OFFICE OF SEN. MARK R. WARNER

Cybersecurity is Patient Safety

POLICY OPTIONS IN THE HEALTH CARE SECTOR

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INTRODUCTION

An Increasingly Dangerous Threat

Over the past decade, the American public has witnessed increasingly brazen and disruptive attacks on its health care sector that jeopardize sensitive personal information, delay treatment, and ultimately lead to increased suffering and death.[1,2,3,4,5] In 2021, cybersecurity attacks on health care providers reached an all-time high, with one study indicating that more than 45 million people were affected by such attacks in 2021 – a 32 percent increase over 2020.[6]

The health care sector is vulnerable to cyberattacks for a number of reasons, including its reliance on legacy technology, a wide and highly varied attack surface (that only grows more complex from the ever-increasing number of connected devices), a high-pressure environment where even the slightest delay can have life-or-death consequences, funding constraints, and an outdated mode of thinking that views cybersecurity as a secondary or tertiary concern.

These challenges are compounded when coupled with the incredibly alluring target that the health care sector presents to cybercriminals. Personal health information is more valuable on the black market than even credit card information, as hackers can sell stolen medical records for anywhere from $10 to $1,000 per record.[7] These attacks are also costly, with the health care industry seeing the highest cost per breach of any industry, according to IBM's annual Cost of a Data Breach report.[8]

45
MILLION

people were affected by attacks on the health care sector in 2021.

Although these cybersecurity vulnerabilities certainly leave health care organizations exposed to patient data theft, they often have far-reaching, and more serious, impacts beyond privacy concerns. Cyberattacks can be detrimental to patient safety, as they can lock physicians out of treatment tools, shut down hospital equipment used for care, and create backlogs that delay appointments and treatment. When it comes to cyberattacks affecting patient care, the question is no longer a matter of if or when, but how often and how catastrophic the consequences.

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1 Joseph Marks, "Ransomware attack might have caused another death." *The Washington Post*. October 1, 2021. https://www.washingtonpost.com/politics/2021/10/01/ransomware-attack-might-have-caused-another-death/

2 Joseph Marks, "The Cybersecurity 202: This was the month cyberattacks turned fatal." *The Washington Post*. September 23, 2020. https://www.washingtonpost.com/politics/2020/09/23/cybersecurity-202-this-was-month-cyberattacks-turned-fatal/

3 Independently conducted by Ponemon Institute LLC, "The Impact of Ransomware on Healthcare During COVID-19 and Beyond." *Ponemon Institute*. September 2021. https://www.censinet.com/ponemon-report-covid-impact-ransomware/

4 Jill McKeon, "Cyberattacks Increase Mortality Rates, But Healthcare Is In Denial." *Health IT Security*. January 12, 2022. https://healthitsecurity.com/news/cyberattacks-increase-mortality-rates-but-healthcare-is-in-denial

5 CISA COVID Task Force, "Measuring the COVID-19 Pandemic's Effect on the National Critical Function Provide Medical Care." *CISA Insights*. July 1, 2021. https://www.cisa.gov/sites/default/files/publications/Insights_MedicalCare_FINAL-v2_0.pdf

6 Jake Milstein, "Critical Insight Finds 35 Percent Increase in Attacks on Health Plans in 2021 End of Year Healthcare Data Breach Report." *Critical Insight*. January 31, 2022. https://www.criticalinsight.com/resources/news/article/critical-insight-finds-35-percent-increase-in-attacks-on-health-plans-in-2021-end-of-year-healthcare-data-breach-report

7 Darrell West and Emily Skahill, "Why hospitals and healthcare organizations need to take cybersecurity more seriously." *Brookings*. August 9, 2021. https://www.brookings.edu/blog/techtank/2021/08/09/why-hospitals-and-healthcare-organizations-need-to-take-cybersecurity-more-seriously/

8 IBM Security, "Cost of a Data Breach Report 2022." *IBM*. July 2022. https://www.ibm.com/downloads/cas/XZNDGZKA

Senator Warner's Work on Cybersecurity

Senator Mark R. Warner (D-VA) has a history of crafting legislation that addresses the cybersecurity challenges facing our nation. Recognizing that cybersecurity is an increasingly complex issue that affects the health, economic prosperity, national security, and democratic institutions of the United States, Senator Warner cofounded the bipartisan Senate Cybersecurity Caucus with Senator Cory Gardner (R-CO) in 2016. A year later, in 2017, he authored the Internet of Things (IoT) Cybersecurity Improvement Act with Senator Gardner. This legislation, signed into law by President Donald Trump in December 2020, requires that any IoT device purchased with federal funds meet minimum security standards. As Chairman of the Senate Select Committee on Intelligence, Senator Warner co-authored legislation that requires companies responsible for U.S. critical infrastructure report cybersecurity incidents to the government. This legislation was signed into law by President Joe Biden as part of the Consolidated Appropriations Act, 2022 in March 2022.

This is not the first time that Senator Warner has examined cybersecurity in the health care sector specifically. In 2019, Senator Warner sent a letter to several health care providers and industry trade associations – from large hospital networks to trade associations representing rural providers and medical technology vendors – asking a series of questions related to the steps their organizations and/or members had taken to improve their cybersecurity posture. Senator Warner received a number of thoughtful responses to those questions that revealed a wide-range of cybersecurity capabilities and depth of understanding of the problems health care providers are facing.

The Path Forward – Cybersecurity is Patient Safety

In recent months, Senator Warner and his staff (in this paper referred to as "staff") have engaged with numerous security researchers, business leaders, advocacy groups, and trade associations to gather input on the cybersecurity challenges facing the health care sector and potential solutions to these issues with the ultimate goal of protecting patient safety.

Following these conversations, it has become readily apparent that the way that cybersecurity is treated by those in health care sector needs to change. Cybersecurity can no longer be viewed as a secondary concern; it must become incorporated into every organization's – from equipment manufacturers to health care providers – core business models. This paper will consider various challenges and proposals aimed at changing the way that the health care sector addresses the cybersecurity challenges it faces.

Changing the health care sector's posture toward cybersecurity will require significant effort and resources from both the public and private sector. The first chapter of this paper covers challenges that the federal government needs to address to improve our national risk posture when it comes to cybersecurity in the health care sector. The second chapter looks at ways that the federal government can help the private sector meet this threat as well as potential requirements that could be mandated by the federal government. Finally, the third chapter considers policies that could help health care providers respond to attacks after they have occurred.

Submission Guidance

Senator Warner is releasing this policy options document with the intent of soliciting feedback from stakeholders on the potential options described within. Any individuals, researchers, businesses, organizations, or advocacy groups that are interested in submitting comments – specific to the content and questions outlined in this document or additional ideas or language for inclusion in eventual legislation – should send a letter or an email to cyber@warner.senate.gov.

All submissions should:

- Be in the form of a PDF attachment. The attachment should be saved using the name of the organization and/or individual submitting the comment.

- Be as specific and detailed in their recommendations as possible.

- Include the contact name, organization, phone number, and email address in the body of the email. Please be advised that Senator Warner's office requests individuals refrain from including any personally identifiable information, such as private home addresses or social security numbers, in their submission.

- Be submitted prior to December 1, 2022.

Acknowledgements

Staff would like to thank the numerous individuals and groups that offered their time and expertise in formulating and reviewing early versions of this policy options paper.

