cyber defenders.

Contrastingly, medical device vulnerabilities, especially within legacy equipment, remain a growing concern influential within FDA and CISA legislation concerning information exchange and cybersecurity investment. We see many HDOs lacking up-to-date, complete and accurate inventories of the medical devices within their organizations, undermining any efforts made to address this issue. As a result, 'Medical Device Vulnerabilities' and 'AI and Machine Learning' have been designated as our third and fourth key themes for HealthSec 2024.

Over the course of this year's HealthSec, we will discuss these themes in depth, offering guidance and insight into balancing concerns, mitigating risk and navigating upcoming legislation, with a look towards the more practical and pragmatic solutions often overlooked.



Part 2: Health Sector Cybersecurity: **Key Developments**

Over the reporting period ransomware has continued to reign as the predominant cyber threat, driving an unprecedented surge in the US healthcare cyber threat landscape. The Change Healthcare attack of February 2024 in particular represents perhaps the most severe cyber attack on US Healthcare in recent history. While the majority of ransomware attacks have only impacted personal information and medical records, a number of more severe attacks have disrupted patient care, leading to an increase in fatalities, which has been dubbed 'death by ransomware'.

'Ransomware and the Cyber Threat landscape' is our first key theme for HealthSec 2024. Further on in this section we will hear from Rick Gilmore. Mohammad Wagas and Rick Doten on their considerations on how the threat

landscape and ransomware will continue to change moving forward, and what best practices CISOs ought to be implementing in response.

The 2023/4 reporting period sees the debate over whether to pay ransomware actors remain contentious. While the Federal Bureau of Investigation (FBI) does not condone payments to ransomware actors, breached healthcare providers still grapple with the urgent need to maintain patient care and access to medical records. Despite the escalating legal and regulatory repercussions of a breach, many see hospitals as having little choice but to pay, whilst others question the efficacy of such payments in the broader context.

Another significant development within ransomware over 2023/4 has been the increased sophistication of attacks. We have seen the beginning of a shift away from spray-and-pray attacks via phishing,

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towards more advanced social engineering attacks facilitated by Gen AI. This trend is only expected to intensify in 2024/5. Additionally, ransomware actors are becoming more mature in their business operations, with the continued adoption of more commercialized models such as Ransomware-As-A-Service (RaaS) and the increasing utilization of nation-state backing to fund larger projects.

Although there is still uncertainty over how ransomware actors will evolve moving forward, it is evident that the geopolitical landscape will continue to play a key role.

The increased uptake of Gen AI (See Theme 2) by threat actors may also increase the vulnerability of smaller hospitals and healthcare providers. This is the result of the reduced operational costs of more sophisticated attacks (i.e. social engineering) that Gen AI facilitates. This has the potential to produce a change in focus towards more attacks on smaller providers.

Historically advanced techniques have been reserved for attacks on bigger healthcare providers, who are correspondingly better defended. If such a change does occur, there is little debate that smaller healthcare providers will be woefully unprepared. Additionally, this in turn increases the risk for bigger healthcare providers and insurers due to the prominence of third-party risk.

It is very possible for breached systems and Advanced Persistent Threats (APTs) to spread vertically across the supply chain.

In terms of compliance and government action (See Theme 4), the HSS has announced plans to provide greater resources and incentives for improving cybersecurity measures, as well as increasing the regulatory penalty for data breaches.



Healthcare stands out as one of the top targeted industries, facing severe impacts and limited means to effectively remediate its growing attack surface. This positioning continues to make the healthcare industry a prime target for cyber threats. We are witnessing larger and more complex healthcare attacks targeting 'whales'.

While attackers persist in utilizing 'simpler' phishing-based attack vectors as entry points, particularly for harvesting credentials and distributing ransomware, there has been a notable rise in more sophisticated attacks meticulously crafted for large organizations after extensive reconnaissance and 'living off the land' for days, weeks, and sometimes months. This results in more devastating attacks able to bring down multi-national, and multi-state healthcare systems, amounting from tens to hundreds of clinical care locations going offline, ambulances being diverted, and much higher patient wait times.

Furthermore, these advanced attacks are also focused on exfiltrating personal health information (PHI), often threatening organizations with releasing the sensitive data if the ransom is not paid. Consequently, healthcare organizations not only face system outages and patient care disruptions, but also regulatory scrutiny and reputational damage. Additionally, these large-scale attacks come with much higher costs. This includes ransom in the tens of millions, or similar restoration costs. It takes

organizations weeks, and sometimes upwards of 3 months to fully restore operations.

Compounding the issue, the healthcare device ecosystem and patient care models are diverse, posing challenges for security teams attempting to implement a 'one size fits all' security approach. While healthcare delivery organizations were historically resistant to innovation, an inflection point is evident, with hospital operations, clinical departments, and physicians embracing innovation and technological advancements. However, this presents a challenge for security teams tasked with securing both legacy equipment and newer patient care delivery models.

The challenge is further exacerbated by the traditionally flat structure of hospital networks or network segments with minimal access controls between them, amplifying the risk of cyberattacks. For instance, If a staff computer that is used to browse the web during a lunch break gets infected, and it has access to medical devices, servers or facilities management systems, it can cause catastrophic amounts of damage in an extremely short period of time. Effective segmentation policies can greatly limit the blast radius of cybersecurity attacks, but may entail a complex and costly journey to be implemented correctly.

The COVID-19 pandemic accelerated the adoption of remote care delivery models, prompting HDOs to expedite the implementation of modern clinical solutions, cloud infrastructure, remote patient services, newer medical device types, patient portals, and support for remote workers. Each of these initiatives expands the attack surface, contributing to the cyber threats faced by hospitals. GenAl emerges as another focal point for innovation in patient care, streamlining workflows whether it is from a physician



documentation, clinical workflow, or patient experience perspective. GenAl, however, also comes with a great deal of privacy and security risk. For instance, if identifying information is consumed by the models, if data is reconstructed in a response, or if attackers leverage GenAl for vocal imitation. Additionally, a number of HDOs are undergoing construction of new smart hospitals, equipped with thousands of IoT, OT, and Building Management System (BMS) devices - each contributing to the hospital's overall attack surface.

In summary, while healthcare undergoes significant innovation and technology adoption, the hospital attack surface remains complex and highly targeted. From decades-old medical devices to misconfigured IoT devices and smart hospitals, the diversity of technologies poses challenges in quantifying, gualifying, and reducing risks effectively. It is crucial now more than ever for information security & privacy teams to be engaged from the onset, and build security into not only the projects, but the organizational culture, fostering collaboration amongst all teams, whether clinical, facilities, or supporting services.



