# SECURING TELEHEALTH REMOTE PATIENT MONITORING ECOSYSTEM

# Cybersecurity for the Healthcare Sector

Jennifer Cawthra National Cybersecurity Center of Excellence National Institute of Standards and Technology

Ronnie Daldos Kevin Littlefield Sue Wang David Weitzel The MITRE Corporation

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The National Cybersecurity Center of Excellence (NCCoE), a part of the National Institute of Standards and Technology (NIST), is a collaborative hub where industry organizations, government agencies, and academic institutions work together to address businesses' most pressing cybersecurity challenges. Through this collaboration, the NCCoE develops modular, easily adaptable example cybersecurity solutions demonstrating how to apply standards and best practices using commercially available technology. To learn more about the NCCoE, visit <a href="http://www.nccoe.nist.gov">http://www.nccoe.nist.gov</a>. To learn more about NIST, visit <a href="http://www.nist.gov">http://www.nist.gov</a>.

This document describes a particular problem that is relevant across the healthcare sector. NCCoE cybersecurity experts will address this challenge through collaboration with members of the healthcare sector and vendors of cybersecurity solutions. The resulting reference design will detail an approach that can be used by healthcare delivery organizations (HDOs).

#### **Abstract**

HDOs are leveraging a combination of telehealth capabilities, such as remote patient monitoring (RPM) and videoconferencing, to treat patients in their homes. These modalities are used to treat numerous conditions, such as patients battling chronic illness or requiring postoperative monitoring. As use of these capabilities continues to grow, it is important to ensure that the infrastructure supporting them can maintain the confidentiality, integrity, and availability of patient data, and to ensure the safety of patients. It is also important to ensure the privacy of patient data by considering the privacy engineering objectives of predictability, manageability, and disassociability of data. The goal of this project is to provide a practical solution for securing the telehealth RPM ecosystem. The project team will perform a risk assessment on a representative RPM ecosystem in the laboratory environment, apply the NIST Cybersecurity Framework and guidance based on medical device standards, and collaborate with industry and public partners. This project will focus on the diagnostic aspects of remote patient monitoring. The project team will also create a reference design and a detailed description of the practical steps needed to implement a secure solution based on standards and best practices. This project will result in a freely available NIST Cybersecurity Practice Guide.

#### **Keywords**

application programming interface; API; application security; cybersecurity; data privacy; data privacy and security risks; health delivery organization; HDO; remote patient monitoring; RPM; telehealth; user interface; UI

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# **1** EXECUTIVE SUMMARY

#### Purpose

This document defines a National Cybersecurity Center of Excellence (NCCoE) project focused on providing guidance and a reference architecture that address security and privacy risks to stakeholders leveraging telehealth and remote patient monitoring (RPM) capabilities.

Health delivery organizations (HDOs) are leveraging a combination of telehealth capabilities, such as RPM and videoconferencing, to treat patients in their homes. Traditionally, patient monitoring systems have been deployed in healthcare facilities, in controlled environments. RPM, however, is different, in that monitoring equipment is deployed in the patient's home, which traditionally does not offer the same level of cybersecurity or physical-security control to prevent misuse or compromise. These RPM devices may use application programming interfaces (APIs) or rule engines developed by third parties that act as intermediaries between the patient and the healthcare provider. Telemetry data from the RPM device may be displayed through a user interface (UI) for visual review.

It is important to review the end-to-end architecture to determine whether security and privacy vulnerabilities exist and what security controls are required for proper cybersecurity of the RPM ecosystem and to protect individuals' privacy.

While the field of telehealth is broad, a focus on the application of telehealth modalities involving telehealth platform providers that use videoconferencing capabilities and leverage cloud and internet technologies coupled with RPM mechanisms provides the NCCoE with an opportunity to develop practical recommendations. The intended audience for these recommendations is HDOs, patients, and independent healthcare providers employing RPM products and services.

This project will result in a publicly available National Institute of Standards and Technology (NIST) Cybersecurity Practice Guide, a detailed implementation guide of the practical steps needed to implement a cybersecurity reference design that addresses this challenge.

#### Scope

The objective of this project is to demonstrate a proposed approach for improving overall security in the RPM environment. This project will address cybersecurity concerns about having diagnostic monitoring devices in patients' homes, including the home network and patient-owned devices such as smartphones, tablets, laptops, and home computers. This project will also identify cybersecurity measures that HDOs may consider when offering RPM with video telehealth capabilities. A proposed component list is provided in the High-Level Architecture section (Section 3).

Telehealth solutions are, by nature, an integration of disparate parties and environments. However, out of scope for this project are the risks and concerns specific to the third-party provider (i.e., the telehealth platform provider) that may offer services that are cloud-hosted or that provide functionality through a software-as-a-service model. Additionally, this project does not evaluate monitoring devices for vulnerabilities, flaws, or defects. This project will focus on the medical diagnostic aspects of remote patient monitoring. The NCCOE does not evaluate medical device manufacturers. While telehealth solutions may include software development kits (SDKs) and APIs, this project will not explore the secure software development practice in detail.