IMPROVING FEDERAL LEADERSHIP AND OUR NATIONAL RISK POSTURE

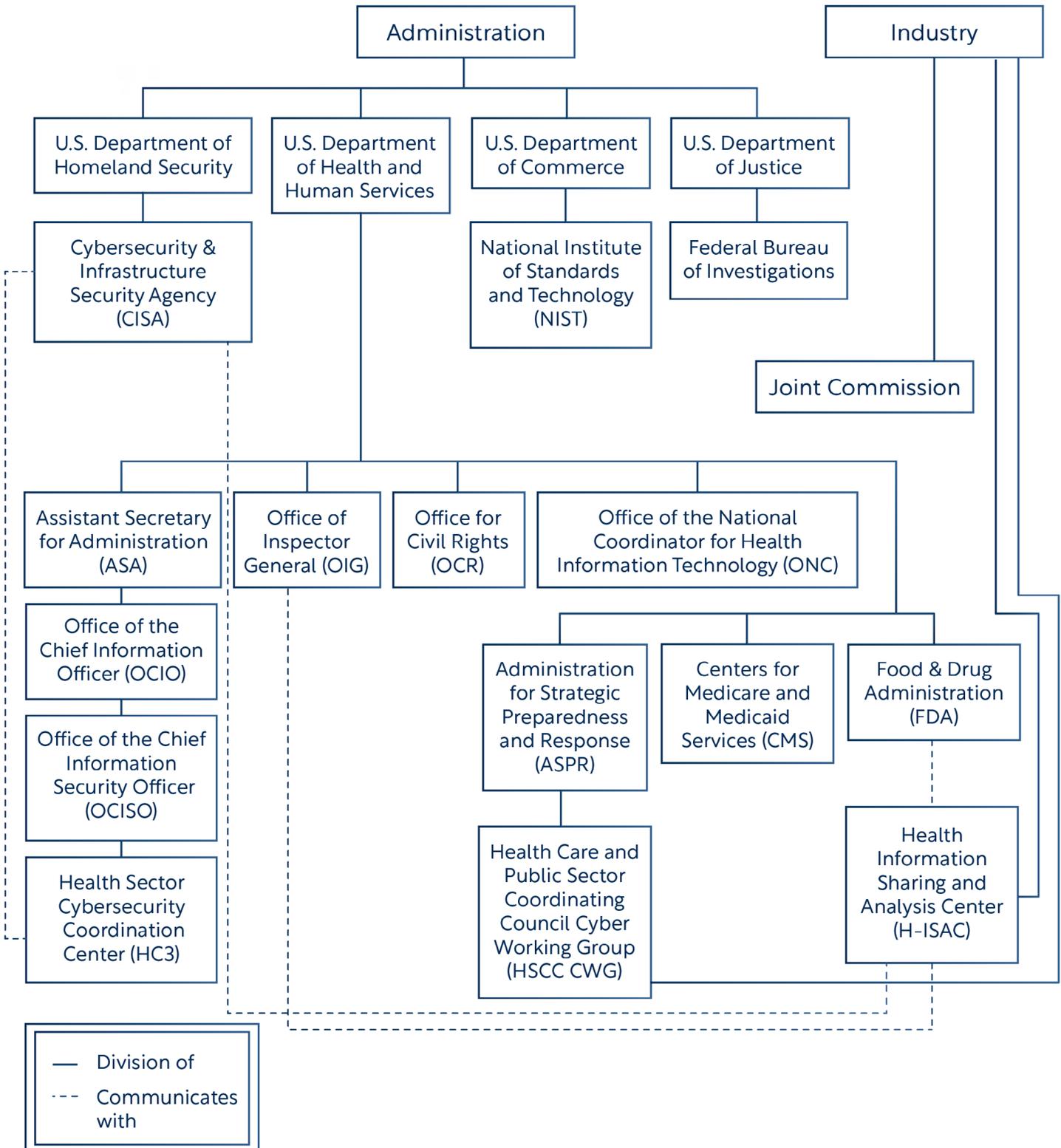**Mark R. Warner**
U.S. Senator from the Commonwealth of **Virginia**

In order to understand whether any reforms are needed to the federal government's health care cybersecurity prevention and response capabilities, one must first understand the current landscape of actors.

Fig. 1 The Health Care Cybersecurity Ecosystem

Organization descriptions follow on subsequent pages.

Fig. 2 Jurisdictions of policy options presented in this paper

	Policy Subchapter	HHS	DHS	DOJ	Education	Treasury	Commerce
CHAPTER 1	1.1 Health Care Cybersecurity Leadership within the Federal Government	X	X	X			X
	1.2 Protecting Health Care Research and Development from Cyberattacks			X			
	1.3 Health Care Specific Guidance from the National Institute of Standards and Technology						X (NIST)
	1.4 Modernizing HIPAA to Address Cyber Threats	X					
	1.5 Stark Law and Anti-Kickback Statute	X (OIG & CMS)					
	1.6 Federal Workforce Development Program that Focuses on Health Care Cybersecurity		X (CISA)	X			X (NIST)
	1.7 Student Loan Forgiveness for Service in Rural Areas	X			X		
CHAPTER 2	2.1 Establishing Minimum Cyber Hygiene Practices for Health Care Organizations	X					
	2.2 Addressing Insecure Legacy Systems	X (FDA)					
	2.3 Software Bill of Materials	X (FDA)	X (CISA)				X (NTIA)
	2.4 Streamlining Information Sharing	X (OCR)	X (CISA)	X (FBI)			
	2.5 Financial Implications for Increased Cybersecurity Requirements	X (CMS)					
CHAPTER 3	3.1 Cyber Emergency Preparedness	X (CMS)					
	3.2 Strategic National Stockpile of Common Equipment	X (ASPR)					
	3.3 Disaster Relief Program		X (FEMA)				
	3.4 Safe Harbor/Immunity if Health Care Organization has Implemented Adequate Security Measures	X		X			
	3.5 Cyber Insurance		X (CISA)			X	

Institutional actors span both the public and private sectors:

- **Administration for Strategic Preparedness and Response (ASPR)** is the Sector Risk Management Agency (SRMA) lead at the U.S. Department of Health and Human Services (HHS) responsible for securing the Healthcare and Public Health Sector (HPH) cyber infrastructure.

- **Assistant Secretary for Administration (ASA)** provides leadership for U.S. Health and Human Services (HHS) departmental administration, including human resource policy, information technology, and departmental operations. The ASA also serves as the operating division head for the HHS Office of the Secretary.

- **ASA Office of the Chief Information Officer (OCIO)** supports the HHS mission by leading the development and implementation of information technology infrastructure across the agency.

- **ASA OCIO Chief Information Security Officer (CISO)** leads the HHS Cybersecurity Program, leading HHS's enterprise-wide information security and privacy program to help protect HHS against potential information technology threats and vulnerabilities.

- **Centers for Medicare and Medicaid Services (CMS)** is an operating division within the Department of Health and Human Services (HHS). CMS administers the two largest federal health care programs - Medicare and Medicaid - as well as the Children's Health Insurance Program (CHIP) and the federal marketplaces.

- **Cybersecurity and Infrastructure Security Agency (CISA)** is a federal agency under the Department of Homeland Security (DHS). It leads the national effort to understand, manage, and reduce risk to our cyber and physical infrastructure.

- **Federal Bureau of Investigation (FBI)** is an agency under the U.S. Department of Justice (DOJ) and works to protect the American people by protecting civil rights, combatting transnational criminal enterprises, combatting significant white-collar crime, and combatting significant violent crime. It is the lead federal agency for investigating cyber attacks and intrusions. They collect and share intelligence and engage with victims while working to unmask those committing malicious cyber activities wherever they are.

- **Food and Drug Administration (FDA)** is an agency under the Department of Health and Human Services (HHS). The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed, and veterinary products.

- **Health Information Sharing and Analysis Center (H-ISAC)** is a global, non-profit, member-driven organization offering health care stakeholders a trusted community and forum for coordinating, collaborating, and sharing vital physical and cyber threat intelligence and best practices with each other. H-ISAC disseminates to community members timely, actionable and relevant information with each other including intelligence on threats, incidents, and vulnerabilities that can include data such as indicators of compromise, tactics, techniques, and procedures (TTPs) of threat actors, advice and best practices, mitigation strategies, and other valuable material. Sharing can occur via machine to machine or human to human.

- **Health Sector Cybersecurity Coordination Center (HC3)** is a branch of the Department of HHS's Office of Information Security's Cybersecurity Operations Division within the Office of the Chief Information Officer (OCIO). The OCIO reports to the Assistant Secretary of Administration. HC3 collects and analyzes threat indicators and known system vulnerabilities affecting the HPH sector and facilitates technical cybersecurity information sharing between organizations in the HPH sector.

- **Healthcare and Public Health Sector Coordinating Council (HSCC)** is the HHS industry partner for coordinating strategic, policy, and operations approaches to prepare for, respond to, and recover from significant cyber and physical threats to the health sector. HSCC represents the primary health care subsectors of direct patient care; public health; health plans and payers; pharma, blood and labs; medical technology; health information technology; and funeral homes and mass fatality managers.

- **HSCC Cybersecurity Working Group (CWG)** collaborates with HHS and other federal agencies to identify and mitigate systemic risks that affect patient safety, security, and privacy and, consequently, national confidence in the health care system.

- **Joint Commission** is a United States-based nonprofit organization that accredits more than 22,000 US health care organizations and programs.