QUESTION:

How would you describe the current cyber threat landscape for US Healthcare?

Healthcare is heavily targeted by threat actors for ransomware because they know that it is an availability-based platform and mission, and if they can disrupt that, there is a greater chance that someone will pay. They know that the majority of healthcare providers lack adequate cybersecurity support, making them easy targets.

We witness this firsthand as a big payer: nearly every week one of our providers falls victim to a ransomware or business compromise attack, email where cybercriminals attempt to falsely change the provider's payment account. the last few years Moreover, over ransomware actors have become much more organized and mature in their business operations, which has amplified an existing problem.

Right now healthcare providers are struggling; during Covid I heard a great analogy that we are NOT all on the same boat, we are all in the same storm, but some of us are in yachts, some of us are in row boats, and some of us are treading water. Considering that many healthcare providers are only small doctor's offices, most of them are 'treading water' so to speak. They often don't even have the expertise, knowledge or even the funding to support having outside expertise help them out.

QUESTION:

What are some key changes that healthcare organizations can implement to bolster their cyber defenses?

I'd say the answer differs depending on what your company does and its market positioning. But for everyone, understanding the business and what the real risks are to the business is foundational. Everyone knows this is important, but in some ways not everyone truly does.

Particularly in healthcare; we have a big wealth gap between the large Fortune 500 payers, which have ample money, resources and people, and the healthcare providers who are not as well-funded and lack the necessary resources. It is important to understand that IT risk management is not about protecting IT, it is about protecting the business. Our business is to make sure patients are taken care of, that systems are up and running, that we have systems that are secure so we can provide the requisite care, and for the providers to be paid.

Most security technology is geared toward protection, which though important, is not 100% effective. What happens when it is misconfigured or bypassed? We purchase them to protect our assets, but we cannot expect it to always work. I remember asking my friends who went to West Point Army Academy what they were taught in War 101: they said that if you have something of value, you protect it with a

barrier, then you monitor that barrier with firepower for when it is inevitably breached, be it days, months or years. You have to have that response capability. Protections are there to slow people down, not to stop them. Particularly within cybersecurity, these protections only reduce risk, because something will eventually get by, be it through a vulnerability, or misconfiguration. So you need to know when something goes wrong, to be able to respond to it before it can cause you harm.

Overall, it is not about avoiding being 'hacked' or 'infiltrated', it is about being able to identify and stop an attack before it can cause business harm. During my years as a virtual CISO this is what I saw missing the most: companies had plenty of protection tools, but lacked the detection and response capabilities to maintain business operations through an attack. This is definitely an area I would recommend focusing on.



QUESTION:

In our previous meeting you mentioned the potential role of the U.S. Government in mediating and stimulating change, could you tell me a little more?

I think there is an opportunity for government support, particularly within critical infrastructure like healthcare, to help smaller companies better protect themselves. Because crucially, when all the smaller organizations are insecure, we are all insecure.

While smaller healthcare providers cannot afford to buy the best platforms or hire the

best people, perhaps there are ways for them to gain access to reduced rates to tools or managed cybersecurity providers. Because they will never be able to afford to protect themselves to the level that they need to based on the maturity of current threat actors.

Big companies and little companies are fighting the same fight against the same adversaries, but whilst Fortune 500 companies have money, resources and people, arguably 99% of healthcare organizations do not.

QUESTION:

Do you have any last words of wisdom for the Healthcare cybersecurity community?

I would say that if you are part of these 99% of healthcare providers who are underfunded, my advice is to find your community. H-ISAC is very mature and active, with good information from your peers to help you.

There are many membership cybersecurity organizations such as ISA (ISC)2, ISACA and the Cloud Security Alliance which you can join and participate in to find your community and gain their insights. It's important to realize that you are not alone, and to ask for help, because you will not be able to do this on your own.





Challenge of Cybersecurity as an Operational, Policy and Cultural Challenge for the Health System

The health sector is at an inflection point in the journey to shore up its cyber defenses against the onslaught of cyber threats to clinical care, operational continuity, and data and financial integrity. Since 2017 when an HHS-industry task force diagnosed healthcare cybersecurity to be in "critical condition", industry and government stakeholders have mobilized address to the threats through operational; governance and policy initiatives.

On the industry side, the Health Sector Coordinating Council Cybersecurity Working Group - an advisory committee of more than 400 health organizations in a public-private partnership to protect critical healthcare infrastructure - has published more than 25 leading cybersecurity practices to guide health providers, medical technology, Health I.T., pharmaceutical companies, and payers toward a more secure posture.

Seven years after that task force diagnosis, the HSCC is now looking ahead to the next five years in a Health Industry Cybersecurity Strategic Plan published on February 27 that projects major trends in the industry, the cybersecurity challenges those trends present and how we should be prepared with next generation cyber preparedness. When implemented across the sector, this Plan will help upgrade the industry's cybersecurity diagnosis from "critical" to "stable condition."

At the same time, the government recognizes its own role in finding a balance between the "carrots and sticks" to hold the industry accountable for protecting patient care and operational continuity from cyber disruptions. Among the most recent developments:

 Cyber Incentives in HIPAA Enforcement A law passed in 2021 (P.L. 116-321 - the HITECH Amendment Act) directed HHS, when enforcing a data breach violation under HIPAA, to consider as possible mitigating circumstances the extent to which a breached entity implements recognized security practices such as the NIST Cybersecurity Framework or the joint HHS-HSCC "Health Industry Cybersecurity Practices (HICP)." This presents a positive incentive that HIPAA audits and fines could be lessened if breached health systems do "the right thing" and invest in appropriate cyber control frameworks.

 Increased FDA Scrutiny on Cybersecurity of Medical Devices
 In December 2022, Congress passed a law, and FDA subsequently issued guidance, that enhances FDA regulatory authority to consider medical device cybersecurity as a part of safety and quality in determining approval of pre-market submissions from medical device manufacturers.

Mandatory Incident Reporting

Also in 2022, Congress enacted the "Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA)". Among other things, CIRCIA directs the DHS Cybersecurity and Infrastructure Security Agency (CISA) to develop and oversee implementation of regulations requiring defined entities to submit reports to CISA detailing covered cyber incidents and ransom payments.