#### Assumptions

- Patient monitoring devices (e.g., blood pressure cuffs, body mass index [BMI]/weight scales) may leverage commercially available communications (e.g., Bluetooth, Wi-Fi/ wireless, or cellular) to transmit telemetry data to the home monitoring application.
- The home monitoring application is a provider-managed solution that may be installed on a provider-managed or unmanaged patient-owned mobile device.
- The home monitoring application may transmit telemetry data to the remote monitoring server via a cellular or Wi-Fi connection.
- The patient is in his or her home during the telehealth interaction (e.g., video, patient monitoring).
- Video telehealth interactions may leverage patient-owned devices or devices provided by the primary care facility.
- Clinicians participating in telehealth interactions use secured communications methods.

#### Background

The NCCoE recognizes the important role that telehealth capabilities play in delivery of healthcare and has commenced research in telehealth, specifically RPM technologies. As the growth and popularity of telehealth capabilities accelerate, it is critical to evaluate the security and privacy risks associated with each identified use case. Once identified, security controls can be implemented to mitigate the security and privacy risks to the patient and other stakeholders. The demand for telehealth capabilities continues to grow as stakeholders (e.g., patients; providers; payers; federal, state, and local governments) see the benefits that telehealth brings to improving the quality of patient care and the accessibility to healthcare. As an example of telehealth capabilities growth, a 2017 Foley Telemedicine and Digital Health Survey found that, in just three years, respondents went from 87 percent not expecting most of their patients to be using telehealth services in 2017 to 75 percent offering or planning to offer telehealth services to their patients [1].

This project examines RPM as a medically prescriptive course that an HDO implements to manage a condition outside a healthcare facility. This differs from discretionary use of personal healthcare technology that individuals may use in improving their fitness.

#### 2 SCENARIO: REMOTE PATIENT MONITORING AND VIDEO TELEHEALTH

The scenario considered for this project involves RPM equipment deployed to the patient's home [2]. RPM equipment that may be provided to patients includes devices for blood pressure monitoring, heart rate monitoring, BMI/weight measurements, and glucose monitoring. An accompanying application may also be downloaded onto the patient-owned device and synced with the RPM equipment to enable the patient and healthcare provider to share data. Patients may also be able to initiate videoconferencing and/or communicate with the healthcare provider via email, text messaging, chat sessions, or voice communication. Data may be transmitted across the patient's home network and routed across the public internet. Those transmissions may be relayed to a telehealth platform provider that, in turn, routes the communications to the HDO. This process brings the patient and healthcare provider together, allowing for delivery of the needed healthcare services in the comfort of the patient's home.

The following functions may be evaluated during this project:

- connectivity between monitoring devices and applications deployed to mobile devices (e.g., smartphones, tablets) or to patient workstations (e.g., laptops, desktops)
- ability for the application to transmit monitoring data to the HDO
- ability for the patient to initiate requests or notifications
- ability for the patient to interact with a point of contact to initiate care (This ability may be through a chat box, interacting with a live individual via videoconference.)
- ability for the patient to receive medical alerts and notifications
- ability for the monitoring data to be analyzed by the HDO to spot trends and to issue possible alerts to the clinician if the data suggests that there is an issue with the patient
- ability for the patient monitoring data to be shared remotely with the electronic health record system
- ability for the patient to initiate a videoconference session with a care team member through the telehealth application
- ability for the HDO to update the security functionality of the remote monitoring device
- ability for the patient to receive and apply security updates and patches for applications
- ability for the HDO to connect to the remote monitoring device to obtain direct patient telemetry data
- ability for the HDO to connect to the remote monitoring device to update the monitoring device configuration

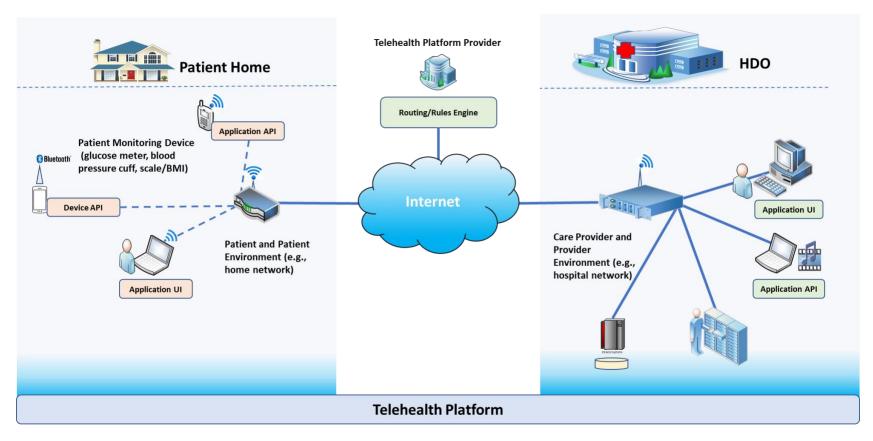
## **3** HIGH-LEVEL ARCHITECTURE

This project examines what happens when remote patient monitoring equipment is hosted in a patient's home environment. Patients who use monitoring devices in their home are able to forward the monitoring data to their physician at regular intervals and can initiate audio and video communication to their care team providers. Physicians receive patient data through the telehealth platform with equipment that captures the patient data and allows real-time audio and video interaction with the patient. This project identifies controls in the HDO environment with a focus on patient home-deployed controls.

