yubico

Phishing-resistant authentication and compliance for healthcare organizations

How the YubiKey helps healthcare organizations meet regulatory requirements

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Authentication in healthcare

Overcoming obstacles to digital transformation

Over the past decade, healthcare organizations have adopted digital tools to improve patient and population health. In reaction to this digital transformation, we are seeing new and revised health regulations that are changing expectations for ensuring the security and privacy of protected health information (PHI).

While the Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires "reasonable" physical, technical, and administrative safeguards for data security and authentication, the lack of standards has meant that many healthcare organizations have continued to rely on passwords.¹ However, with 61% of data breaches traced back to credentials in some way, it is clear that passwords are no longer the answer.²

The COVID-19 pandemic put pressure on healthcare organizations to ramp up to increased patient load, but exceptions were made to the HIPAA Security Rule to keep organizations up and running through the pandemic, which are now becoming problematic.³ Since 2020, healthcare organizations have seen an increase in cyber attacks and data breaches. The risks of remote and virtual services, including care and clinical trials, need to be addressed for security and for compliance. As we will illustrate in this white paper, regulatory change is on the horizon—and phishing-resistant multi-factor authentication is likely to be a part of this change.

Phishing-resistant authentication can be challenging for healthcare organizations, including healthcare payers, providers, pharmaceutical, and service providers. Despite the myriad of regulatory and internal pressures to protect the privacy and security of PHI and the secrecy of intellectual property (IP), common obstacles to improving authentication include infrastructure complexity, shared or BYOD devices, cost, sanitation, and workflow challenges.

The YubiKey, a FIPS 140-2 validated hardware security key, has emerged as a convenient and scalable solution for modern phishing-resistant authentication across a variety of healthcare situations.



61%

of data breaches are traced back to credentials

\$10.93 million

average cost of breach, the most expensive industry⁹



more cyberattacks on healthcare in 2020 compared to 2019¹⁰



of attacks in healthcare were ransomware¹¹

Evolving cyber attack landscape

Healthcare is one of the most highly targeted industries by cyber criminals, due in part to the high value of PHI as well as the potential for a quick ransomware payout. There is no question that the events of the global COVID-19 pandemic made the situation worse, as reflected by a 55.1% increase in breaches in 2020.⁴

The transition to remote work introduced new weaknesses, including unsecured home networks, unpatched devices, shared devices, and weak/reused passwords. In 2020, cyber attacks in healthcare rose to 239.4 million attempted attacks; of this number, there were 816 attempted attacks per endpoint—a 9,851% increase from 2019.⁵

Data breaches in any organization are costly, but in healthcare the costs can be devastating. While the healthcare industry faces the highest average cost of a data breach, \$10.93 million, this cost does not reflect the impact an IT failure or ransomware threat can have on patient care.⁶ We saw Germany explore the potential link between a patient death and a ransomware event.⁷ In 2018, a Finland-based private psychotherapy practice covered up a cyber attack on its patient record system. That breach led to an extortion attack two years later in which patients were directly targeted by cyber criminals (not to mention the subsequent bankruptcy and total collapse of the practice)⁸. In the pharmaceutical industry, the loss of IP can directly impact the race to market and set R&D back by years.

Cyber attacks come in many forms, from malware and DDoS attacks to phishing and ransomware. Credentials are the most sought after type of data in the initial phase of a cyber attack, with threat actors moving laterally to find sensitive and valuable data or compromise systems.

C Unfortunately, the complexity and challenge to secure health care is daunting. We face all the threats of other industries, things like phishing, malware propagation, identity theft, insider threats and more. To that, we can add the targeting of health devices and the systems providing patient care, a large percentage of which is legacy and outdated technology. To compound the difficulty, cyber criminal adversaries appear unwilling to give us a break; they are more than willing to risk harming patients and to profit from misery.¹²

-Esmond Kane, CISO of Steward Health Care

It is unsettling to know that hackers are not only eager to take advantage of the pandemic crisis, but that they're feeding off of a highly profitable supply chain of stolen digital assets to do so. While hospitals are the target, the patient is ultimately the true victim of this cyber attack machine.