• Foundational Cyber Performance Goals

In early 2023 HSCC and HHS worked together at the direction of the White House to prepare a "Hospital Resiliency Landscape Analysis," which identifies the vulnerabilities and threats most frequently resulting in damaging attacks against hospitals, and assesses hospitals' known capabilities for preventing damaging cyber incidents. This analysis helped inform HHS development of "Cyber Performance Goals (CPGs)" for the health sector – a set of minimum voluntary controls and practices that are based on broader, cross-sector critical infrastructure CPGs developed by CISA.

The Path to More Mandates

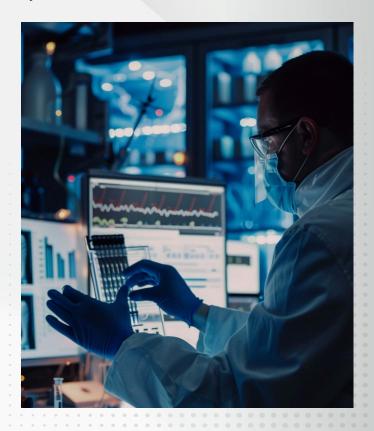
The CPG's will not, however, stop at being voluntary. HHS has telegraphed that they will begin a rulemaking process in the fall to consider amendments to the HIPAA security rule that would prescribe more specific cybersecurity controls as part of a cyber risk management program among health systems and providers. This could include the potential, for example, of using CMS authorities enforcement as an mechanism. While this presumably would be directed exclusively to "covered entities" and "business associates" under HIPAA, it could extend other technology and service to providers if the amendments involve requirements providers' on implementation of third-party cyber risk management protocols. Industry groups representing health providers would prefer to see a positive incentive that would tie increased CMS reimbursement demonstrations of good cyber to hygiene, similar to the construct embodied in P.L. 116-321 above.

Money with Mandates

One truth the government acknowledges is that mandates without corresponding financial and technical support to the smaller, rural, critical access health providers will complicate the objective of protecting patient safety from cyber-attack, as it would force on strapped health providers the existential choice between investing in medical care or cybersecurity compliance. Expect to see some support from government - and perhaps private sector programs as well – to relieve some pressure on the "target rich, cyber poor" stakeholders in the health system.

The Health Sector Coordinating Council (HSCC) Cybersecurity Working Group (CWG) has worked with HHS, CISA and other federal agencies over the past several years to develop leading cybersecurity practices that are provided to all health organizations in the ecosystem.

This work amplifies the recognition among large, medium and small health providers, and all the supporting subsectors in the health system, that cyber safety is patient safety, and that focused investment and accountability are imperative to inoculate our data, systems, medical technology and patients against the rising epidemic of cyber-attacks on the sector.



Part 3: Al & Machine Learning

Amidst rapid advancements in AI and machine Learning tools, the healthcare industry is undergoing a transformative shift in the manner in which medical services are administered, organized and fine-tuned. The continued integration of cutting-edge technologies, Internet of Things (IoT) and Internet of Medical Things (IoMT) within medical devices has significantly expanded the attack surface area of Healthcare Delivery Organizations (HDOs).

In this perpetual struggle between cyber defenders and cybercriminals, Artificial Intelligence (AI) emerges as a pivotal force, offering immense potential for both cybercriminals and cyber defenders. Consequently, 'AI & Machine Learning' is our second key theme for HealthSec USA 2024. Later in this section we hear from senior thought leader Ty Greenhalgh, and their considerations on the nature of building trust within AI, stressing its importance within the US healthcare cybersecurity landscape.

In recent years AI tools have been welcomed by healthcare providers and EMR software vendors, streamlining workflows and enhancing data analysis. During this time there has been a parallel surge in the adoption of AI and Machine Learning tools by threat actors and cybersecurity leaders, who have been leveraging AI in increasingly innovative ways.

The Department of Health and Human Services (HHS) recently issued a warning, anticipating a rise in AI-assisted attacks, particularly in phishing emails and vulnerability exploitation. One growing use-case among threat actors utilizes large language models (LLMs) for more sophisticated social engineering and



phishing attacks. Another finds Al designing malware capable of adapting and evading traditional detection systems. Moreover, a 2021 study conducted by the University of Pittsburgh Medical Center suggests that threat actors may even target medical Al algorithms, potentially manipulating diagnoses or treatment recommendations. This has far reaching implications that remain to be fully understood.

On the other hand, many healthcare providers have been slow to harness AI for cyber defense due to the significant hardware and labor costs (TCOs) associated with its development and maintenance. While Managed Security Service Providers (MSSPs) offer a practical solution to accessing AI automation tools, they often remain financially out of reach for many cash-strapped HDOs.

Nonetheless, some HDOs and industry associations are taking proactive steps, establishing committees to assess Al capabilities for offensive, defensive, and clinical care purposes. Overall, the potential applications of Al and machine learning in both cyber offense and defense are vast and expanding. Looking ahead, it will be critical for CISOs to not only understand the use cases for Al in cybersecurity but also how threat actors are leveraging these technologies.



Artificial Intelligence (AI) has the capacity to redefine how we live, work and interact, but uncontrolled development of the technology comes with risks. Its capability of generating content at speed and at scale will threaten the foundations of our health and longevity. Healthcare applications of AI are arguably the most mature, offering unprecedented benefits while simultaneously posing the greatest risks to society.

Al hype has consumed our media and vendor marketing campaigns. Caregivers and consumers need to distinguish and differentiate between the types of Al, their strengths, risks and the function being applied. The different types of Al that support healthcare range from administrative tasks, to cybersecurity, to patient diagnostics. Mark Twain said, "The best tool for the job is the one that works." HCA is enhancing clinical documentation using an Al technology called "Ambient".

This type of AI leverages "Natural Language Processing" (NLP) and "Large Language Models" (LLM) which listens to a physician and patient's encounter, accesses relevant and non-relevant content, then constructs the clinically and legally appropriate documentation saving countless late-night hours of non-patient facing burnout compliance. NLPs and LLMs are types of AI unto themselves thus making Ambient Al technology а multi-modal solution.

Siemens Healthineers uses Al guided

Computed Tomography (CT). This computer companion offers physicians guided lung cancer screenings, improving the identification of small nodules and other suspicious abnormalities. Machine Learning is the type of AI that reconstructs images from raw data and conducts an image analysis prioritizing high risk patients, identifying previously missed nodules and accelerating early treatment.