For this project, two separate environments will be constructed: the HDO environment and the patient home setting. Figure 3-1 shows the high-level architecture for RPM that uses a third-party telehealth platform provider. The high-level architecture addresses the scope noted in Section 1. The component list and the desired security characteristics are listed in the subsections that follow.

The HDO infrastructure would adopt the deployments used in previous NCCoE healthcare projects [3], [4] that implement network zoning and layered defenses aligning to NIST Cybersecurity Framework functions. As this project develops, identity and access management (IdAM) controls will be identified. IdAM may be limited based on selected technologies, and those limitations are to be determined.

#### Figure 3-1: High-Level Architecture



#### **Component List**

The NCCoE has a dedicated lab environment that includes the following features:

- network with machines using a directory service
- virtualization servers
- network switches
- remote access solution with Wi-Fi and a virtual private network (VPN)

Collaboration partners (participating vendors) may provide specialized components and capabilities to realize this solution, including, but not limited to, those listed in the subsections below.

#### Components for RPM Technologies

- **telehealth platform**–a solution that enables data and communication flow from the patient monitoring device to the home monitoring device to the care providers
  - o internet-based communications
    - transmission of telemetry data
    - videoconference
    - audioconference
    - email
    - secure text messaging
  - routing/triage functionality–The telehealth platform enables patients to identify an appropriate, networked team of care providers.
  - SDKs and APIs that enable telehealth applications to interface with patient monitoring devices
  - $\circ$   $\;$  patient monitoring devices that send telemetry data via the home monitoring device
    - blood pressure
    - heart monitoring
    - BMI/weight scales
    - other telemetry devices, as appropriate
  - home monitoring device (e.g., specialized mobile application, stand-alone device) that transmits telemetry data to the telehealth platform and provides video connectivity

#### Components for Remote/Patient Home Environment

- personal firewall—an application that controls network traffic to and from a computer, permitting or denying communications based on a security policy
- wireless access point router—a device that performs the functions of a router and includes the functions of a wireless access point
- endpoint protection (anti-malware)—a type of software program designed to prevent, detect, and remove malicious software (malware) on information technology (IT) systems and on individual computing devices
- mobile device—a multimodal, small form factor, communications mechanism that has characteristics of computing devices that include wireless network capability, memory,

data storage, and processing. The device may provide real-time audio, video, and text communications as well as support email, web browsing, and other internet-enabled methods to interact with locally and remotely stored information and systems.

- modem—a device that provides a demarcation point for broadband communications access (e.g., cable, digital subscriber line [DSL], wireless, long-term-evolution [LTE], 5G) and presents an Ethernet interface to allow internet access via the broadband infrastructure
- **wireless router**-a device that provides wireless connectivity to the home network and provides access to the internet via a connection to the cable modem
- **telehealth application**—an application residing on a managed or unmanaged mobile device or on a specialized stand-alone device and that facilitates transmission of telemetry data and video connectivity between the patient and HDO
- **patient monitoring device**—a peripheral device used by the patient to perform diagnostic tasks (e.g., measure blood pressure, glucose levels, or BMI/weight) and to send the telemetry data via Bluetooth or wireless connectivity to the telehealth application

#### Components for HDO Environment

- network access control-discovers and accurately identifies devices connected to wired networks, wireless networks, and VPNs and provides network access controls to ensure that only authorized individuals with authorized devices can access the systems and data that access policy permits
- network firewall-a network security device that monitors and controls incoming and outgoing network traffic, based on defined security rules
- intrusion detection system (IDS) (host/network)—a device or software application that monitors a network or systems for malicious activity or policy violations
- intrusion prevention system (IPS)—a device that monitors network traffic and can take immediate action, such as shutting down a port, based on a set of rules established by the network administrator
- VPN-a secure endpoint access solution that delivers secure remote access through virtual private networking
- governance, risk, and compliance (GRC) tool-automated management for an organization's overall governance, enterprise risk management, and compliance with regulations
- **network management tool**—provides server, application-management, and monitoring services, as well as asset life-cycle management
- endpoint protection and security—provides server hardening, protection, monitoring, and workload micro-segmentation for private cloud and physical on-premises data-center environments, along with support for containers, and provides full-disk and removable media encryption
- **anti-ransomware**—helps enterprises defend against ransomware attacks by exposing, detecting, and quarantining advanced and evasive ransomware
- **application security scanning/testing**-provides a means for custom application code testing (static/dynamic)

#### **RPM Ecosystem Actors**

- patients-individuals being monitored in their home settings
- **HDO clinicians**—physicians, nursing staff, and medical technicians in the HDO environment
- **independent healthcare providers**—those who may need to access patient information for patient-initiated care and diagnostic requests
- **support/maintenance staff**-technical staff in the HDO facility who maintain the HDOresident components and the HDO-managed components in the patient's home environment

#### Desired Security Characteristics

The primary security functions and processes to be implemented for this project are listed below and are based on NIST Cybersecurity Framework Version 1.1.