- **National Institute of Standards and Technology (NIST)** is an agency in the U.S. Department of Commerce that promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST develops cybersecurity standards, guidelines, best practices, and other resources to meet the needs of U.S. industry, federal agencies and the broader public.

- **National Telecommunications and Information Administration (NTIA)** is an agency in the U.S. Department of Commerce that advises the President on telecommunications and information policy issues. NTIA's cybersecurity multistakeholder processes, conducted in an open and transparent manner, contribute to the security of the nation's Internet architecture. The consensus-based development of market-based cybersecurity solutions and guidance creates a foundation for increasing digital security.

- **Office for Civil Rights (OCR)** is HHS's primary enforcement and regulatory agency for civil rights and health information privacy and security, including enforcement of the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules and the Patient Safety Rule.

- **Office of Inspector General (OIG)** in HHS provides objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs. It is the largest inspector general's office in the federal government and the majority of the agency's resources go towards oversight of Medicare and Medicaid, including enforcement of the Anti-Kickback Statute and the Physician Self-Referral Law.

- **Office of the National Coordinator for Health Information Technology (ONC)** is a division of HHS and is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

As noted in the preceding descriptions, the health and public health actors each play different, but specific roles in ensuring our nation's health care system's national risk posture. In any effort to bolster our national risk posture, all actors must be aligned in that the mission of every health and public health actor must prioritize patient safety.

1.1 HEALTH CARE CYBERSECURITY LEADERSHIP WITHIN THE FEDERAL GOVERNMENT

Background

There are 16 critical infrastructure sectors whose assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof.

The Presidential Policy Directive 21 (PPD-21): Critical Infrastructure Security and Resilience spells out the policy for how the federal government builds trusted partnerships and "advances a national unity of effort to strengthen and maintain secure, functioning, and resilient critical infrastructure." The directive also designated a sector-specific agency, now called the Sector Risk Management Agency (SRMA), for each of the identified critical sectors.

SRMAs are to:

• Coordinate with DHS and other relevant federal departments and agencies and collaborate with critical infrastructure owners and operators, where appropriate with independent regulatory agencies, and with State, local, tribal, and territorial (SLTT) governments, as appropriate, to implement PPD-21;

• Serve as a day-to-day federal interface for the dynamic prioritization and coordination of sector-specific activities;

• Carry out incident management responsibilities consistent with statutory authority and other appropriate policies, directives, or regulations;

• Provide, support, or facilitate technical assistance and consultations for that sector to identify vulnerabilities and help mitigate incidents, as appropriate; and

• Support the Secretary of Homeland Security's statutory reporting requirements by providing, on an annual basis, sector-specific critical infrastructure information.

The U.S. Department of Health and Human Services is the SRMA for the Healthcare and Public Health Sector. Of the 16 critical infrastructure sectors, the Department of Homeland Security is designated as the SRMA for eight sectors and the co-lead for two other sectors. HHS is a large department composed of agencies like the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and others. Each sets its own policy regarding cybersecurity in its jurisdiction, such as what is required of Medicare providers in the former and what is required for medical device manufacturers in the latter.

The HHS 405(d) Program, which started as a Congressional mandate under the Cybersecurity Act of 2015, brings together the health care industry and the federal government to raise awareness and develop best practices for providers that can be implemented by health care providers.

Staff has heard from industry experts about a lack of coordination between HHS (as the SRMA) and CISA, the U.S. government's lead on ensuring cybersecurity integrity in commercial and infrastructure networks. Stakeholders have shared no matter who is in charge, so to speak, they would welcome increased timely, actionable, health care-specific cybersecurity guidance. Some stakeholders have also shared that when it comes to policies improving cybersecurity in health care, the agencies within HHS often have different postures and levels of activity, leading to varied levels of experience regarding cybersecurity as well as varied prioritization.

Policy under Consideration

Given the large number of actors and lack of clearly defined roles, particularly across operational divisions within the Department of Health and Human Services, there is a need for a senior leader at HHS who reports directly to the Secretary of Health and Human Services to lead the Department's work on and be accountable for cybersecurity. The person in this role should be empowered—both operationally and politically—to ensure HHS speaks with one voice regarding cybersecurity in health care, including expectations of external stake-holders and the government's role. This person should also work to effectively partner with other agencies to further these goals and advocate for HHS having the resources it needs to be successful.

Questions regarding Policy

1. Is the U.S. Department of Health and Human Services succeeding in its role as the Sector Risk Management Agency for health care and is HHS the most appropriate SRMA?

2. What is the current status of coordination between HHS and CISA? How could that coordination be improved?

3. Should the 405(d) Program continue to be the "hub" of HHS and federal government partnership with industry?

    3a. What other agencies should be part of such an effort, and how should they coordinate?

    3b. Does the 405(d) Program need additional resources to ensure it can continue to develop and disseminate its work? How do we effectively measure the efficacy of 405(d) in order to evaluate what is the appropriate level of additional resources?

1.2 PROTECTING HEALTH CARE RESEARCH AND DEVELOPMENT FROM CYBERATTACKS

Background

The health care sector is consistently one of the biggest investors in research and development (R&D) across the United States, with domestic medical and health R&D investment reaching $245.1 billion in 2020.[9] Additionally, the COVID-19 pandemic brought a surge of investment in vaccine research, leading to significant spending on innovation in the health care industry in recent years.[10]

This massive investment in R&D, while contributing to the development of life-saving therapies and products, also creates a large target for intellectual property (IP) and trade secret theft. This threat is particularly prominent from countries that are looking to expand their own health R&D portfolio. China, for example, included in its Five Year Plan for Economic and Social Development a desire to build its biotech industry and high-performance medical equipment capabilities. While it can be difficult to quantify the scope of IP theft, China has long engaged in efforts to steal U.S. intellectual property across industries, with a number of cases involving China using cybersecurity methods to steal American IP taking place in just the last few years.[11]

Policy under Consideration

To begin addressing this longstanding issue, one proposal under consideration would direct the Department of Justice (DOJ), through the existing DOJ Task Force on Intellectual Property, to develop guidance for industry and academia on evaluating the potential economic impact, reputational damage, loss of intellectual property, and other cybersecurity risks for health care R&D, as well as recommendations on how to best combat these threats.

Questions regarding Policy

1. What guidance is currently available to industry and academia to help them protect against IP theft generally? Is there any guidance that is tailored specifically to health care R&D?

2. What challenges specific to small or rural research institutions and organizations should be considered in the development of the guidance?

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9 "U.S. Investments in Medical and Health Research and Development." *Research America*. January 2020. https://www.researchamerica.org/sites/default/files/Publications/Research%21America-Investment%20Report.Final.January%202022.pdf
10 "A Significant Rise in Health Care R&D Provides Investors Opportunity in this Sector." *Nasdaq*. July 23, 2020. https://www.nasdaq.com/articles/a-significant-rise-in-health-care-rd-provides-investors-opportunity-in-this-sector
11 Nicole Sganga, "Chinese Hackers Took Trillions in Intellectual Property from About 30 Multinational Companies." *CBS News*. May 4, 2022. https://www.cbsnews.com/news/chinese-hackers-took-trillions-in-intellectual-property-from-about-30-multinational-companies/

1.3 HEALTH CARE SPECIFIC GUIDANCE FROM THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

Background

On February 12, 2013, President Barack Obama signed Executive Order 13636, Improving Critical Infrastructure Cybersecurity, which required the National Institute of Standards and Technology (NIST) to develop a voluntary framework for reducing cybersecurity risks to critical infrastructure. Exactly one year later, NIST released their Framework for Improving Critical Infrastructure Cybersecurity ("Cybersecurity Framework"). Over the years, NIST's work on the Cybersecurity Framework has received positive reviews and been held up as a model of public-private collaboration. Some health delivery organizations believe that they "comply with the NIST Framework," including organizations whose responses to separate lines of inquiry (such as their identification of IT inventory under their control) revealed a clear lack of compliance with the framework.