With minimal prompting, Generative Al (GAI) models can create images and text sufficiently human-like as to automate many of the healthcare industries manual tasks. From transcribing doctor-patient visits, reading and drafting response emails, to dispensing general health information, Generative AI dramatically decreases time spent on non-patient facing activities. ER doctors are seeing a 25% increase in patient time.

While General Practitioners can leverage Al to increase access to knowledge, the risk of error and liability dictate the physician stay in-the-loop. There are a host of problems preventing AI from replacing most doctors tomorrow. Yet these technical problems, however difficult, need only be solved once. The training of a human doctor is complicated and expensive. When the physician education process is complete, after a decade of studies and internships, you get one doctor. If you want two doctors, you have to repeat the entire process from scratch

In contrast if you solve the technical problems hampering AI, you get not one, but an infinite number of digital doctors available 24/7 in every corner of the world. However, any errors are now compounded globally overnight. The risk reward calculus should be conducted by sober humanists, and not left to algorithms. With all great opportunities comes risk. Al is not automatically trustworthy, safe, unbiased, nor transparent. Taking AI out of

the proverbial black box, you find it is ultimately a data challenge. We need Gold Standard data to train Als if we want to reduce the risk of poisoning our future. Organizations can't simply teach their Al based on an EHR record with patient encounters containing false diagnosis, inaccurate data and undocumented outcomes.

In July 2023, HHS issued a threat brief about the ways in which threat actors might use AI to exploit vulnerabilities, overwhelm human defenses, and automate attack processes. Al systems can malfunction when exposed to untrustworthy data, and cybersecurity hackers are exploiting this vulnerability. This Adversarial Machine Learning is a type of AI attack which can poison the data within "good" AI, creating a new vulnerability to exploit. Healthcare security and privacy experts are well aware of the danger of Al-assisted cyberattacks for patient safety and HIPAA violations.

Harkening back to Mad Magazine's Spy vs, Spy, it will take AI to fight AI. Unlike the large public LLMs underpinning ChatGPT that have been built on the entire corpus of the World Wide Web, smaller cybersecurity knowledge bases will be created from private LLMs. Vendors will curate, technically vet, continuously update and integrate with other types of AI delivering tailored multi-modal cybersecurity defense solutions.

Labeling and Categorizing of data are critical but time consuming cybersecurity tasks. Medical device logs and network activity can be labeled as normal or anomalous behavior automatically. Device vulnerabilities can be categorized by severity and exploit potential without human intervention. Al models can detect compromised devices and potential security breaches, allowing healthcare providers to take proactive measures to patch vulnerabilities and prevent unauthorized access. Als exponential productivity impact digital on cybersecurity defense is our best hope for addressing healthcare's cybersecurity skills gap.

Healthcare organizations should start their Al journey by comparing their Al policies with trusted regulations and frameworks; NIST AI RMF, HTI-1, EO 14110, NIST CSF, HIPAA. Will we balance prudence and the necessary gradual deployment of AI with speed for speed's sake? What is the remediation process for proactively mitigating digital doctor's misdiagnosis? Will we hold people personally accountable for failures in AI or allow corporations to obscure transparency behind unexplainable code? Asking the right questions now will enable us to create the future that we want, rather than the future we may end up with. Trust can come, but it requires relentless dedication to data integrity first.

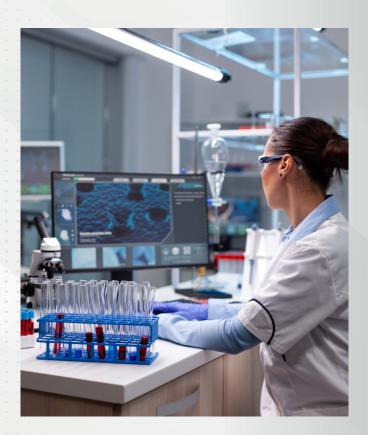


Part 4: Vulnerabilities Within Medical Devices

'Anything that is not analog is hackable' despite becoming a LinkedIn buzzword among cybersecurity leaders in recent years, the underlying point continues to ring true. In this respect, the reporting period perhaps reveals a lack of communication between the C-Suite, eager to integrate the Internet of Medical Things (IoMT) wherever possible to improve performance and information exchange, and the CISOs, who may perceive this as a security risk. Nevertheless, the increasing implementation of IoMT within medical devices indicates its growing prominence healthcare cybersecurity and in US information exchange.

As a result, we have designated 'Vulnerabilities Within Medical Devices' as our third key theme for HealthSec 2024. Later in this section, we hear from senior cybersecurity leaders Mohammad Waqas and Phil Englert, who share their insights on the current state of medical device security, as well as their considerations on best practices.

Over the 2023/4 reporting period we witnessed a continued increase in the implementation of IoMT in both size and diversity within Healthcare Delivery Organizations (HDOs), driving increased smart device network traffic and expanding the size and complexity of the cyber attack surface. Concurrently we saw many HDOs lacking up-to-date, complete and accurate inventories of the medical organizations, devices within their undermining any efforts made to thwart vulnerabilities. medical device Fortunately, market solutions addressing these issues have matured; from basic discovery and risk scoring, we now see fully-fledged security protection systems dedicated specifically to IoMT.



According to an HHS study, though medical device vulnerabilities are not yet commonly exploited in comparison to more prevalent cyber threats, they still pose a significant risk to hospital networks. Attacks to medical devices in their own right have the potential to delay critical patient care, reveal sensitive patient data, shut down healthcare operations and necessitate costly recovery efforts.

Moreover, a breach of one device can very easily spread across a server or network. Additionally, the increased attack surface area from IoMT within medical devices is a cause for concern, as securing a larger surface area with the same resources inevitably stretches resources thinner. To address this, the HHS have identified a lack of vulnerability testing within hospitals as a major concern, calling for higher forms of assessment testing to more advanced forms detect of ransomware moving forward.

While considering compliance concerns (See Theme 4), the FDA & CISA's formal

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agreement on medical device security is now six years old. A Government Accountability Office (GAO) report has identified practices not reflected in the 2018 agreement, and has called for updates to reflect the organizational and procedural changes that have occurred in the interim. The report also found that non-federal entities lacked awareness of available resources or contacts and faced difficulties understanding vulnerability communications from the federal government. As a result, we expect to see corresponding changes to medical device regulations moving forward.