**IDENTIFY (ID)**–These activities are foundational to developing an organizational understanding to manage risk.

- asset management-includes identification and management of assets on the network and management of the assets to be deployed to equipment. Implementation of this category may vary depending on the parties managing the equipment. However, this category remains relevant as a fundamental component in establishing appropriate cybersecurity practices.
- **governance**—Organizational cybersecurity policy is established and communicated. Governance practices are appropriate for HDOs and their solution partners, including technology providers and those vendors that develop, support, and operate telehealth platforms.
- **risk assessment**-includes the risk management strategy. Risk assessment is a fundamental component for HDOs and their solution partners.
- **supply chain risk management**—The nature of telehealth with RPM is that the system integrates components sourced from disparate vendors and may involve relationships established with multiple suppliers, including cloud services providers.

**PROTECT (PR)**—These activities support the ability to develop and implement appropriate safeguards based on risk.

- identity management, authentication, and access control-includes user account management and remote access
  - o controlling (and auditing) user accounts
  - o controlling (and auditing) access by external users
  - o enforcing least privilege for all (internal and external) users
  - enforcing separation-of-duties policies
    - privileged access management (PAM) with an emphasis on separation of duties
  - o enforcing least functionality
- data security-includes data confidentiality, integrity, and availability
  - securing and monitoring storage of data-includes data encryption (for data at rest)

- access control on data
- data-at-rest controls should implement some form of a data security manager that would allow for policy application to encrypt data, inclusive of access control policy
- securing distribution of data-includes data encryption (for data in transit) and a data loss prevention mechanism
- o controls that promote data integrity
- Cryptographic modules validated as meeting NIST Federal Information Processing Standards (FIPS) 140-2 are preferred.
- information protection processes and procedures—include data backup and endpoint protection
- maintenance-includes local and remote maintenance
- protective technology-host-based intrusion prevention, solutions for malware (malicious-code detection), audit logging, (automated) audit log review, and physical protection

**DETECT (DE)**–These activities enable timely discovery of a cybersecurity event.

- **security continuous monitoring**—monitoring for unauthorized personnel, devices, software, and connections
  - vulnerability management-includes vulnerability scanning and remediation
  - o patch management
  - o system configuration security settings
  - user account usage (local and remote) and user behavioral analytics
  - o security log analysis

**<u>RESPOND (RS)</u>**–These activities support development and implementation of actions designed to contain the impact of a detected cybersecurity event.

- **response planning**–Response processes and procedures are executed and maintained to ensure a response to a detected cybersecurity incident.
- **mitigation**—Activities are performed to prevent expansion of a cybersecurity event, mitigate its effects, and resolve the incident.

**<u>RECOVER (RC)</u>**—These activities support development and implementation of actions for the timely recovery of normal operations after a cybersecurity incident.

- **recovery planning**—Recovery processes and procedures are executed and maintained to ensure restoration of systems or assets affected by cybersecurity incidents.
- **communications**—Restoration activities are coordinated with internal and external parties (e.g., coordinating centers, internet service providers, owners of attacking systems, victims, other computer security incident response teams, vendors).

# 4 RELEVANT STANDARDS AND GUIDANCE

#### **General Cybersecurity and Risk Management**

- Association for Advancement of Medical Instrumentation (AAMI) Technical Information Report 57, *Principles for medical device security–Risk management*
- Department of Health and Human Services (HHS), "The HIPAA Privacy Rule," https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
- HHS, "The HIPAA Security Rule," <u>https://www.hhs.gov/hipaa/for-professionals/security/index.html</u>
- International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard 27001:2013, Information technology–Security techniques–Information security management systems–Requirements
- American National Standards Institute/AAMI/IEC Standard 80001-1:2010, Application of risk management for IT-networks incorporating medical devices–Part 1: Roles, responsibilities and activities
- IEC Technical Report (TR) 80001-2-1 Edition 1.0 2012-07, Application of risk management for IT-networks incorporating medical devices–Part 2-1: Step-by-step risk management of medical IT-networks–Practical applications and examples
- IEC TR 80001-2-2 Edition 1.0 2012-07, Application of risk management for IT-networks incorporating medical devices—Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
- NIST Cybersecurity Framework Version 1.1, "Framework for Improving Critical Infrastructure Cybersecurity," https://www.nist.gov/cyberframework/framework
- NIST Interagency/Internal Report 8062, An Introduction to Privacy Engineering and Risk Management in Federal Systems, https://csrc.nist.gov/publications/detail/nistir/8062/final
- NIST Special Publication (SP) 800-30 Revision 1, *Guide for Conducting Risk Assessments*, <u>http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-30r1.pdf</u>
- NIST SP 800-37 Revision 2, Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy, <u>https://csrc.nist.gov/publications/detail/sp/800-37/rev-2/final</u>
- NIST SP 800-39, Managing Information Security Risk: Organization, Mission, and Information System View, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-39.pdf
- NIST SP 800-53 Revision 4, Security and Privacy Controls for Federal Information Systems and Organizations, http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf

Cybersecurity/Technology-Related Standards

- NIST Interagency/Internal Report 8228 Draft, *Considerations for Managing Internet of Things (IOT) Cybersecurity and Privacy Risks*, <u>https://doi.org/10.6028/NIST.IR.8228-draft</u>
- NIST FIPS 140-2, Security Requirements for Cryptographic Modules, https://csrc.nist.gov/publications/detail/fips/140/2/final

- NIST SP 800-41 Revision 1, *Guidelines on Firewalls and Firewall Policy*, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-41r1.pdf
- NIST SP 800-52 Revision 1, Guidelines for the Selection, Configuration, and Use of Transport Layer Security (TLS) Implementations, http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-52r1.pdf
- NIST SP 800-57 Part 1 Revision 4, Recommendation for Key Management: Part 1: General, http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-57pt1r4.pdf
- NIST SP 800-77, Guide to IPsec VPNs, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-77.pdf
- NIST SP 800-95, Guide to Secure Web Services, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-95.pdf
- NIST SP 800-121 Revision 2, *Guide to Bluetooth Security,* <u>https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-121r2.pdf</u>
- NIST SP 800-144, Guidelines on Security and Privacy in Public Cloud Computing, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-144.pdf
- NIST SP 800-146, Cloud Computing Synopsis and Recommendations, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-146.pdf
- NIST SP 1800-1, Securing Electronic Health Records on Mobile Devices, https://csrc.nist.gov/publications/detail/sp/1800-1/final

Other Relevant Regulations, Standards, and Guidance (Healthcare/Medical Devices)

- Department of Health and Human Services Office for Civil Rights, "HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework," <u>https://www.hhs.gov/sites/default/files/nist-csf-to-hipaa-security-rule-crosswalk-02-22-</u> <u>2016-final.pdf</u>
- Department of Homeland Security, National Cybersecurity and Communications Integration Center, "Attack Surface: Healthcare and Public Health Sector," <u>https://info.publicintelligence.net/NCCIC-MedicalDevices.pdf</u>
- Food and Drug Administration (FDA), "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance" (revision in Draft), <u>https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc</u>
- FDA, "Radio Frequency Wireless Technology in Medical Devices—Guidance for Industry and FDA Staff," <u>https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guida</u> <u>nceDocuments/UCM077272.pdf</u>
- FDA, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff," <u>https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guida</u>
- FDA, "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software,"

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guida nceDocuments/UCM077823.pdf

- FDA, "Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff," <u>https://www.fda.gov/regulatory-information/search-fda-guidance-</u> <u>documents/postmarket-management-cybersecurity-medical-devices</u>
- NIST SP 800-66 Revision 1, An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-66r1.pdf

# 5 SECURITY CONTROL MAP

<u>Table 5-1</u> maps the characteristics of the commercial products that the NCCoE will apply to this cybersecurity challenge to the applicable standards and best practices described in the Framework for Improving Critical Infrastructure Cybersecurity (NIST Cybersecurity Framework) and to healthcare-specific standards and guidance, such as IEC TR 80001-2-2, HIPAA, and ISO/IEC 27001. This exercise is meant to demonstrate the real-world applicability of standards and best practices but does not imply that products with these characteristics will meet an industry's requirements for regulatory approval or accreditation.

Table	5-1:	Security	Control	Мар
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	NIST Cyberse	curity Framework Version 1.1		Sector-Spe	cific Standards and Bes	t Practices
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
IDENTIFY (ID)	Asset	ID.AM-1: Physical devices and systems within the organization are inventoried.	CM-8	Not applicable	45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.310(a)(2)(ii), 164.310(d)	A.8.1.1, A.8.1.2
	Management (ID.AM)	ID.AM-5: Resources (e.g., hardware, devices, data, time, and software) are prioritized based on their classification, criticality, and business value.	CP-2, RA-2, SA-14	DTBK	45 C.F.R. § 164.308(a)(7)(ii)(E)	A.8.2.1
	Risk	ID.RA-1: Asset vulnerabilities are identified and documented.	CA-2, CA-7, CA-8, RA-3, RA-5, SA-5, SA-11, SI-2, SI-4, SI-5	RDMP	45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.308(a)(7)(ii)(E), 164.308(a)(8), 164.310(a)(1), 164.312(a)(1), 164.316(b)(2)(iii)	A.12.6.1, A.18.2.3
	Assessment (ID.RA)	ID.RA-4: Potential business impacts and likelihoods are identified.	RA-2, RA-3, PM-9, PM-11, SA-14	SAHD, SGUD	45 C.F.R. §§ 164.308(a)(1)(i), 164.308(a)(1)(ii)(A), 164.308(a)(1)(ii)(B), 164.308(a)(6), 164.308(a)(7)(ii)(E), 164.308(a)(8), 164.316(a)	A.12.6.1, A.18.2.3