- David Sygula for CPO Magazine¹⁶

SolarWinds & Blackbaud attacks underscore supply chain risk

In 2020, a major threat actor backed by the Russian government penetrated thousands of organizations. It created a backdoor in the SolarWinds Orion Software, which in turn installed malware to spy on over 18,000 product customers, including hospitals and technology companies, opening up the risk for further supply chain risk.¹³ 2020 also saw the hack and attempted ransomware of cloud provider Blackbaud that has been linked to over 100 healthcare data breaches and affected over 12.3 million patient records.¹⁴

The SolarWinds attack went undetected for months, in part due to the supply chain attack method used to move laterally between systems and gain additional privileges. Similarly, the Blackbaud attack began on February 7th 2020, but went undetected until May and uncommunicated until July 2020.¹⁵

Of note in the SolarWinds attack is the supposed misuse of Identity and Access Management (IAM) systems like single sign on, network logon systems, SAML/ OAuth/OIDC federation systems, and the like.

With SolarWinds and Blackbaud, and many other breaches, you'll find that stolen credentials cause the initial breach. Once the attacker gains access to the victim's environment, they diversify their access to help maintain a persistent foothold.



In this white paper, we will take a look at existing and emerging regulations and how the YubiKey, a FIPS 140-2 validated and NIST 800-63 AAL3 authenticator, can help healthcare organizations rapidly and seamlessly deploy modern phishingresistant authentication take an immediate stand against cyber attacks while preparing for tomorrow's compliance challenges. For years, achieving a balance between high security and ease of use was near impossible, but new authentication technologies are finally bridging the gap. With the availability of passwordless login and security keys, it's time for the healthcare industry to step up their security options.

- Stina Ehrensvärd, Co-Founder

The solution

o L

YubiKey is the **only** solution that is proven to stop 100% of account takeovers in independent research.¹⁷

Smart Card/PIV

<1>

Out-of-the-box native integration for the Microsoft environment using Smart Card/PIV functionality based on the NIST SP 800-73 specification.

FIDO2 & FIDO U2F

Phishing-resistant two-factor, multi-factor and passwordless authentication public key crypto to protect against phishing, session hijacking, man-in-the-middle, and malware attacks.

One time passcodes

Integrate Yubico OTP natively with the free YubiCloud authentication service or program unique TOTP or HOTP secrets.

Modern phishing-resistant authentication with the YubiKey

Legacy multi-factor authentication solutions including mobile authentication such as SMS, OTP, and push notifications are better than just username and passwords, but are still not 100% effective against mitigating risks from evolving cyber risk vectors. In comparison, hardware security keys based on modern FIDO protocols are proven to stop successful phishing attacks and account takeovers in their tracks.

The YubiKey is a hardware security key manufactured by Yubico, that offers easyto-use two-factor, multi-factor, and passwordless authentication at scale, helping healthcare organizations be compliant to MFA requirements across various regulations, certifications, and frameworks. Organizations receive a choice of FIPS 140-2 validated keys Overall Level 1 (Certificate #3907) and Level 2 (Certificate #3914), Physical Security Level 3, and can also avail of the YubiKey Bio Series -FIDO Edition, a gold standard in biometric authentication.

With the YubiKey, healthcare organizations can:

- Stop account takeovers and prevent man-in-the-middle attacks with superior hardware cryptographic security
- Provide unmatched simplicity for users with 4x faster logins that ensure proof of presence and possession
- Comply with existing and emerging regulations such as HIPAA, GDPR, and 21 CFR Part 11
- Support secure remote access and secure access to Electronic Health Records (EHRs)
- Support pharmaceutical use cases, including NFC for sterile environments and clean rooms, and the storage of SAFE-BioPharma certified identity credentials

By supporting multiple authentication protocols on a single YubiKey, such as OTP, OpenPGP, and phishing-resistant authentication protocols such as Smart Card, FIDO U2F and FIDO2/WebAuthn, the YubiKey offers healthcare organizations the flexibility to deploy phishing-resistant authentication using a single key across a variety of legacy and modern infrastructures.

To authenticate, users simply plug their security key into their desktop or laptop and touch to authentication, or tap their security key against devices such as a tablet or a phone. Where sterile environments are important, the YubiKey can be combined with a wearable to leverage NFC communication for a touchless authentication experience.