In February 2022, NIST began the process of updating the Cybersecurity Framework, issuing a request for information. That request asks respondents to provide NIST with information on:

- Potential metrics that could be used to measure improvements to cybersecurity resulting from implementation of the Cybersecurity Framework

- Challenges that may prevent organizations from using the Cybersecurity Framework

- Steps NIST should consider to increase international uptake of the Cybersecurity Framework

Policy under Consideration

Many relevant parties lauded NIST's work on the Cybersecurity Framework, but some have suggested that more detailed guidance for the health care industry is required. For example, the Health Care Industry Cybersecurity Task Force report (see appendix) suggests developing a "consensus-based health care specific Cybersecurity Framework." This could take the form of a "Framework Profile," such as those developed by NIST for manufacturing and election infrastructure. Others have suggested that NIST should develop a subsection within the current framework specifically focused on health care cybersecurity. Regardless of whether this framework would be separate or nestled under the existing Cybersecurity Framework, it would be voluntary guidance specifically geared toward addressing the cybersecurity challenges unique to the sector. Finally, some have suggested that the health care industry has insufficiently implemented existing health care-specific playbooks, such as the ones from HSCC, and that additional NIST guidance is unlikely to be voluntarily adopted by health care providers.[12]

Questions regarding Policy

1. What should be included in a health care cybersecurity framework? Is sector-specific guidance from NIST for the health care sector necessary?

2. Is the current guidance from NIST sufficient? Has your organization or members of your organization implemented the recommendations in the Cybersecurity Framework? If not, why?

3. Has your organization implemented the health care-specific playbook developed by HSCC? If not, why?

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12 "Critical Infrastructure Protection: Agencies Need to Assess Adoption of Cybersecurity Guidance." Government Accountability Office, Feb. 2022. https://www.gao.gov/assets/gao-22-105103.pdfCirit

1.4 **MODERNIZING HIPAA TO ADDRESS CYBER THREATS**

Background

As health care cybersecurity vulnerabilities continue to evolve, the regulatory landscape must be able to keep up with these threats.

Through the Health Insurance Portability and Accountability Act (HIPAA), Congress required the Secretary of Health and Human Services (HHS) to ensure, through rulemaking, the privacy and security of an individual's protected health information.

The Security Standards for the Protection of Electronic Protected Health Information ("Security Rule") "establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity" or business associate.[13] Covered entities are individuals, organizations, and agencies that identify as a health care provider; a health plan; or a health care clearinghouse. A business associate is a third-party vendor who has a written business associate contract or other arrangement that establishes what the third-party vendor has been engaged to do. The Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

HIPAA requirements remain focused on a covered entity and business associate's responsibilities to protect patient confidentiality, but they have not been sufficiently updated to address emerging threats to data integrity and availability (e.g. ransomware).

There are also many areas and actors that HIPAA does not cover currently. Non-covered entities that are not subject to HIPAA can include software applications and consumer devices that collect and share similar health information. Currently, non-covered entities are not obligated to adhere to HIPAA Privacy and Security Rules while having access to patient health information, and there are growing indications that consumers are not aware of this gap.[14]

Policy under Consideration

One proposal under consideration is mandating a regular process to modernize HIPAA regulations to address a broader scope of cybersecurity threats instead of just focusing on covered entities' responsibility to protect a patient's personal health information. Congress could direct HHS to update HIPAA to expand what entities are covered and what actions are permitted.

Questions regarding Policy

1. Is it appropriate to address both privacy and security within a single enforcement regime or are the risks, solutions, and institutional competencies sufficiently distinct to warrant separate regulatory regimes?

2. Where are the gaps in HIPAA currently, and how should it be expanded?

3. How should HIPAA regulations align with those of the Federal Trade Commission, such as the Health Breach Notification Rule?

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13 "The HIPAA Security Rule." *U.S. Department of Health & Human Services*, 2022. https://www.hhs.gov/hipaa/for-professionals/security/index.html

14 Thomas Germain, "Guess What? HIPAA Isn't a Medical Privacy Law." *Consumer Reports.* June 13, 2022. https://www.consumerreports.org/health-privacy/guess-what-hipaa-isnt-a-medical-privacy-law-a2469399940/

1.5 **STARK LAW AND ANTI-KICKBACK STATUTE**

Background

There are a number of laws that work to protect federal health care programs, such as Medicare, from waste, fraud, and abuse. Two of those are the Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) and the Physician Self-Referral Law, commonly referred to as the Stark Law (42 U.S.C. §1395nn).

Under the Anti-Kickback Statute, any person who knowingly and willfully offers or receives remuneration, or something of value, in return for a patient referral or other increased business in a federal health care program is subject to criminal penalties. Under the Stark Law, if a health care provider has a financial relationship with an entity, the provider cannot refer to that entity under Medicare or Medicaid, and the entity cannot bill for services pursuant to such a referral.

Under the Anti-Kickback Statute, the HHS Office of Inspector General can issue "safe harbors" to the statute in regulation in order to allow health care providers to enter into legitimate business arrangements. In addition, providers are able to seek an official HHS OIG opinion about their situation's compliance with the statute, although one is not required to be considered in compliance if it otherwise is in accordance with the statute. Under the Stark Law, the HHS Centers for Medicare and Medicaid Services can establish exceptions in regulation "that do not pose a risk of patient or program abuse."

In October 2019, HHS OIG and CMS proposed a number of safe harbors and exceptions to improve coordination in health care and provide clarity in the application of these statutes. The regulations were finalized in November 2020 and included a new safe harbor/exception for donations of cybersecurity and technology and related services that are "necessary to implement, maintain, or reestablish security." These regulations aim to make it easier for health care providers who have financial relationships to donate cybersecurity software and other related technology that will result in shared protection.

Policy under Consideration

The Stark Law and Anti-Kickback Statute are important laws that work to prevent waste, fraud, and abuse in the Medicare program. However, these laws should be clear and should not prevent stakeholders in legitimate partnerships from working together on cybersecurity improvements that would protect the health care system collectively and not introduce financial risk in the Medicare program.

Questions regarding Policy

1. What types of providers have taken advantage of the new 2020 safe harbor/exception?

2. Are there providers for whom even the safe harbor/exception introduces too much legal risk for the provider, leading to not taking advantage of cooperation that other providers with a higher risk tolerance are comfortable with? Or are the regulations clear enough even for the most risk-averse providers? Can Congress amend the statute to make it more clear and effective regarding cybersecurity partnerships?

3. Are there downsides to allowing health care providers to accept donations of cybersecurity and IT products, such as encouraging health care organizations to externalize responsibility and cost for IT security?

1.6 WORKFORCE DEVELOPMENT PROGRAM THAT FOCUSES ON HEALTH CARE CYBERSECURITY

Background

There is a longstanding shortage in the cybersecurity workforce across industries, with NIST estimating the global shortage of cybersecurity professionals to be 2.72 million in 2021.[15,16,17] When cybersecurity teams are stretched too thin – or worse, when lacking a cyber team altogether – an organization is left especially vulnerable to cyber threats.

Policy under Consideration

To address the shortage of cybersecurity professionals in the health care sector, Congress could consider establishing a workforce development program that focuses on health care cybersecurity. This program could be tailored to prepare cybersecurity professionals to confront cyber threats that are specific to the health care environment and would leverage community colleges and professional certification programs to develop a skilled workforce. Additional training could also be offered by Regional Extension Centers (RECs).

2.72
MILLION

NIST estimate of the global shortage of cybersecurity professionals in 2021.

Questions regarding Policy

1. Who should administer this program? Who should develop its curriculum?

2. Are there other workforce development programs with a similar mission that could be used as a model?

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15 "Cybersecurity Workforce Demand - NIST." *NIST*, July 2022. https://www.nist.gov/system/files/documents/2022/07/06/NICE%20FactSheet_Workforce%20Demand_Final_20211202.pdf

16 "2020 HIMSS Cybersecurity Survey." *Healthcare Information and Management Systems Society*, 2020. https://www.himss.org/sites/hde/files/media/file/2020/11/16/2020_himss_cybersecurity_survey_final.pdf

17 "Navisite Research Finds 45% of Companies Do Not Employ a Chief Information Security Officer." *Navisite*, November 17, 2021. https://www.navisite.com/press-releases/navisite-research-finds-45-of-companies-do-not-employ-a-chief-information-security-officer/

1.7 **STUDENT LOAN FORGIVENESS FOR SERVICE IN RURAL AREAS**

Background

Organizations across all sectors of the economy face a persistent challenge in hiring and retaining cybersecurity professionals. According to a 2016 survey by the Center for Strategic & International Studies (CSIS), 82 percent of employers reported a shortage of cybersecurity skills and 71 percent believed this caused "direct and measureable damage" to their organizations.[18] Research by the National Initiative for Cybersecurity Education (NICE) found that the United States faced a shortfall of 314,000 cybersecurity professionals as of 2019.[19]

The health care sector is not immune to this challenge, and staffing cybersecurity-focused positions in rural areas is an especially acute problem. Staff has heard from rural providers that have significant difficulty attracting and retaining cybersecurity talent.