With regards to Quantum, the reporting period sees updated estimates that Quantum Computing is roughly a decade away. However, despite being on the horizon, the potential for Quantum Computing to render large portions of the medical device market functionally incentivises obsolete heavily any investments into new medical devices to include some form of post-quantum cryptography or crypto-agility. This would in turn allow for medical devices to either handle the quantum hurdle as we currently understand it, or be adapted and updated continually to meet such a threat.





As we enter 2024, the state of medical device cybersecurity remains a critical healthcare sector, concern in the underscored by recent events and ongoing challenges. The landscape is characterized by the pervasive adoption of the Internet of Things (IoT) and Internet of Medical Things (IoMT) devices, extending the potential attack surface and necessitating heightened vigilance. Additionally, with the digitization of medical devices healthcare, are increasingly sending data to a cloud environment before redistribution to caregivers and patients. The additional transactions further extend the threat surface often beyond an organization's immediate control.

The enactment of Section 3305 and Section 524B of the Federal Food Drug and Cosmetic Act in 2022 marked a significant step in ensuring the cybersecurity of medical devices. These regulations outlined requirements for manufacturers to prioritize cybersecurity throughout the device lifecycle, emphasizing that cybersecurity is integral to patient safety.

However, despite regulatory efforts, the healthcare industry continues to grapple with cybersecurity vulnerabilities. The 2023 State of Cybersecurity for Medical Devices and Healthcare Systems report revealed alarming findings, including numerous vulnerabilities across various classes of medical devices. Legacy technologies, in particular, pose significant risks due to their lack of robust security features, leaving patients, data, and network environments vulnerable to exploitation.

Recent cyberattacks, such as the ransomware attack on Akumen, serve as stark reminders of the real-world consequences of inadequate cybersecurity measures. The attack resulted in the shutdown of diagnostic imaging systems across the country, disrupting essential healthcare services and compromising patient care. The use of sophisticated attack techniques, including script-based PowerShell attacks, highlights the evolving tactics employed by threat actors to exploit vulnerabilities in medical devices and infrastructure.

response to these In challenges, healthcare organizations must adopt proactive risk management strategies and implement robust cybersecurity controls. Comprehensive risk assessments, network segmentation, and access controls are essential measures to identify and mitigate device vulnerabilities. Improvements to passive monitoring and response tools provide greater clarity in asset identification and classification as well as mapping traffic patterns so indicators of exploit are recognized sooner and responded to more efficiently. Timely patching and updates, along with user education and awareness programs, play crucial roles in strengthening cybersecurity posture and reducing the risk of successful attacks.

For medical devices in particular, organizations must assess the impact of a cyber incident. This may include data breaches if the device is used as an infiltration or data exfiltration point. Patient care may be delayed, interrupted, or even prevented resulting in various degrees of patient harm. Once inside a healthcare network, hackers may shut down servers supporting patient care services and may disable the ability to diagnose or monitor patients. In worse-case scenarios, patient care services may even be shut down.

Collaboration between stakeholders, including manufacturers, healthcare providers, regulators, and cybersecurity experts, is imperative to address cybersecurity challenges effectively. By sharing threat intelligence, best practices, and lessons learned, the healthcare industry can enhance its collective resilience against emerging cyber threats.



Medical Device Vulnerabilities remain a challenge that security teams and Health Delivery Organizations (HDOs) as a whole continue to struggle with. There are a number of different dimensions to consider here that link back to the expanded attack surface discussed previously (See Section 2.1.1).

First, it relates to the technical builds - and resulting incompatibilities - of these devices to the traditional security solution stack. Early generation medical devices were focused on 'digitizing' and thereby increasing the efficiency of clinical workflows or procedures. They were purpose built for their specific medical operation, and so security capabilities were an afterthought. Operating Systems (OS) were specialized, making it impossible to install software agents, including inventory, vulnerability, or endpoint protection agents. The second here is due to the nature of the devices,

they were purpose built by medical device manufacturers to perform a specific operation only - they would support specific packets or messages on specific ports. Any unexpected messages, or deviations from normal operating procedures could knock these devices offline. This inhibited the ability for security teams to enumerate and qualify risk for such devices using any form of active vulnerability scanning. An active scanning packet received by such medical devices when they're expecting other messages can result in a form of denial of service - because the medical device cannot process that packet, it becomes queued up in the processing interface, and all other packets including legitimate ones can be held up behind it, bringing operations to a stand still.

Beyond this, vulnerability patching was not something vendors regularly did, if at all. Often, devices were sold in 'as-is' configurations due to the extensive certification processes required for major changes. While vendors have gotten better in this regard, there is still much room for improvement. The lack of regular patching has led to older medical devices accumulating an increasing number of vulnerabilities over time, such as Log4Shell, without the ability for security teams to patch them, resulting in expanding risks for each device.

As aforementioned, because many of them are sold in a certified as-is state, even doing compensating actions to the vulnerabilities mitigate proves difficult. A prime example of this is disabling SMBv1 across all medical devices. Given their legacy nature, and how widespread this protocol is as well as the lack of support for newer protocols, despite being a clear risk and the prime exploit vector for WannaCry and other Ransomware variants, cybersecurity teams simply cannot disable the SMBv1 protocol for their medical device infrastructure.

Considering teams' inability to patch or apply mitigating controls like disabling vulnerable services, the question arises: how do teams remediate vulnerabilities? The only recourse is often purchasing the latest & greatest devices, introducing cost considerations into the risk formula. For instance, medication dispensing cabinets running End-of-Life (EOL) operating systems (OS) such as Windows XP or Windows 7 pose challenges. If the security mandate is to retire assets, and a single cabinet costs \$100,000 - with 30 in a moderate sized hospital, that amounts to \$3,000,000. With this being a security mandate and limited budgets across all units in an HDO, it is financially unfeasible to replace all devices. Consequently, other compensating controls must be assessed.



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Part 5: Compliance

US Healthcare Cybersecurity, Within companies often have senior cybersecurity officials dedicated to key pieces of legislation (i.e., Director of HIPPA or HITRUST). The fact that this is seldom seen in any other industry is a testament to the prominence of regulatory compliance within US Healthcare Cybersecurity in 2024, for better and for worse. As such, compliance has been designated our fourth key theme for HealthSec 2024. Later in this section, we will hear from senior cybersecurity thought leaders Aaron Weisman, Rick Gilmore and Ty Greenhalgh on their current considerations and observations regarding compliance within US Healthcare Cybersecurity.

period The 2023/4 reporting sees compliance continuing to be a key driver for Healthcare Delivery Organizations (HDOs). Following the release of the US National Cybersecurity Strategy in 2023, we expect the current regulatory noise to persist as data breaches and ransomware attacks only worsen. Another key touchpoint during the reporting period has been the lack of resources for smaller HDOs. Amidst increasing regulation, many continue to be unable to afford the reauisite cybersecurity talent and resources needed to achieve compliance and ensure organizational safety (See Section 2.1.1).