YubiKeys can be used to stop phishing attacks and account takeovers for a variety of internal and patient use cases including privileged users such as doctors, nurses and pharmacists, call center workers, hybrid and remote workers, virtual patient health, electronic prescriptions, data sharing, and virtual R&D.

Healthcare regulatory compliance

How the YubiKey for modern phishing-resistant authentication addresses regulatory requirements

The healthcare industry is subject to strict security requirements and an increasing regulatory burden. The number of global regulations continues to increase, with new changes emerging to industry frameworks and standards as well as state, federal and global levels.

The YubiKey helps healthcare organizations comply with existing and emerging regulations with modern, phishing-resistant authentication that offers highest-assurance two-factor, multi-factor, and passwordless authentication. The following sections outline the various healthcare regulations and the YubiKey capabilities that help organizations satisfy regulatory requirements related to authentication.

HIPAA Security Rule, HITECH, & HIPAA Safe Harbor

The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, includes base standards for the security and privacy of protected health information (PHI), further supported by its final Security Rule in 2003, the HITECH Act (Health Information Technology for Economic and Clinical Health) of 2009, and the most recent HIPAA Safe Harbor Bill of 2021.

In the HITECH act, a data breach in healthcare is defined as the "unauthorized acquisition, access, use, or disclosure of protected health information," (Sec. 13400 1A) clearly underscoring the importance of authentication in the provisioning of access.¹⁹ The most recent Safe Harbor Bill asks regulators to consider the NIST framework when looking at audits and fines, placing the strict NIST standards as the new goal post for authentication.²⁰

Requirement	Section	YubiKey capabilities
Facility Access Controls	HIPAA 4.10	Hardware-backed MFA access controlsCentralized authorization policies to control accessYubiKey as smart card
Workstation Security	HIPAA 4.12	 MFA through multiple protocols Something you know: PIN (FIDO2, SmartCard) Something you have: private key stored on the YubiKey
Access Controls	HIPAA 4.14	 Support password / PIN for MFA (FIDO U2F, FIDO2 or OTP)



of healthcare organizations believe their security program is successful in meeting compliance regulations¹⁸

Requirement	Section	YubiKey capabilities
Person or Entity Authentication	HIPAA 4.17	 Hardware-backed MFA access controls Centralized authorization policies to control access YubiKey as smart card MFA through multiple protocols (Smart Card, OTP,
Ensuring security methods to ensure appropriate authorization	HITECH 3001 3(A)(iv)	 FIDO U2F, FIDO2, OpenPGP) Support password / PIN for MFA (FIDO U2F, FIDO2 or OTP)
Recognition of security practices, including the NIST Cybersecurity Framework	Safe Harbor Sec. 13412	 Multiple-protocol support OTP, OATH, HOTP, U2F, PIV, Open PGP 2FA and MFA options Multi-factor cryptographic device Hardware-based authenticator

What's next for HIPAA?

While HIPAA began with merely "reasonable" physical, technical, and administrative safeguards for data security and authentication, there has been a push to see greater specificity. In addition to the 2021 Cybersecurity Safe Harbor Provision, there are proposed modifications to the HIPAA Privacy Rule, providing patients with greater access to data, potentially introducing new risks and vulnerabilities.²¹

The NIST (National Institute of Standards and Technology) provides guidance for HIPAA implementation, but this document dates to 2008, pre-dating many of the more recent NIST special publication (SP) requirements, including those of SP 800-63 and SP 800-53 (Security and Privacy Controls for Information Systems and Organizations). NIST is preparing to update its HIPAA guidance for the first time in 10 years.²²

The NIST Cybersecurity Framework suggests phishing-resistant authentication, including a multi-factor combination of something a user *owns*, *knows*, and *is*. NIST further clarifies these in SP 800-63, Digital Identity Guidelines. Currently, only 44% of healthcare organizations adhere to NIST.²³ YubiKey is an AAL3 certified authenticator, providing the highest level of confidence.

NIST NIST

With HIPAA transitioning toward NIST, let's take a look specifically at the NIST cybersecurity framework standards around authentication.