314,000

United States shortfall of cybersecurity professionals as of 2019.

Policy under Consideration

One proposal that has been raised is the use of loan forgiveness as an incentive to get cybersecurity professionals to spend several years serving in a rural community, akin to the National Health Service Corps (NHSC) Loan Repayment Program (LRP).

Questions regarding Policy

1. Should a loan repayment program focused on cybersecurity in the health care sector focus on the size of a provider or the community that it operates in?

2. Is it more efficacious to increase the cybersecurity staff present at health care providers in rural areas or make it easier for these providers to contract with third-party service providers for their cybersecurity needs?

3. Given the demand for cybersecurity talent across industries, would a loan forgiveness program make an impact?

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18 *CSIS*, "Hacking the Skills Shortage." (Santa Clara, CA: McAfee, July 2016), https://www.mcafee.com/enterprise/en-us/assets/reports/ rp-hacking-skills-shortage.pdf.
19 *CyberSeek*, "Cybersecurity Supply/Demand Heat Map," accessed January 4, 2019, https://www.cyberseek.org/heatmap.html.

IMPROVING HEALTH CARE PROVIDERS' CYBERSECURITY CAPABILITIES THROUGH INCENTIVES & REQUIREMENTS

Mark R. Warner
U.S. Senator from the Commonwealth of **Virginia**

CHAPTER TWO INTRODUCTION

Health care presents unique challenges when it comes to security and privacy due to the added risk of patient safety that needs to be taken into consideration. The need to access information and deliver care quickly to provide patient care has to be balanced with and often conflicts with the need for ideal cybersecurity protection. For example, to respond to critical care issues quickly and to maintain a seamless workflow, health care providers may leave workstations unlocked and unattended to expedite access to patient information in order to provide comprehensive care.

Additionally, financial constraints, the use of legacy devices that were not designed to resist cyberattacks of today, a lack of understanding of the patient safety risks cyber threats pose, and limited education and awareness programs for health care professionals increase the impact that cyber threats have on the sector. Experts repeatedly shared their concern with gaps within health care organizations related to managing enterprise-wide security. For example, clinicians are often given extraordinary discretion in the adoption and installation of health IT without consultation with, or approval of, those responsible for enterprise-wide IT. Many security professionals and organizations have difficulty demonstrating the importance of cyber protections to their superiors and the value of proactive risk mitigation without experiencing a breach or data loss.

> **Many security professionals and organizations have difficulty demonstrating the importance of cyber protections to their superiors and the value of proactive risk mitigation without experiencing a breach or data loss.**

Many health care organizations face resource constraints, and some organizations have argued that they cannot afford to retain in-house information security personnel or dedicate an IT staff member primarily to cybersecurity. These organizations often lack the infrastructure to identify and track threats, the capacity to analyze and translate the threat data they receive into actionable information, and the capability to act on that information. Several experts highlighted the need for health care providers to recognize cybersecurity as a key element of patient safety and core expense that they must find room for in their budgets.

Many organizations may not know that they have experienced an attack until long after it has occurred. Additionally, both large and small health care delivery organizations struggle with numerous unsupported legacy systems that cannot easily be replaced, with large numbers of vulnerabilities and few modern countermeasures.

The following sections propose solutions to help the most vulnerable health care delivery organizations meet their cyber threats needs by introducing financial incentives and regulatory requirements for health systems to consider cybersecurity a business and patient care consideration.

2.1 ESTABLISHING MINIMUM CYBER HYGIENE PRACTICES FOR HEALTH CARE ORGANIZATIONS

Background

Outside of software vulnerabilities, one of the primary attack vectors that health care organizations face are phishing campaigns. While increasing health care staff preparedness is a necessary and worthwhile endeavor, having entire health IT systems vulnerable to a single user's momentary lapse in judgement represents a failure in system architecture and design.

Experts shared that flexible and adaptable best practices are needed as the threats health care organizations face are often evolving. However, it's clear that a small set of cybersecurity hygiene practices, when consistently applied, protect against the majority of threats faced by organizations. The U.S. Department of Health and Human Services 405(d) Program, which was established in response to the Cybersecurity Act of 2015, has identified and released current best practices in its important report, Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP).

Staff also heard concerns that current regulatory requirements lead to many health care organizations primarily focusing on data breaches and their electronic health records as likely targets of cybersecurity intrusions. However, there are many other points of vulnerabilities that, when disrupted, lead to significant patient safety risks.[20] Examples of these are providers' elevators, internet and telephone networks, and HVAC systems. Health care organizations must ensure these are similarly protected.

Policy under Consideration

Given the risks to patient safety that result from cybersecurity intrusions, all health care organizations should be familiar with and apply certain minimum cybersecurity practices as standard operating procedure. Any regulation should be proportionate to the risk it is mitigating, but cybersecurity should be seen as critical to patient health and safety as air quality and infection control.

Medicare Conditions of Participation and Conditions for Coverage are developed by CMS, and health care organizations must meet these health and safety standards to participate in the Medicare and Medicaid programs. These standards work to protect beneficiaries, and facility accreditation relies on meeting or exceeding these standards. For example, hospitals must have active programs to prevent the spread of hospital-acquired infections. Another example is that hospitals must have emergency and standby power systems. Many stakeholders believe cybersecurity is as important as those two examples, and that some minimum level of cybersecurity hygiene practices should be included in these regulations.

Questions regarding Policy

1. How should Congress go about creating minimum cyber hygiene practices? Which federal agency should be responsible for development and implementation? What should be the incentives or penalties for compliance or noncompliance?

2. Regarding including these are part of a facility's Medicare Conditions of Participation – if this is not the preferred framework, why not? What makes cybersecurity—which we've learned has patient safety risks— different from other critical patient safety protections that are currently required?

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20 CISA COVID Task Force, "Provide Medical Care is in Critical Condition: Analysis and Stakeholder Decision Support to Minimize Further Harm." *CISA INSIGHTS.* September, 2021. https://www.cisa.gov/sites/default/files/publications/Insights_MedicalCare_FINAL-v2_0.pdf

2.2 **ADDRESSING INSECURE LEGACY SYSTEMS**

Background

One significant source of vulnerability in the health care ecosystem comes from legacy medical equipment. Due to the high cost of equipment like magnetic resonance imaging (MRI) machines and the – at least traditionally – long lifespan of the equipment, health care providers tend to keep them in service as long as possible. In years past, these providers could expect their new pieces of equipment to last for upwards of 20 years. As long as the machine could function properly, it could keep being used.

As medical equipment has become more connected and technologically advanced, more software is needed to run these devices. Software, however, does not have a lifespan of 20 years. As software developers retire older versions of software and no longer patch these products, more medical devices are left vulnerable to attacks. In one instance, a prominent software vendor learned its end-of-life application was still being used in a major health care IT vendor's product as a result of requests from the vendor for custom, beyond end-of-life patches. In such a situation, the medical equipment is likely to continue to be used, operating as it has always done but leaving a yawning gap through which bad actors may enter a provider's network.

This presents health care providers with a dilemma: what do they do about the life cycle gap between the physical equipment and the software that is in it? Do they replace an expensive piece of equipment that is still functioning properly but may be insecure? Do they keep using the machine, hoping that the vulnerabilities are not exploited?

The gap between the equipment and software life cycles will likely get worse as new medical equipment relies increasingly on connected software. Some have shared concerns that more structural change is needed, or we would simply be replacing legacy equipment with new technology that will become similarly outdated in a short period of time. Any efforts to replace legacy systems must also ensure the gaps are either eliminated or minimized to avoid the predicament of investing in tomorrow's legacy systems.

Policy under Consideration

The Health Care Industry Cybersecurity Task Force report recommended that government and industry develop incentive programs to phase out legacy equipment. Some have suggested that a model based on the 2009 Car Allowance Rebate System (CARS) or "cash for clunkers," the federal program that helped take less fuel-efficient cars off the road, would be a helpful way to phase out these insecure pieces of equipment. Any incentive program should only cover equipment that meets certain minimum requirements that also include eliminating or minimizing equipment and software lifecycles gaps. An incentive-based program (such as legacy product replacement) could be used as a means to push the industry towards developing more modular, updatable medical equipment that conforms to some minimum standards in cybersecurity. However, larger-scale changes to product development and product procurement are needed to make these trends self-sustaining.