A prominent update to breach reporting over the last year has been a new CISA mandate requiring cybersecurity breaches to be reported within 72 hours of the organization becoming aware of the attack. This initiative aims to support CISA and other governing bodies in understanding the extent of cybersecurity breaches within US critical infrastructure, while fostering a more collaborative relationship between the public and private sectors. Overall, prompt, consistent and mandatory

reporting on cyber breaches is poised to be a significant step forward from today's ad industry-specific quidance hoc, for disclosures by affected voluntary companies. Additionally, CISA has launched a new 'Ransomware Vulnerability Warning Pilot' program (RVWP), designed to warn organizations prior to an attack, providing them with precious hours to prepare their defenses and response procedures. Our initial research suggests that the program has so far been somewhat late in its warnings, though it is still in its early stages, giving us hope for its effectiveness in the future.

Regarding medical device regulation, the FDA & CISA's formal agreement on medical device security is now six years old. A late report by the Government 2023 Accountability Office (GAO) identified practices not reflected in the 2018 agreement, calling for updates to reflect organizational and procedural changes. The report also found that non-federal entities lacked awareness of available resources or contacts and faced difficulties understanding vulnerability communications from federal the government.

Amidst other notable steps taken to address this, the FDA's authority over medical device security has increased. One notable update is their plan to monitor, identify and address cybersecurity vulnerabilities for any new medical device introduced to consumers starting in March 2023. However, this has since been changed to apply only to devices introduced before March 2023.

Nevertheless, if corresponding medical device vulnerabilities are not remediated, the FDA is now liable to find the device in violation of federal law, subject to enforcement actions. Therefore we anticipate the size and significance of medical device vulnerabilities to decrease moving forward.

Key Regulation & Frameworks to be Aware of in 2023/24:

- HIPAA Health Insurance Portability and Accountability Act (1996)
- MDS² Manufacturer Disclosure Statement for Medical Device Security (2004)
- HITRUST Health Information Trust Alliance Framework (2007)
- HITECH Health Information Technology for Economic and Clinical Health Act (2009)
- Center for Internet Security (CIS) Critical Security Controls v8 (2021)
- Cyber Incident Reporting for the Critical Infrastructure Act (2022)
- Healthcare Cybersecurity Act of 2022
- PATCH, Protecting and Transforming Cyber Health Care Act 2022
- Food and Drug Amendments of 2022
- ISO/IEC 27001 (last updated 2022)
- Consolidated Appropriations Act of 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)
- 405(d) Health Industry Cybersecurity Practices (HICP) Update (2023)
- New Telehealth Guidance (2023)
- NIST Cybersecurity Framework 2.0 (last updated 2024)
- Quality System Regulation (QSR) (last updated 2024)



In my opinion, regulatory compliance is one of the greatest, if not the greatest, tool in a CISO's toolbox. Regulatory compliance gives you an immutable objective against which to benchmark security: you can literally point to a document that tells you what you need to do and the consequences for noncompliance. It provides certainty in the face of fear, uncertainty, and doubt. That, in turn, drives legitimacy for your security program.

At one point, HIPAA compliance was the primary regulatory source focused on security. That's great for healthcare providers and payers, but largely not for other industries. With the recent introduction of amendments to the Securities Exchange Act of 1934 and the regulations introduced soon-to-be promulgated under the Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA) (not to mention various state privacy and security laws), more CISOs can now enjoy the benefits of regulatory information security controls.

Achieving compliance and transforming those regulatory sources into solid cybersecurity demands nuance. Here are some strategies I've found effective:

1. Integrate Compliance into your Security Culture: weave compliance into the fabric of your organization's security culture by educating on the importance of regulatory requirements beyond the fear of fines. Regulatory compliance drives data safety and trust.

2. Leverage Compliance for Risk Assessment: use regulatory frameworks as tools to develop comprehensive risk assessments. The HIPAA Security Rule, for example, provides intentionally amorphous and light security requirements. It is typically used to outline the minimum requirements for protecting sensitive information, upon which more robust assessments are based.

3. Automate Compliance Processes: implementing automation and compliance management tools can streamline compliance processes, ensure accuracy, and free up your team to focus on more strategic security initiatives. Automation can also help with reporting, which is key to drive business engagement and accountability.

4. Collaborate Across Departments: compliance isn't solely the security team's responsibility. Engage with your legal, human resources, data privacy, and other departments to ensure a comprehensive approach to compliance. This collaboration can lead to more holistic and effective partnerships.

There's a common theme to those strategies: effective regulatory compliance elevates security through communication and collaboration. The legitimacy comes from the conversations you drive around regulatory compliance, not the regulations themselves. By making security tangible to other departments through regulatory compliance, security becomes less relegated to an avoidable "technology thing" for organizational leadership and more of a central and critical pillar to organizational operations. You can, of course, do that without regulations but provide regulations commonly а understood conversation starter.



GRC Challenges For Healthcare:

Healthcare industry leaders pride themselves on improving shareholder results. Cost-cutting and financial planning occurs in perpetuity, not just once annually as most believe. Every spend must be tied to a billable source. Here's where the Governance Risk and Compliance (GRC) challenge begins. A GRC tool is very costly to implement and maintain, and the cost is not billable. It is an internal operating expense. Not only does the tool itself require heavy financial commitments up front, the staff to learn and manage the tool require funding from a non-billable source. So, right out of the gate GRC tools are disliked by accountants.

The challenge facing healthcare today is, where is the value in a GRC tool then? The answer is, it depends. It depends on how often you're audited, and how many policies, procedures, processes, or standards you have, and if you value metrics, or how much importance you place on regulatory reporting (HIPAA HITECH, GDPR, PCI) etc. There are a myriad of reasons why you may benefit from a GRC tool.

The most important to achieving success as a well-managed organization is your policy program. Do you have policies? Where do you store them? Are they HIPAA compliant? Are they communicated regularly? Are they updated annually? Etc. Without a well structured and managed documentation management program you are sunk from the beginning. A GRC tool

immediately provides structure to this program so humans do not have to manage the mountains of documents in multiple locations throughout the company.