Standard	NIST SP FIPS	YubiKey capabilities	YubiKey certification level
Digital identity guidelines define authenticator assurance level (AAL)	SP 800-63	 Multiple-protocol support OTP, OATH, HOTP, FIDO U2F, PIV, Open PGP 2FA and MFA options Multi-factor cryptographic device Hardware-based authenticator Touch-button test of user presence 	AAL3
Guidelines for the protection of controlled unclassified information	SP 800-171	 Hardware-backed MFA access controls YubiKey used as smart card Centralized authorization policies to control access 	
Security and privacy controls for information systems and organizations	SP 800-53	YubiKey used as smart cardCentralized authorization policies to control access	
Security requirements for cryptographic modules	FIPS 140-2	 Cryptographic module supports multiple protocols YubiKey used as smart card Touch-button test of user presence Time or hash-based synchronous OTP FIDO U2F, FIDO2 	 Overall Level 1 #3907 Overall Level 2 #3914 Physical Security Level 3 #3517

21 CFR Part 11

The Code of Federal Regulations (CFR) establishes regulations on electronic records and electronic signatures (ERES) under the FDA, with Part 11 defining which controls, systems, audits, measures, signatures, and documentation are acceptable for pharmaceutical development and medical device manufacturing.²⁴ The regulations were updated in 2020 specifically to address the minimum requirements for systems used to process digitally signed orders.²⁵ Other minimum requirements related to validation and audit have been provided in supplementary guidance.²⁶

Requirement	Section	YubiKey capabilities
Limit system access to authorized individuals	§ 11.10 (d) ; (k)	 Hardware-backed MFA access controls YubiKey used as smart card Centralized authorization policies to control access
Electronic signatures and system access, validation	§ 11.10 (a) ; (h)	Hardware-backed MFA access controlsYubiKey used as smart card

The SUPPORT Act / EPCS

In 2018, a revised SUPPORT Act aimed to better control opioid abuse with the introduction of Section 2003, a requirement to use an EPCS (Electronic Prescription for Controlled Substances) application for the prescribing of controlled substances under Medicare Part D. The amended SUPPORT Act came into effect on January 1, 2021, with CMS delaying enforcement of penalties under an extended grace period to January 1, 2022.²⁷

In addition to the SUPPORT Act at the Federal level, 24 states have State-Specific EPCS requirements, with several other states with upcoming and proposed legislation.²⁸

Requirement	Section	YubiKey capabilities
Identity controls	85 FR 47154	 2FA and MFA options Multi-factor cryptographic device Hardware-based authenticator Touch-based test of user presence
Digital signature with cryptographic module of at least FIPS 140-2 Security Level 1	85 FR 47154 §1311.08	 Hardware-backed MFA access controls YubiKey used as smart card Multi-factor cryptographic device FIPS Level 2+

Requirement	Section	YubiKey capabilities
Two-factor authentication with FIPS 140-2 Security Level 1 hard token with 2FA at minimum	85 FR 47154, §1311.115	 2FA and MFA options Multi-factor cryptographic device Hardware-based authenticator FIPS Level 2+ Touch-button test of user presence MFA through multiple protocols (Smart Card, OTP, FIDO U2F, FIDO2, OpenPGP)
Hard token must be FIPS 140-2 Security Level 1 and be separate from the mobile device for access	DEA Statement on Mobile Devices for EPCS ²⁹	 FIPS Level 2+ Cryptographic module supports multiple protocols YubiKey used as smart card Touch-button test of user presence Private key stored on the YubiKey

CURES Act Final Rule

The ONC Cures Act Final Rule (the 21st Century Cures Act), was designed to support greater access and exchange of electronic health information.³⁰ The following requirements apply to any Health IT Module currently looking to meet the Certified Health IT Product requirements.