Staff also heard the benefits of having inventory tracking of medical equipment. One proposal is to incentivize health care organizations to purchase such as system.

Various proposals have been considered as ways to reduce the life cycle gap. Some have proposed requiring software developers to continue patching and servicing their products for a longer period that would better align with the life cycle of large medical equipment. Others have suggested that Congress should require large medical devices have modular components that allow for the replacement of outdated parts of the equipment, without necessitating the replacement of the entire machine. Staff also heard that requiring providers that are using outdated legacy equipment to provide notice of this fact to their patients could help encourage the development and use of supported software. Finally, staff heard about the need to address barriers to after-market repair and maintenance of devices, after (or beyond) an original equipment manufacturer's support.

Staff heard that often health care organizations and medical device manufacturers do not consider all factors when developing contracts. The Healthcare and Public Health Sector Coordinating Council's published Model Contract-Language for Medtech Cybersecurity (MC2) could serve as the starting point for contract negotiations between medical device manufacturers and health care organizations.

Finally, some groups believe there should be a requirement to restrict sales of medical devices with software that is already no longer supported.

Questions regarding Policy

1. How should Congress help incentivize the alignment of the life cycles for medical equipment and the software that runs it?

2. What sorts of requirements should medical devices have to meet in order to be eligible for reimbursement under a "cash for clunkers" style program? Does such an approach pose an unacceptable moral hazard?

3. Should providers have a "right to repair" medical equipment by contracting with third-party providers?

4. Should medical equipment manufacturers be required to update their products for a certain length of time?

5. Is medical equipment becoming more modular, meaning that parts can be swapped out and replaced? Is the market for health IT moving towards alternative procurement models, such as device leasing, that address these risks?

2.3 **SOFTWARE BILL OF MATERIALS**

Background

A "software bill of materials" (SBOM) has emerged as a key building block in software security and software supply chain risk management. A SBOM is a nested inventory, or a list of ingredients that make up software components. Relevant work on SBOM has advanced since 2018 as a collaborative community effort, driven by the National Telecommunications and Information Administration's (NTIA) multi-stakeholder process.

A SBOM-related concept is the Vulnerability Exploitability eXchange (VEX). A VEX document is an attestation, or a form a security advisory uses to indicate whether a product or products are affected by a known vulnerability or vulnerabilities. This effort is currently being led by CISA.

Various actions have been taken by multiple parties to address SBOM. In 2021, the Biden Administration issued Executive Order 14028 that included a requirement for SBOM for software vendors contracting with the federal government and tasked NTIA to publish a standards for SBOM.

Specifically on health care, NTIA has been leading the effort to evaluate SBOM in the industry via its Health Care SBOM Proof of Concept group. Currently, the group is looking into automating SBOM sharing and driving the adoption of SBOM.

Additionally, in April 2022, the FDA released a draft guidance document in which it would, if finalized, recommend that medical device manufacturers prepare a SBOM for both the FDA and users to have access to. Finally, the PATCH Act, introduced in March 2022 by Senator Bill Cassidy (R-LA) and Senator Tammy Baldwin (D-WI), would require a SBOM for devices going through FDA approvals.

Policy under Consideration

One of the proposals being considered is for Congress to require SBOM publication for all software and devices used by the health care industry. This requirement could be enforced during pre-market approval (as proposed by the PATCH Act) and coupled with post-market monitoring to ensure cybersecurity vulnerabilities are addressed. In addition, staff is also looking into various incentives to promote the adoption of SBOM.

Questions regarding Policy

1. Should a single agency or group be in charge of SBOM requirements?

2. Are health IT risks sufficiently grave or unique to warrant an accelerated or heightened SBOM approach from other commercial IT products? Should SBOM requirement be applied retroactively?

3. Should SBOM creation, publication, and sharing be mandatory or voluntary?

2.4 **STREAMLINING INFORMATION SHARING**

Background

Currently, there are a number of requirements and recommendations for health care systems to share information related to security breaches and vulnerabilities, but it is often difficult to know where one is supposed to share relevant information. It is equally difficult for health care organizations to know where to locate relevant information. Meanwhile, smaller organizations may not currently have the resources or technical expertise to participate in information sharing organizations.

In addition to traditional avenues like reporting to the Federal Bureau of Investigation (FBI) and Cybersecurity and Infrastructure Security Agency (CISA), multiple options for information sharing exist within the U.S. Department of Health and Human Services (HHS):

- For covered entities with breaches of unsecured protected health information affecting 500 or more individuals, health and public health systems must report to the U.S. Department of Health and Human Services Office for Civil Rights. As required by section 13402(e)(4) of the HITECH Act, the U.S. Secretary of Health and Human Services must post a list of these breaches of unsecured protected health information.

- For covered entities with health care cybersecurity questions or a need for technical assistance, they may direct concerns to the HHS Administration for Strategic Preparedness and Response's (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE).

- For tips regarding health care cybersecurity vulnerabilities, tips may be shared with HHS's Health Sector Cybersecurity Coordination Center (HC3), which provides technical victim and vulnerability notifications to the public.

- For industry leaders to coordinate, the Healthcare and Public Health Sector Coordinating Council (HSCC) Cybersecurity Working Group (CWG), as the HHS recognized critical infrastructure industry partner with the government, communicates to HHS strategic, policy and operational approaches to prepare for, respond to, and recover from significant cyber and physical threats.

For information sharing within the health and public health sector industry but not with government partners, the Health Information Sharing and Analysis Center (H-ISAC), consists of industry leaders who share in real time vulnerabilities and cybersecurity information with one another to produce and share recommended tools, guidance, and best practices.

For ransomware incidents, every event will need to be reported to CISA per the Cyber Incident Reporting For Critical Infrastructure Act of 2022 (CIRCIA), which was signed into law as part of the Consolidated Appropriations Act, 2022 (Public Law 117–103). Under the law, a covered entity must report a "covered cyber incident" no later than 72 hours after the covered entity believes the event occurred.

Finally, entities may share information with local, state, or federal law enforcement as relevant and appropriate.

Policy under Consideration

Health care entities are often unsure of with whom in the U.S. government and how they should share cybersecurity information. At the same time, experts have shared that diverse health care cybersecurity responsibilities and needs necessitate the involvement of a variety of federal agencies. For example, HHS employs technical cybersecurity experts HC3 because of the nature of their products being more technical, whereas CISA is known to have extensive ransomware expertise among cyber industry experts. There are likely ways to streamline information sharing while still recognizing that an organization's needs and constraints and the threats they face will vary and require different assistance. In particular, it is often most difficult for smaller and independent health care providers, who do not have as much cybersecurity and government relations capabilities, to be familiar with the resources and offices within HHS and elsewhere that oversee health care

cybersecurity. Lastly, information sharing is no panacea; as security researchers have emphasized, unless organizations have sufficient resources to operationalize threat information and remediate security risks, additional threat information will often hold limited value.[21]

Larger health care providers have a higher capacity than smaller entities to employ their own cybersecurity staff to monitor agency communications and procure and implement products. The biggest barriers for smaller health and public health sector entities to employ these teams is a lack of cyber staff and resources. There is more we can do to help providers of all sizes protect their practices and their patients.

Finally, some experts have suggested that Congress should act to increase membership in H-ISAC to facilitate maximum participation among industry. As the health sector's information sharing and analysis center (ISAC), H-ISAC is made up of the largest and most cyber-equipped and knowledgeable health industry leaders in the world, sharing health care cybersecurity information with members in real time. Additionally, real-time sharing between industry entities is usually the most efficient and preferred modality of information sharing due to the rapid pace in which cybersecurity evolves. There is recognition of the potential for H-ISAC to serve as a liaison to connect smaller health and public health sector entities with information resources. However, it is also important to note barriers for smaller health sector entities to joining H-ISAC, including a lack of cybersecurity staff to implement recommendations, network capabilities, and resource constraints.

Questions regarding Policy

1. As the office responsible for overseeing the cyber response within HHS, is the Administration for Strategic Preparedness and Response the best office within the agency to manage intake of information sharing?

2. How can Congress partner with HHS to better inform the health sector about the landscape of the Department's health care cybersecurity resources as well as capabilities?

3. If H-ISAC is the best entity for information sharing among health care organizations, could an incentive for smaller health sector entities be beneficial to the nation's health care system? How should "smaller" health entities be defined? What would be an appropriate incentive for? Should H-ISAC be responsible for any incentive?