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		ID.RA-5: Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.	RA-2, RA-3, PM-16	SGUD	45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.308(a)(1)(ii)(B), 164.308(a)(1)(ii)(D), 164.308(a)(7)(ii)(D), 164.308(a)(7)(ii)(E), 164.316(a)	None
		ID.RA-6: Risk responses are identified and prioritized.	РМ-4, РМ-9	DTBK, SGUD	45 C.F.R. §§ 164.308(a)(1)(ii)(B), 164.314(a)(2)(i)(C), 164.314(b)(2)(iv)	None
PROTECT (PR)		(Note: not directly mapped in Cybersecurity Framework)	AC-1, AC-11, AC-12	ALOF	Not applicable	None
	Identity Management and Access Control (PR.AC)	PR.AC-1: Identities and credentials are issued, managed, revoked, and audited for authorized devices, users, and processes.	AC-2, IA Family	AUTH, CNFS, EMRG, PAUT	45 C.F.R. §§ 164.308(a)(3)(ii)(B), 164.308(a)(3)(ii)(C), 164.308(a)(4)(i), 164.308(a)(4)(ii)(B), 164.308(a)(4)(ii)(C), 164.312(a)(2)(i), 164.312(a)(2)(ii), 164.312(a)(2)(iii),	A.9.2.1, A.9.2.2, A.9.2.4, A.9.3.1, A.9.4.2, A.9.4.3

	NIST Cyberse	curity Framework Version 1.1		Sector-Spe	cific Standards and Bes	t Practices
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.AC-2: Physical access to assets is managed and protected.	PE-2, PE-3, PE-4, PE-5, PE-6, PE-9	PLOK, TXCF, TXIG	45 C.F.R. §§ 164.308(a)(1)(ii)(B), 164.308(a)(7)(i), 164.308(a)(7)(ii)(A), 164.310(a)(1), 164.310(a)(2)(i), 164.310(a)(2)(ii), 164.310(b), 164.310(c), 164.310(d)(1), 164.310(d)(2)(iii)	A.11.1.1, A.11.1.2, A.11.1.4, A.11.1.6, A.11.2.3
		PR.AC-3: Remote access is managed.	AC-17, AC-19, AC-20	NAUT, PAUT	45 C.F.R. §§ 164.308(a)(4)(i), 164.308(b)(1), 164.308(b)(3), 164.310(b), 164.312(e)(1), 164.312(e)(2)(ii)	A.6.2.2, A.13.1.1, A.13.2.1
		PR.AC-4: Access permissions and authorizations are managed, incorporating the principles of least privilege and separation of duties.	AC-2, AC-3, AC-5, AC-6, AC-16	AUTH, CNFS, EMRG, NAUT, PAUT	45 C.F.R. §§ 164.308(a)(3), 164.308(a)(4), 164.310(a)(2)(iii), 164.310(b), 164.312(a)(1), 164.312(a)(2)(i), 164.312(a)(2)(ii)	A.6.1.2, A.9.1.2, A.9.2.3, A.9.4.1, A.9.4.4

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.AC-5: Network integrity is protected, incorporating network segregation where appropriate.	AC-4, SC-7	NAUT	45 C.F.R. §§ 164.308(a)(4)(ii)(B), 164.310(a)(1), 164.310(b), 164.312(a)(1), 164.312(b), 164.312(c), 164.312(c),	A.13.1.1, A.13.1.3, A.13.2.1
		PR.AC-6: Identities are proofed and bound to credentials and asserted in interactions when appropriate.	AC-2, AC-3, AC-5, AC-6, AC-16, AC-19, AC-24, IA-2, IA-4, IA-5, IA-8, PE-2, PS-3	AUTH, CNFS, EMRG, NAUT, PLOK, SGUD	Not applicable	A.6.1.2, A.7.1.1, A.9.1.2, A.9.2.2, A.9.2.3, A.9.2.5, A.9.2.6, A.9.4.1, A.9.4.4
	Data Security (PR.DS)	PR.DS-1: Data at rest is protected.	SC-28	IGAU, STCF	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(b)(1), 164.310(d), 164.312(a)(1), 164.312(a)(2)(iii), 164.312(a)(2)(iv), 164.312(b), 164.312(c), 164.312(d), 164.314(b)(2)(i)	A.8.2.3

	NIST Cyberse	curity Framework Version 1.1		Sector-Spe	Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001	
		PR.DS-2: Data in transit is protected.	SC-8	IGAU, TXCF	45 C.F.R. §§ 164.308(b)(1), 164.308(b)(2), 164.312(e)(1), 164.312(e)(2)(i), 164.312(e)(2)(ii), 164.314(b)(2)(i)	A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3	
		PR.DS-3: Assets are formally managed throughout removal, transfers, and disposition.	CM-8, MP-6, PE-16	Not applicable	45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.310(a)(2)(ii), 164.310(a)(2)(iii), 164.310(a)(2)(iv), 164.310(d)(1), 164.310(d)(2)	A.12.3.1	
		PR.DS-4: Adequate capacity to ensure availability is maintained.	AU-4, CP-2, SC-5	AUDT, DTBK	45 C.F.R. §§ 164.308(a)(1)(ii)(A), 164.308(a)(1)(ii)(B), 164.308(a)(7), 164.310(a)(2)(i), 164.310(d)(2)(iv), 164.312(a)(2)(ii)	A.12.3.1	