Requirement	Section	YubiKey capabilities
Encrypt authentication credentials	§170.315(d)(12)	Multi-factor cryptographic devicePrivate key stored on the YubiKey
Multi-factor authentication (MFA) consistent with NIST SP 800-63B	§170.315(d)(13)	 2FA and MFA options Multi-factor cryptographic device Hardware-based authenticator Validated to NIST SP 800-63-3 AAL 3 requirements MFA through multiple protocols (Smart Card, OTP, FIDO U2F, FIDO2, OpenPGP)



The European Union General Data Protection Regulation (GDPR) came into effect in 2018, mandating that organizations that offer goods or services (including healthcare) to EU citizens meet data protection and privacy standards, provided those healthcare organizations have more than 250 employees. GDPR fines are among the most severe -4% of global annual turnover or \notin 20 million, whichever is higher.³¹ There are no exceptions for healthcare organizations that are compliant with HIPAA.

Authentication is key to securing computer systems and is usually the very first step in using a remote service or facility, and performing access control.

-European Union Agency for Cybersecurity (ENISA)³²

Requirement	Section	YubiKey capabilities
Data protection impact assessment	Article 35	Hardware-backed MFA access controls
Security of processing	Article 32	 Centralized authorization policies to control access Multi-factor cryptographic device
Data protection by design and by default	Article 25	

CCPA, 23 NYCRR 500 & other state laws

The California Consumer Privacy Act (CCPA) was the first US-based data privacy bill to adopt stringent measures in line with the GDPR. Followed by the California Privacy Right Act (2023) amendment, which introduces even more requirements, other states are following suit, including the recent Virginia Consumer Data Protection Act (CDPA), that came into effect January 1, 2023.³⁷

These regulations require financial institutions to implement "appropriate" and "reasonable" precautions to protect and secure data.³⁸

Main Features



Hardware-backed MFA access controls

- Something you know:
 PIN (for FIDO2, Smart Card)
- Something you have (Private key stored on the YubiKey)



Support password / PIN for MFA (FIDO U2F, FIDO2 or OTP)

U.S. executive order on improving the Nation's cybersecurity (EO)

Having phishing-resistant authentication is a foundational security component of a Zero Trust architecture. Yubico and YubiKeys help fill the gap, for example, where weak passwords have been used, by providing validated, phishingresistant security keys.

> -John Kindervag, Creator of Zero Trust

The recent number of attacks on critical systems has triggered increased regulatory pressure from the U.S. Federal government. On May 12 2021, the Biden administration issued an Executive Order 14028 on "Improving the Nation's Cybersecurity."³⁷

This new order requires agencies and organizations in the public and private sector who work with the government, including financial services. The order includes the requirement to adopt Zero Trust frameworks within 60 days, as well as multi-factor authentication and encryption for data at rest and in flight within 180 days.³⁸

The Zero Trust emphasis in the order demonstrates the high priority status the government is placing on modernizing agencies' infrastructure. Phishing-resistant, modern authenticators, like the YubiKey, will be essential to reaching Zero Trust goals while providing a low-friction and secure user experience.

Main Features



Hardware-backed MFA access controls



Centralized authorization policies to control access

What are passkeys?

Passkeys are a new term in the industry, but the concept is not new. Passkeys are simply passwordless-enabled FIDO credentials that enable a move away from passwords, delivering phishing resistance. There are different passkey implementations:

- Synced passkeys live on a smartphone, tablet or laptop and can be copied between devices. While synced passkeys enable easier account recovery in the case of a lost or stolen phone or laptop, the FIDO credential is harder to track, so it is suitable for lower security assurance scenarios.
- Device-bound passkeys offer greater manageability than synced passkeys, and therefore better suited for the enterprise.

However, there are different types of devicebound passkeys and those that live in hardware security keys are known to offer the highest security assurance and provide enterprises with the trusted credential lifecycle management and attestation abilities they need to have the phishingresistantest security, the simplest user onboarding and credential/ account recovery experience across devices and platforms, and stay in compliance with the most stringent requirements across industries.

YubiKey used as

smart card



The YubiKey 5 Series

From left to right: YubiKey 5 NFC, YubiKey 5C NFC, YubiKey 5Ci, YubiKey 5C, YubiKey 5 Nano and YubiKey 5C Nano.



The YubiKey 5 FIPS Series

From left to right: YubiKey 5 NFC FIPS, YubiKey 5C NFC FIPS, YubiKey 5Ci FIPS, YubiKey 5C FIPS, YubiKey 5 Nano FIPS and YubiKey 5C Nano FIPS.