Another benefit of a GRC tool is auditing. An auditor can be onsite for weeks while your staff compiles artifacts and endures interviews, or, just a few days because you have a GRC tool that is auditable and contains all the artifacts necessary to maintain a high degree of compliance. Hand over the artifacts in a day or so to the auditor, allow them time to review, and you're done. The GRC tool just took the fun out of your audit. All of this so that you avoid regulatory fines and penalties, as well as possible SEC penalties and negative reputational impacts. Bonus, you may save on labor knowing your audit support staff don't have so much work to do.

So, where do you come up with the funding for a comprehensive GRC tool implementation, that is up to the accounting and finance group to fix. Let us make them earn their keep and help maintain compliance throughout the organization. Having a GRC tool fully implemented and functional is a badge of honor among successful healthcare leaders.

Improving Incident Response:

From a Governance Risk and Compliance (GRC) perspective, healthcare organizations today should be laser focused on ensuring a GRC tool, as well as a comprehensive reporting tool, exists to ensure precision execution of the incident response process. The GRC tool hosts procedures, processes, policies, and standards for the entire organization necessary to guide the staff and subject matter experts in managing incidents to closure. This tool hosts the required corporate directives governing the reporting and processing of all reported incidents. Additionally, auditors typically

look favorably on healthcare organizations that take this extra step to ensure regulatory compliance throughout the organization due to the ease of collecting compliance artifacts.

Next, the reporting process requires an effective and efficient reporting tool facilitating collaboration between all responsible organizations (i.e. cybersecurity, corporate investigations, legal, insider threat, business information security, etc.). This reporting process must communicated throughout be the organization on a regular basis for maximum assimilation by staff. Simply having the reporting tool in place is not enough. The tool must be used as designed and in all instances. In addition to providing meaningful metrics, this reporting tool tracks actions, owners, due dates, and other activities necessary in remediation of a security event.

And finally, a competent team of well-trained Incident Coordinators ties the program together resulting in timely responses, clean execution, effective notifications (i.e. patient and/or client), and thorough remediation plans bringing the organization quickly back into compliance. The entire process succeeds when the incident activities conclude with a post mortem session tying the lessons learned back to process improvements to be monitored through metrics collected in the reporting tool.







How HPH-CPGs are Prescribing Minimum Requirements

In January 2024 the Department of Health and Human Services released the Healthcare and Public Health (HPH) Cybersecurity Performance Goals (CPGs) a new landmark initiative spearheaded by the Department of Health and Human Services (HHS). These voluntary, sector-specific goals are not merely checklists; they represent a paradigm shift, empowering healthcare organizations to proactively bolster their defenses against a sophisticated and dynamic adversary. As a member of the HHS Health Sector Cybersecurity Council Coordinating Working Group and an Ambassador for the HHS 405(d) Task Group, I have witnessed the maturation and refinement of these best practices first hand.

The HPH-CPGs have been meticulously crafted by healthcare industry experts to address the unique vulnerabilities of the healthcare ecosystem. They move beyond reactive patching, instead forging a path towards proactive resilience. These goals are informed in part by common industry cybersecurity frameworks, directives, guidelines, best practices, and strategies found within the following documents:

- White House National Cybersecurity Strategy (NCS)
- HHS 405(d) Healthcare Industry Cybersecurity Practices

- HHS Hospital Resiliency Landscape Analysis
- CISA Critical Infrastructure Cybersecurity Performance Goals
- NIST Cybersecurity Framework

The Biden White House NCS outlines 5 pillars describing how the Federal Government will achieve unity of effort in collaboration and maximize gains in defensibility and systemic resilience. Objective 1.1: Strategic Establish Cybersecurity Requirements to Support National Security and Public Safety notes how voluntary approaches to critical infrastructure cybersecurity have produced meaningful improvements, but the lack of mandatory requirements has resulted in inadequate and inconsistent outcomes. Regulations will be created by each of the 16 critical infrastructure's Sector Risk Management Agencies (SRMA) defining minimum expected cybersecurity practices, although the Administration encourages entities to exceed these requirements. HHS is the SRMA for the Healthcare and Public Health critical infrastructure sector.

The White House's NCS Strategic Objective 3.3: Shift Liability for Insecure Software Products & Services, requires a shift in responsibility to the organizations best equipped to handle risks, strategically align incentives to protect against urgent threats, and align to the long-term vision for the future. This shift is represented in the FDA's new authorities to establish Medical Device cybersecurity requirements for manufacturers. The HPH CPGs continue the emphasis on securing vulnerable medical devices by assigning broader aspects of cybersecurity to the most appropriate stakeholders. HHS has chosen the 405(d) Health Industry Cybersecurity Practices (HICP) as the consensus for best practice and guidance within the sector. HICP is well established

and its recommended practices have been

referenced as Healthcare and Public Health Sector "Recognized Security Practices" within the HITECH amendment PL 116-321. This incentive offers breached healthcare organizations potential financial and audit relief if they have been leveraging these practices.

Knowing that activity alone will not guarantee achievement, HHS sought to prioritize the best practices via additional authorities and resources to determine the most efficient and effective practices. The Hospital Resiliency Landscape Analysis developed a clear understanding of current cybersecurity capabilities and preparedness across participating hospitals, prioritized, and benchmarked

them against the HICP guidance. The results created a short list of impactful risk reducing and financially feasible practices.

In January 2024, HHS moved forward in compliance with the White House Executive Order for mandatory minimum cybersecurity requirements. Cross-walking the new Prioritized Recognized Security Practices to both CISA CPGs and the NIST CSF, HHS has now released informed and substantive recommendations. Other concurrent steps being conducted by HHS include opening the HIPAA Security Rule to include Cybersecurity, incentives, increased enforcement and improved resource collaboration.

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Part 6: Epilogue -6 Concluding Remarks & **Recommendations**

Altogether, though there are rising geopolitical tensions stirring state-backed hackers, technological innovations such as Al facilitating more sophisticated cyber attacks, irremediable legacy systems and old medical device vulnerabilities too expensive to replace and a steadily expanding cyber surface area, among other ailments, we do not think the current state of cybersecurity in US Healthcare is entirely dire.

The US Healthcare cybersecurity community, both public and private, have shown themselves to have a good awareness of the current opportunities and threats, understanding why cybersecurity needs to be taken more seriously, as well as having the requisite passion to overcome these challenges.