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.DS-5: Protections against data leaks are implemented.	AC-4, AC-5, AC-6, PE-19, PS-3, PS-6, SC-7, SC-8, SC-13, SC-31, SI-4	AUTH, CNFS, STCF, TXCF, TXIG	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(3), 164.308(a)(4), 164.310(b), 164.310(c), 164.312(a), 164.312(e)	A.6.1.2, A.7.1.1, A.7.1.2, A.7.3.1, A.8.2.2, A.8.2.3, A.9.1.1, A.9.1.2, A.9.2.3, A.9.4.1, A.9.4.4, A.9.4.5, A.13.1.3, A.13.2.1, A.13.2.3, A.13.2.4, A.14.1.2, A.14.1.3
		PR.DS-6: Integrity checking mechanisms are used to verify software, firmware, and information integrity.	SI-7	IGAU	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.312(b), 164.312(c)(1), 164.312(c)(2), 164.312(e)(2)(i)	A.12.2.1, A.12.5.1, A.14.1.2, A.14.1.3
		PR.DS-7: The development and testing environment(s) are separate from the production environment.	CM-2	CNFS	45 C.F.R. § 164.308(a)(4)	A.12.1.4
	Information Protection Processes and Procedures (PR.IP)	PR.IP-4: Backups of information are conducted, maintained, and tested periodically.	CP-4, CP-6, CP-9	DTBK	45 C.F.R. §§ 164.308(a)(7)(ii)(A), 164.308(a)(7)(ii)(B), 164.308(a)(7)(ii)(D), 164.310(a)(2)(i), 164.310(d)(2)(iv)	A.12.3.1, A.17.1.2, A.17.1.3, A.18.1.3

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.IP-6: Data is destroyed according to policy.	MP-6	DIDT	45 C.F.R. §§ 164.310(d)(2)(i), 164.310(d)(2)(ii)	A.8.2.3, A.8.3.1, A.8.3.2, A.11.2.7
		PR.IP-9: Response plans (Incident Response and Business Continuity) and recovery plans (Incident Recovery and Disaster Recovery) are in place and managed.	CP-2, IR-8	DTBK	45 C.F.R. §§ 164.308(a)(6), 164.308(a)(7), 164.310(a)(2)(i), 164.312(a)(2)(ii)	A.16.1.1, A.17.1.1, A.17.1.2
		PR.IP-10: Response and recovery plans are tested.	CP-4, IR-3, PM-14	ОТВК	45 C.F.R. § 164.308(a)(7)(ii)(D)	A.17.1.3
		PR.IP-12: A vulnerability management plan is developed and implemented.	RA-3, RA-5, SI-2	MLDP	45 C.F.R. §§ 164.308(a)(1)(i), 164.308(a)(1)(ii)(A), 164.308(a)(1)(ii)(B)	A.12.6.1, A.18.2.2
	Maintenance (PR.MA)	PR.MA-1: Maintenance and repair of organizational assets is performed and logged in a timely manner, with approved and controlled tools.	MA-2, MA-3, MA-5	CSUP, RDMP	45 C.F.R. §§ 164.308(a)(3)(ii)(A), 164.310(a)(2)(iv)	A.11.1.2, A.11.2.4, A.11.2.5

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.MA-2: Remote maintenance of organizational assets is approved, logged, and performed in a manner that prevents unauthorized access.	MA-4	CSUP	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(3)(ii)(A), 164.310(d)(1), 164.310(d)(2)(ii), 164.310(d)(2)(iii), 164.312(a), 164.312(a)(2)(ii), 164.312(a)(2)(iv), 164.312(b), 164.312(d), 164.312(e)	A.11.2.4, A.15.1.1, A.15.2.1
		PR.PT-1: Audit/log records are determined, documented, implemented, and reviewed in accordance with policy.	AC-4, AC-17, AC-18, CP-8, SC-7	AUDT	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(5)(ii)(C), 164.310(a)(2)(iv), 164.310(d)(2)(iii), 164.312(b)	A.12.4.1, A.12.4.2, A.12.4.3, A.12.4.4, A.12.7.1
	Protective Technology (PR.PT)	PR.PT-3: The principle of least functionality is incorporated by configuring systems to provide only essential capabilities.	AC-3, CM-7	AUTH, CNFS	45 C.F.R. §§ 164.308(a)(3), 164.308(a)(4), 164.310(a)(2)(iii), 164.310(b), 164.310(c), 164.312(a)(1), 164.312(a)(2)(i), 164.312(a)(2)(ii), 164.312(a)(2)(iv)	A.9.1.2