The YubiKey Bio - FIPS Series From left to right: YubiKey Bio USB-A and YubiKey Bio USB-C

By integrating directly with the Yubico SDK, Allscripts is improving the multi-factor authentication (MFA) experience that is needed to comply with the electronic prescription of a controlled substance (EPCS).

> -Steve Pascht, Allscripts Senior Solutions Manager

YubiKeys offer a bridge to passwordless for healthcare organizations

It is clear from the cyber attack landscape that passwords are no longer the answer. It is also clear that healthcare regulations are recognizing this fact, with a clear move toward phishing-resistant authentication such as FIDO2—true passwordless authentication. However, going passwordless is a journey, not an overnight transition.

With the YubiKey, healthcare organizations can implement FIDO2 passwordless, smart card passwordless or a hybrid strategy, depending on the infrastructure and use cases that need to be addressed. As the passwordless ecosystem continues to expand, YubiKeys are perfectly designed to help financial organizations bridge the transitory period from modern phishing-resistant MFA to passwordless. YubiKeys support the broadest set of authentication protocols, enabling a single security key to work across a wide range of applications and services, regardless of where healthcare organizations are in their phishing-resistant authentication and passwordless journey.

Yubico offers the fastest way to meet today's complex compliance and security requirements, while accelerating your journey to passwordless. Take a stand against cyberattacks and future-proof your compliance stance with the YubiKey.

CASE STUDY

How Allscripts achieved EPCS compliance with the YubiKey

Due to the complex compliance requirements and fast-moving nature of hospitals or other healthcare environments, it's important that doctors, nurses, and medical staff have quick, yet secure, access to critical systems and information. However, mobile devices are a source of privacy risk in healthcare, responsible for up to 25% of breaches in previous years.

Mobile phones are not purpose-built for security. They are multi-purpose computing devices that, by nature, have a larger attack surface. An external, single-purpose authentication device like the YubiKey significantly minimizes the level of risk exposure to malware or phishing attacks.

Allscripts, a leader in healthcare information technology solutions, is actively working with the Yubico Android SDK to make YubiKey support available in its Allscripts Sunrise[™] Mobile and Allscripts Professional[™] EHR Mobile and Desktop.

"By integrating directly with the Yubico SDK, Allscripts is improving the multifactor authentication (MFA) experience that is needed to comply with the electronic prescription of a controlled substance (EPCS)," said Steve Pascht, Allscripts Senior Solutions Manager. "It's easier for providers to use hard tokens on mobile and desktop platforms by simply plugging in—and eventually tapping—the YubiKey without having to read, remember, re-type, or copy and paste OTP codes when prescribing controlled substances."

YubiKey authentication is up to four times faster than copying and pasting onetime codes. Not only is this a more preferred and enjoyable user experience, but it has also been shown to reduce support costs by up to 92%.⁴¹



Summary

Due to the growing threat of cyber attacks, healthcare regulations are moving to adopt phishing-resistant zero trust frameworks, with all signs pointing to phishing-resistant authentication in line with NIST SP 800-63.

Today, globally accepted standards such as FIDO2/WebAuthn are helping healthcare organizations and their supply chains to combat the threats of cyber attacks such as phishing, ransomware, and account takeovers.

Easy, efficient, phishing-resistant authentication is finally a reality with the YubiKey. Designed to be cost effective, user friendly, and portable, the YubiKey provides a modern, phishing-resistant authentication solution for the most highly sensitive patient information, for the strict requirements of digital identity verification in sterile environments, and EPCS requirements for e-prescribing.

Trust the YubiKey to secure your healthcare organization and supply chain.



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About Yubico

Yubico (Nasdaq First North Growth Market Stockholm: YUBICO) is the inventor of the YubiKey, a hardware security key that is the gold standard in phishingresistant multi-factor authentication (MFA). Yubico's solutions offer organizations and users deployment expertise and operational flexibility as YubiKeys work across hundreds of consumer and enterprise applications and services.

Yubico is a creator and core contributor to the FIDO2/passkey, WebAuthn, and FIDO Universal 2nd Factor (U2F) open authentication standards, and is a pioneer in delivering modern, hardware-based passkey authentication security at scale to customers in over 160 countries.

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