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21 Zack Whittaker, "The Do's and Don'ts of Bug Bounty Programs with Katie Moussouris." *TechCrunch,* April 8, 2021. https://techcrunch. com/2021/04/07/the-dos-and-donts-of-bug-bounty-programs-with-katie-moussouris/

2.5 FINANCIAL IMPLICATIONS FOR INCREASED CYBERSECURITY REQUIREMENTS

Background

Generally, there is insufficient investment in cybersecurity by health care organizations. A 2021 survey on the lack of investment found that more than 60 percent of hospital IT teams said they have "other spending priorities," with less than 11 percent identifying cybersecurity as a "high-priority spend."[22]

This issue is compounded for smaller hospitals and health care organizations, which may be struggling to remain financially solvent. When there is interest among health care organizations to build out a cyber team, they must navigate the cybersecurity talent shortage and are often waiting more than 100 days to fill roles after posting.[23] In many cases, a single security professional is often responsible for a large network of hospitals and facilities, sometimes spread across an extensive geographic area. To effectively protect against cybersecurity threats, organizations must reprioritize cybersecurity within their systems and establish a model for adequately resourcing the cyber-security workforce for qualified individuals.

60%

of hospital IT teams said they have "other spending priorities," with less than 11 percent identifying cybersecurity as a "high-priority spend."

Policy under Consideration

Cybersecurity should be the "cost of doing business" - but given the Medicare program's outsized role in setting the standards for health care payments outside the program, it's necessary to determine how those literal costs of doing cybersecurity business are reflected in payment formulas the way paying the electricity or water bills are. Further, some settings, such as independent providers or those in rural settings, may need assistance in "startup" costs in technology and workforce talent.

Questions regarding Policy

1. How should Medicare payment policies be changed to ensure cybersecurity expenses are incorporated into practice expense and other formulas the same way other basic expenses are?

2. For "startup" grants, what should the eligibility criteria be for a grant program that provides small, rural. and independent providers with funding for cybersecurity? Who should administer such a grant program? What should be allowable uses of such funds?

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22 Jocelyn Duran and Mallory Newall. "CyberMDX/Philips/Ipsos Study: Perspectives in Healthcare Security." *CyberMDX/Philips/Ipsos,* August 16, 2021. https://www.ipsos.com/en-us/news_and_polls/cybermdx-philips-ipsos-perspectives-healthcare-security-081621

23 Jill McKeon, "Cybersecurity, Vulnerabilities Not Priorities for Most Hospitals." *HealthITSecurity*, August 12, 2021. https://healthitsecurity.com/news/cybersecurity-vulnerabilities-not-priorities-for-most-hospitals

RECOVERY FROM CYBERATTACKS

CHAPTER THREE INTRODUCTION

The Federal Bureau of Investigation's (FBI) Internet Crime Complaint Center (IC3) found that the health care sector faced the most ransomware attacks in 2021 compared to other critical infrastructure sectors.[24] The same report also noted a seven percent increase in total internet crime complaints in 2021 compared to 2020.

Health care delivery organizations that suffer a catastrophic cyberattack that inhibits the organization's ability to protect patient safety may require financial and technical assistance to recover. An organization may require short-term aid in the immediate aftermath of a cyberattack to ensure they can continue to serve patients and longer-term assistance to return the organization into a standard operational posture.

In 2017, as the NotPetya malware spread around the globe, it also affected hospitals and their ability to deliver patient care. When the malware brought down Nuance's speech-to-text transcription service, it took away doctors' ability to dictate changes into patients' medical records. One large non-profit integrated health delivery system told staff it took them multiple weeks to fully transition to a new system and clear their backlog.

A more recent cyberattack on the University of Vermont Medical Center (UVM) in October 2020 illustrates the scale of the destruction and the difficulty of recovering from cyberattacks.[25]

28 days length of time the UVM IT system was offline.	**1,300 servers & 5,000 additional devices** infected with malware.	**800 applications** brought down for several weeks.

While UVM successfully switched to "downtime procedures" that UVM staff has practiced, they soon realized how insufficient it was as the drill prepared providers for a scenario in which systems were unavailable for only 12 hours. Staff also learned about other non-tech issues, such as newer medical staff without experience with charting and writing paper orders quickly.

Unfortunately, these attacks won't be the last, and they should serve as cautionary tales for other hospitals seeking to continue operations and recover from cyber-incidents. The following sections propose solutions to prepare health care delivery organizations for the eventuality of a cyberattack and offer solutions for coordinated response efforts to minimize damage and recover within hours or days instead of weeks or months.

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24 "FBI Releases the Internet Crime Complaint Center 2021 Internet Crime Report." *FBI.gov.* FBI, March 22, 2022. https://www.fbi.gov/news/press-releases/press-releases/fbi-releases-the-internet-crime-complaint-center-2021-internet-crime-report

25 Theresa Defino, "Hacked, Shut down, but Still Seeing Patients: U. of Vermont Medical Center Shares Strategies." *JD Supra.* Health Care Compliance Association, June 2022. https://www.jdsupra.com/legalnews/hacked-shut-down-but-still-seeing-9608051/

3.1 CYBER EMERGENCY PREPAREDNESS

Background

On September 8, 2016, CMS published in the Federal Register the Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers Final Rule (EP Rule). This rule established national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan adequately for both natural and man-made disasters and to coordinate with federal, state, tribal, regional, and local emergency preparedness systems.

Health care providers and suppliers affected by this rule needed to be compliant and implement all regulations by November 15, 2017.

Policy under Consideration

Despite the intent of the regulation directing health care providers and suppliers to use an "all-hazards" approach to emergency preparedness, CMS also notes certain hazards, such as earthquakes, hurricanes, and others, require unique responses. CMS could better direct facilities to consider cyberattacks in the same category as the other hazards above for the purpose of developing specific emergency preparedness procedures. This may include mandating training of hospital staff to use analog equipment. Additionally, experts suggested encouraging cyberattack response and recovery joint trainings between health care organizations and relevant federal and state cyber response teams.

Questions regarding Policy

1. Should health care providers be required to train all staff members within the health care system to use alternate or legacy systems in the event of catastrophic failure to connected systems?

2. What types of cyberattacks should health care providers prepare for? Should the FDA require medical devices to have a failsafe mode in the event of connectivity failure or other security incidents?

3. Is the EP rule the appropriate regulation for such requirements?

3.2 STRATEGIC NATIONAL STOCKPILE OF COMMON EQUIPMENT

Background

The Strategic National Stockpile (SNS), administered by the HHS Administration for Strategic Preparedness and Response (ASPR), is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The SNS team works to prepare for and respond to emergencies, support state and local preparedness activities, and ensure availability of critical medical assets to protect the health of Americans.

The Strategic National Stockpile (SNS) has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (e.g. terrorist attack, disease outbreak, earthquake) severe enough to cause local supplies to run out. These supplies include personal protective equipment (PPE), antibiotics, chemical antidotes, antitoxins, life-support medications, airway maintenance supplies, and medical/surgical items.

Once federal and local authorities agree that the SNS is needed, supplies are delivered to states. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible.

Policy under Consideration

One proposal that is being considered is to augment the stockpile with common equipment needed by hospitals facing cyberattacks such as analog equivalent medical devices, laptops, walkie-talkies, and other mobile devices.

Questions regarding Policy

1. Who can declare an emergency that would allow these resources to be accessed?

2. Should this assistance be targeted only to under-resourced health care organizations, which likely struggle to maintain a supply of their own emergency backup resources?

3. Should organizations that do not employ minimum cyber hygiene practices have access to the SNS for analog, equivalent medical devices and other equipment?

3.3 **DISASTER RELIEF PROGRAM**

Background

With cyber incidents taking place at hospitals and health care organizations surging in recent years, there is a clear need for additional resources for health care organizations to rebuild after an attack. A 2021 survey of the College of Healthcare Information Management Executives (CHIME) and Association for Executives in Healthcare Information Security (AEHIS) members found that 40 percent of responding CISOs reported needing additional help in terms of grants and federal assistance, highlighting interest on the part of health care organizations in improved federal engagement.

FEMA provides both pre- and post-emergency/disaster-related assistance. Disaster assistance can take the form of funding for emergency work and the repair of damaged facilities to affected organizations after a natural disaster, while non-disaster funds go towards hazard mitigation or emergency/disaster preparedness. Although organizations are currently able to receive preparedness grants to improve their cybersecurity posture, they are not currently eligible for FEMA disaster assistance in the wake of a cyberattack.