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		PR.PT-4: Communications and control networks are protected.	AC-4, AC-17, AC-18, CP-8, SC-7	DTBK	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.312(a)(1), 164.312(b), 164.312(e)	A.13.1.1, A.13.2.1
DETECT (DE)	Anomalies and Events (DE.AE)	DE.AE-1: A baseline of network operations and expected data flows for users and systems is established and managed.	AC-4, CA-3, CM-2, SI-4	AUTH, CNFS	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.312(b)	None
	(DE.AE)	DE.AE-2: Detected events are analyzed to understand attack targets and methods.	CP-2, IR-4, RA-3, SI-4	DTBK	45 C.F.R. § 164.308(6)(i)	A.16.1.1, A.16.1.4
	Security Continuous	DE.CM-1: The network is monitored to detect potential cybersecurity events.	AC-2, AU-12, CA-7, CM-3, SC-5, SC-7, SI-4	AUTH, CNFS, EMRG, MLDP	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(5)(ii)(B), 164.308(a)(5)(ii)(C), 164.308(a)(8), 164.312(b), 164.312(e)(2)(i)	None
	Monitoring (DE.CM)	DE.CM-2: The physical environment is monitored to detect potential cybersecurity events.	CA-7, PE-3, PE-6, PE-20	MLDP	45 C.F.R. §§ 164.310(a)(2)(ii), 164.310(a)(2)(iii)	None
		DE.CM-4: Malicious code is detected.	SI-3	IGAU, MLDP, TXIG	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(5)(ii)(B)	A.12.2.1

	NIST Cyberse	curity Framework Version 1.1		Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
		DE.CM-6: External service provider activity is monitored to detect potential cybersecurity events.	CA-7, PS-7, SA-4, SA-9, SI-4	RDMP	45 C.F.R. § 164.308(a)(1)(ii)(D)	A.14.2.7, A.15.2.1
		DE.CM-7: Monitoring for unauthorized personnel, connections, devices, and software is performed.	AU-12, CA-7, CM-3, CM-8, PE-3, PE-6, PE-20, SI-4	AUDT, CNFS, PAUT, PLOK, MLDP, NAUT, SGUD	45 C.F.R. §§ 164.308(a)(1)(ii)(D), 164.308(a)(5)(ii)(B), 164.308(a)(5)(ii)(C), 164.310(a)(1), 164.310(a)(2)(ii), 164.310(a)(2)(iii), 164.310(b), 164.310(d)(1), 164.310(d)(1), 164.310(d)(2)(iii), 164.312(b), 164.314(b)(2)(i)	None
		DE.CM-8: Vulnerability scans are performed.	RA-5	MLDP	45 C.F.R. §§ 164.308(a)(1)(i), 164.308(a)(8)	A.12.6.1
RESPOND (RS)	Response Planning (RS.RP)	RS.RP-1: Response plan is executed during or after an event.	CP-2, CP-10, IR-4, IR-8	DTBK, SGUD, MLDP	45 C.F.R. §§ 164.308(a)(6)(ii), 164.308(a)(7)(i), 164.308(a)(7)(ii)(A), 164.308(a)(7)(ii)(B), 164.308(a)(7)(ii)(C), 164.310(a)(2)(i), 164.312(a)(2)(ii)	A.16.1.5

NIST Cybersecurity Framework Version 1.1				Sector-Specific Standards and Best Practices		
Function	Category	Subcategory	NIST SP 800-53 Revision 4	IEC TR 80001-2-2	HIPAA Security Rule	ISO/IEC 27001
	Improvements (RS.IM)	RS.IM-1: Response plans incorporate lessons learned.	CP-2, IR-4, IR-8	DTBK	45 C.F.R. §§ 164.308(a)(7)(ii)(D), 164.308(a)(8), 164.316(b)(2)(iii)	A.16.1.6
		RS.IM-2: Response strategies are updated.	CP-2, IR-4, IR-8	<b>DTBK</b>	45 C.F.R. §§ 164.308(a)(7)(ii)(D), 164.308(a)(8)	None
RECOVER (RC)	Recovery Planning (RC.RP)	RC.RP-1: Recovery plan is executed during or after an event.	CP-10, IR-4, IR-8	DTBK	45 C.F.R. §§ 164.308(a)(7), 164.310(a)(2)(i)	A.16.1.5

# **APPENDIX A REFERENCES**

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- G. O'Brien et al., Securing Electronic Health Records on Mobile Devices, National Institute of Standards and Technology (NIST) Special Publication (SP) 1800-1, Gaithersburg, Md., Jul. 2018.
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# APPENDIX B ACRONYMS AND ABBREVIATIONS

ΑΑΜΙ	Association for Advancement of Medical Instrumentation	
ΑΡΙ	Application Programming Interface	
BMI	Body Mass Index	
DE	Detect	
FDA	Food and Drug Administration	
FIPS	Federal Information Processing Standard	
GRC	Governance, Risk, and Compliance	
HDO	Health Delivery Organization	
HHS	Department of Health and Human Services	
ΗΙΡΑΑ	Health Insurance Portability and Accountability Act	
ID	Identify	
IdAM	Identity and Access Management	
IDS	Intrusion Detection System	
IEC	International Electrotechnical Commission	
IPS	Intrusion Prevention System	
ISO	International Organization for Standardization	
ІТ	Information Technology	
NCCoE	National Cybersecurity Center of Excellence	
NIST	National Institute of Standards and Technology	
PAM	Privileged Access Management	
PR	Protect	
RC	Recover	
RPM	Remote Patient Monitoring	
RS	Respond	
SDK	Software Development Kit	
SP	Special Publication	
TR	Technical Report	
VPN	Virtual Private Network	