Based on the conversations with our Steering Committee, here are our top recommendations on the areas you should be focusing on in 2024:

Maintain Cyber Awareness Training (Upskilling & Reskilling)

Upskilling and reskilling are pivotal tools in teaching staff how to recognize bulk attacks, such as phishing. Moving forward, this helps organizations keep pace with improvements to social engineering attacks facilitated by Gen Al. This approach offers several key advantages to consider.

Firstly, cyber awareness training helps rebalance in-house and outsourced or managed services, fostering а cybersecure culture deeply embedded within an organization's day-to-day activities. Secondly, it addresses a key weakness within US healthcare labor, where cyber-safe practices have yet to permeate broader conceptions of 'common sense' and 'professionalism', as a result, many to most employees still lack basic knowledge of cybersecurity or data protection.



Stay Informed on Compliance

Amidst the current regulatory noise it is crucial to stay informed. Make sure your employees are knowledgeable of HIPPA, HITECH and data breach notification laws. Ongoing education, training and conducting reviews of security protocols are important here for staying confident within your knowledge of current compliance needs, not only as this is a requirement of HITECH, but it also has the added benefit of helping to identify and eliminate risk prior to breach.

Industry associations and conferences are an under-utilized tool, providing easy to understand guidance in understanding upcoming legislation and regulatory shifts.

Adopt Automation & Machine Learning Tools

The adoption of AI automation and machine learning tools is an up and coming tool, useful within an increasing majority of cases, either through a third-party vendor or by building in-house capabilities.

It is a labor and cost saving resource that consistently improves the reliability, agility and efficiency of cyber defenses in a manner humans cannot match.

We predict that the crux of successful implementation will be to ensure synergy with human-led processes rather than keeping the two separate.



Ensure Routine Penetration Testing (w. Binary Analysis Tools)

Routine pentesting, whether it is a cadence or exposure assessment, is an essential method of incorporating more realism within your information security defense. If not already enacted, it offers both the vital outside-in perspective of a cybercriminal, and the learning experience of simulating a sophisticated attack or breach without the associated risks. Just as you would shoot a bullet-proof vest to test it works, so should you test your cyber defenses.

An additional point of synergy with penetration testing is the use of binary analysis tools. By incorporating binary analysis tools into your overly security strategy, you are able to create a Software Bill of Materials (SBOM) and leverage these results for your penetration testing.

Emb Assu

Embrace Zero Trust & Assume Breach Principles

If you're not already considering a transition to Zero Trust and Assume Breach principles, you should do so now. Carefully consider the more practical and affordable steps that can be taken while maintaining operationality, prior to a full transition to Zero Trust. Following the breaches at HCA and Change Healthcare, it is evident that no organization is untouchable, and breaches are now more inevitabilities than potentialities. Zero Trust and Assume Breach principles pave the way for mitigating the impact of such breaches when they do occur, so it is best to get ahead of the curve now rather than playing catch up later.



Monitor Mobile & Connected Devices

Mobile phones, apps, Internet of Things (IoT) and Internet of Medical Things (IoMT) have become standard practice devices for doctors and administrative personnel. The key vulnerability here is that attackers can steal information. passwords, smartphones physically, hack connected devices, eavesdrop, and then reconfigure them. To stay ahead of the competition, it is important to protect remote monitoring services, mobile data, IoT and IoMT systems and devices.

Consider creating a separate network for IoMT devices, monitoring them for sudden changes in activity levels, and disabling nonessential processes. Lastly, you should be using multi-factor authentication, application data encryption and remote locking of lost or stolen phones. Though these are your notable options, remember that cryptographic techniques must be selected based on reasonable necessity appropriateness to and prevent unauthorized access to data.



Consider a Security by Design Methodology

With the FDA's latest guidance emphasizing a 'security by design' approach within medical devices, we recommend mandating vendors to follow and adhere to it.

By incorporating security practices throughout the entire development lifecycle, from design to deployment, vendors can build more resilient and medical devices secure and applications. This has the added benefit of incentivising design that facilitates subsequent patching of medical device vulnerabilities, something that has been made difficult on legacy systems notoriously sold in 'as-is' configurations.

However, the crux of enacting these recommendations effectively and on-budget, is in taking an informed approach that covers the more nuanced elements that are only attained through discussion and informed debate. Your community needs you just as much as you need the community.





Join us in **Boston on the 12th - 13th June 2024** for our 2nd annual **HealthSec USA Summit** to hear from the US's leading cybersecurity experts discussing strategies to strengthen your security postures and maintain resilience in 2024 and beyond.

Engage in meaningful conversation on:

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Further Reading

- HHS Cybersecurity Guidance Material https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/ind ex.html
- H-ISAC State of Cybersecurity for Medical Devices & Healthcare Systems https://h-isac.org/2023-state-of-cybersecurity-for-medical-devices-and-healthcare -systems/
- Proofpoint 2023 Ponemon Healthcare CyberSecurity Report https://www.proofpoint.com/us/resources/threat-reports/ponemon-healthcare-cy bersecurity-report
- TrendMicro Healthcare CyberSecurity Best Practices https://www.trendmicro.com/en_za/research/23/e/health-cybersecurity-best-pract ices-2023.html
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- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cyb
 ersecurity-medical-devices-quality-system-considerations-and-content-premarketsubmissions



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Rick Gilmore, Managing Director - Health Sciences, Cognizant

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- Mohammad Waqas, CTO Healthcare, Armis

 Greg Garcia, Executive Director, Health Sector Coordinating Council Cybersecurity Working Group

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And the HealthSec 2024 Steering Committee_

Salwa Rafee, Global Managing Director of Healthcare Cybersecurity, Accenture

- Rick Doten, VP and Healthplan CISO, Centene Corporation
- Rick Gilmore, Managing Director Health Sciences, Cognizant
- Aaron Weismann, CISO, Mainline Health
- Mohammad Waqas, CTO Healthcare, Armis
- Ty Greenhalgh, Industry Principal Healthcare, Medigate by Claroty
- Phil Englert, VP of Medical Device Security, H-ISAC
- Greg Garcia, Executive Director, Health Sector Coordinating Council Cybersecurity Working Group
- Ratana Kong De Luca, vCISO & Cyber Resilience Strategic Advisor, First Health Advisory
- Anahi Santiago, CISO, ChristianaCare
- Patty Ryan, CISO, QuidelOrtho
- Angela Johnson, CISO, Children's Hospital of Wisconsin

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