Policy under Consideration

To help hospitals and other health care organizations recover faster after a cyber disaster, one proposal is to establish a cyber disaster relief program that provides relief to victims of a cyberattack that is similar to assistance provided to victims of natural disasters.

Questions regarding Policy

1. Is creating a new program specifically for cyber-related disasters preferred to simply making certain cybersecurity incidents eligible for FEMA disaster funds? Would states be required to provide non-federal funding matches as they often do under FEMA disaster assistance?

2. What should the criteria be to determine whether a cyber event experienced by a health care organization constitutes a "cyber disaster"? Who should determine this criteria? If the program is outside FEMA, who should administer?

3. Would such a program conflict with existing cybersecurity insurance coverage?

3.4 SAFE HARBOR/IMMUNITY IF HEALTH CARE ORGANIZATIONS IMPLEMENT ADEQUATE SECURITY MEASURES

Background

Stakeholders expressed concerns that information about weaknesses and threats are often not shared among health care organizations or with the government for fear of repercussions, particularly from patients whose information was breached or who experienced harm from an intrusion. This prevents mitigation in real time and also prevents improvement after an intrusion.

Further, many cybersecurity experts believe the nature of this work involves an ever-evolving threat environment, with "perfect security" an unattainable objective. That's why it's critical to have a plan to not just prevent but also to respond to an intrusion and mitigate patient privacy breaches and patient safety harms.

Policy under Consideration

Congress should consider policies that encourage information sharing, including with patients, and encourage industry-wide learning and improvement by being encouraged to share vulnerabilities and responses. Congress should consider incentives that would provide narrowly-defined protections for health care organizations that are transparent with risks, intrusions, and their responses to both.

Any changes, however, should preserve an individual's right to access the justice system when necessary, ensuring patients who experience preventable harm are able to seek redress.

Questions regarding Policy

1. Would health care organizations do more that would be beneficial to health care cybersecurity and patient safety, but for the fact that it opens them up to legal or regulatory liability?

2. Does indemnification of health care organizations present undue moral hazard, preventing them from adopting precautions and mitigations beyond a minimum threshold?

3. How can these provisions ensure patients have the continued right to access the justice system when they experience harm?

3.5 CYBER INSURANCE

Background

Insurance against damages from cyberattacks has increased in prominence, but such insurance is still relatively new compared to the long history of other forms of insurance. The novel nature of cyber insurance, particularly the lack of historical data on losses and legal uncertainty about what is and is not covered by specific policy language, has led to volatility in cyber insurance markets. Cyber insurance overall has been growing, but insurers have experienced dramatically different levels of losses and policyholders have seen significant premium increases.

Insurance policies often contain war risk exclusions, but such exclusions frequently have not been specifically litigated, particularly with regard to damages incurred from cyberattacks. In some cases, even with the presence of war exclusion language, courts have found that insurers may be liable for damages which could be considered due to war. The most notable instances involve the NotPetya attacks, with large lawsuits involving insurers and companies like Merck and Mondalez regarding the application on war risk exclusions. The Merck case has resulted in a $1.4 billion judgment that found the war risk exclusion did not apply, while the Mondalez case was settled after extensive negotiations.[26] The decisions in such cases may shape cyber insurance going forward.

To avoid potentially huge damages, insurers may continue to restrict coverage through more tightly crafted exclusions, more aggressive and active underwriting standards, and higher premiums. Similar dynamics in the past with terrorism coverage following the attacks on September 11, 2001, led to federal intervention, and some have called for similar action in cyber insurance.

Policy under Consideration

Industry experts have shared that cyber insurance is increasingly expensive and that the application process is extensive and sometimes burdensome. A thriving market for cyber insurance could lower overall risks by introducing minimum cyber hygiene requirements. Some proposals that have been raised include:

Creating a federal reinsurance program that covers plans that require minimum cyber hygiene, allowing the industry to adopt a better hygiene posture without a full government mandate.

Standardizing coverage elements and providing incentives for insurance companies to adopt them.

Creating a cyber insurance program similar to the one created by the Terrorism Risk Insurance Act (TRIA) to create a transparent system of shared public and private compensation for certain insured losses resulting from a certified act of nation-state cyberattacks.

Mandating reporting of cyber insurance payouts as a way to capture more cyber incidents reporting.

Creating an information-sharing mechanism for insurers and government agencies to facilitate better risk analysis for the creation of cyber insurance.

Questions regarding Policy

1. Should Congress create a reinsurance program or otherwise regulate cyber insurance?

2. What can Congress do to facilitate information sharing between the intelligence community and insurers?

3. What's the role for cyber insurance in insuring care provided via medical equipment that have been recalled or is currently unpatched?

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26 Alexander Martin, "Mondelez and Zurich reach settlement in NotPetya cyberattack insurance suit." *The Record.* October 31, 2022. https://therecord.media/mondelez-and-zurich-reach-settlement-in-notpetya-cyberattack

CONCLUSION

As cybersecurity becomes an increasingly dangerous threat, so does the potential for harm to patient safety. Any delays caused by cybersecurity inevitably affect patient care negatively. Unless we act now, this situation will get worse.

Unfortunately, the health care sector is uniquely vulnerable to cyberattacks and the transition to better cybersecurity has been painfully slow and inadequate. The federal government and the health sector must find a balanced approach to meet the dire threats, together as partners with shared responsibilities.

Senator Warner believes that cybersecurity is patient safety and must no longer be a secondary concern; it must become incorporated into every organization's business model. Equally as important, cybersecurity policies and their implementation must start upstream to benefit all stakeholders downstream. Equipment must be designed and built with cybersecurity at its core, and regulations and government actions must account for cybersecurity at every step of the way. In this new paradigm, health care providers and organizations can benefit from upstream advances while also implementing a certain level of cyber hygiene to protect everyone in the health care sector, particularly the patients they exist to serve.

In this policy paper, we have laid out ideas in three areas to get us to that new paradigm:

- Areas the federal government needs to address to improve our national risk posture for cybersecurity in the health care sector;

- Ways the federal government can help the private sector meet cyber threats; and

- Aids from the federal government that helps the private sector recover after a cyberattack.

We are sharing these policy ideas to solicit feedback, comments, and ideas. Any individuals, researchers, businesses, organizations, or advocacy groups that are interested in submitting comments – specific to the content and questions outlined in this document or additional ideas or language for inclusion in eventual legislation – should send a letter or an email to cyber@warner.senate.gov

Senator Warner is eager to work with his colleagues in the Senate and the House of Representatives to improve cybersecurity in the health care sector.

APPENDIX

Health Care Industry Cybersecurity Task Force Framework

In 2016, the Department of Health and Human Services (HHS) established the Health Care Industry Cybersecurity Task Force, as directed by the Cybersecurity Act of 2015 (Public Law 114–113). The task force was created to improve cybersecurity practices in the health care industry and was composed of members representing a variety of organizations within the health care sector, including hospitals, insurers, patient advocates, security researchers, pharmaceutical companies, medical device manufacturers, health IT developers and vendors, and clinical labs.[27]

In 2017, the task force released its report to Congress that identified six imperatives to improve cybersecurity in the health care industry.[28] These were:

- Defining leadership and governance for health care industry cybersecurity

- Increasing medical device security

- Developing health care workforce capacity in the context of cybersecurity

- Improving cybersecurity awareness and education

- Protecting R&D efforts and IP from cybersecurity threats

- Improving information sharing of threats and risks

Many of the industry experts that staff spoke to referenced this report as a strong framework for potential legislative action, as it identifies – at least as of 2017 – the gaps in policy and regulation in the health care cybersecurity space.

Staff is exploring the viability of using this report as a starting point for legislation in this space and is in the process of developing language that would address many of the issues the report raised. Some of the specific proposals mentioned in the 2017 report are addressed in detail in this document.

Questions regarding Task Force Report:

1. Which of the recommendations are most salient today? Are there any recommendations that are outdated?

2. What issues have emerged since the publishing of the report in 2017?

3. Should the task force (or similar body) be reassembled to address new issues that have emerged in the space since the publication of the 2017 report?

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27 "Health Care Industry Cybersecurity Task Force Overview" *U.S. Department of Health and Human Services.* June 2017. https://www.phe.gov/ Preparedness/planning/CyberTF/Pages/overview.aspx

28 Health Care Industry Cybersecurity Task Force, "Report On Improving Cybersecurity in the Health Care Industry." *U.S. Department of Health and Human Services.* June 2, 2017. https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf