

Using Digital Transaction Management to Transform Patient Care

Conversations with health plans and providers about digital business processes often begin with a single question: “Is it HIPAA compliant?” With Meaningful Use fueling EHR adoption, in addition to the need for a secure, auditable solution, it is no wonder that regulations are top of mind for healthcare and life science professionals. DocuSign is committed to helping our customers meet compliance requirements across all industry practices, and we have already seen providers, health plans, medical device manufacturers and biopharmaceutical companies adopt DocuSign in a HIPAA-compliant manner.

This overview provides guidance and answers to common questions regarding HIPAA and other regulations governing the use of electronic documents and signatures in healthcare and life sciences organizations.

Understanding HIPAA

How does HIPAA impact me?

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) stipulates requirements for managing electronic health care records and transactions. It chiefly concerns the privacy and security of Protected Health Information (PHI).
- PHI is typically used for patient identification and treatment. It includes information such as demographic data, medical history, insurance details, and lab results.
- While technology providers like DocuSign provide solutions that meet HIPAA compliance standards, healthcare organizations are ultimately responsible for implementing policies and procedures to ensure that these solutions are deployed in a compliant way.

How does DocuSign enable HIPAA compliance?

Using the DocuSign Digital Transaction Management platform increases the reliability, integrity, availability, and authenticity of records and signatures. DocuSign’s solution allows customers to electronically sign documents in full compliance with ESIGN, UETA, and the Health Insurance Portability and Accountability

Act of 1996 (HIPAA). When you implement electronic signatures from DocuSign, you will know that your signature processes are backed by ISO27001 security certification, anti-tampering controls, and a fully traceable audit trail.

What are implications of the HITECH Act and HIPAA Omnibus Rule?

HIPAA compliance requires that PHI (Protected Health Information) is securely transmitted and stored. The HITECH Act, enacted in 2009, extended these protections to include transmission of electronic records and data.

The HIPAA Omnibus Rule, enacted in 2013, put further safeguards on PHI by extending requirements about PHI privacy and security to Business Associates (BA). This established the need for Business Associates, contractors whose products or services access, create, receive, maintain or transmit PHI, to enter into agreements with HIPAA covered entities. These Business Associate Agreements (BAAs) are legally binding documents to ensure BA compliance with use and protection of electronic PHI.

Although DocuSign does not have access to any PHI, it may hold PHI in encrypted form on its servers, and as such is a Business Associate (BA) and has entered into agreements with numerous HIPAA covered entities.

Protecting PHI

What does DocuSign do with PHI? How do you share it?

- DocuSign provides full document encryption to ensure the confidentiality of your data. Documents stored in our ISO 27001 certified and SSAE 16 audited data centers are encrypted with the AES-256 standard and use 256-bit SSL document transmission.
- Only you and those you authorize have access to your documents. Your content stays confidential, including from DocuSign—employees never have access to your content.
- It is the responsibility of each HIPAA covered entity to ensure that PHI stored in encrypted documents is accessed and shared in accordance with HIPAA regulations.

To maintain compliance under HIPAA, what level of authentication do I need to use to make sure the person I am sharing PHI with is actually the person they say they are?

- The level of authentication that is right for your organization depends on your business practices and needs.
- In addition to standard email address authentication, DocuSign offers an industry-leading choice of authentication services including SMS authentication, biometric voice prints, and knowledge-based authentication.
- This flexibility in matching the level of authentication to transaction risk is a key capability for both legal enforceability and complying with regulations in healthcare.
- To decide what level of authentication is right for you, review our white paper, [“Best Practices for Signer Authentication.”](#)

How does DocuSign support HIPAA compliance within its product and platform?

DocuSign helps healthcare and life sciences customers meet compliance requirements by controlling the signing process and ensuring all information is authenticated and remains both private and secure.

- A complete, court-admissible audit trail accompanies each document.
- DocuSign has achieved the highest level of security certification, ISO/IEC 27001:2005, operates SSAE 16 audited datacenters, and is PCI compliant and TRUSTe certified.
- DocuSign delivers industry-leading data confidentiality with application level AES 256 bit encryption.
- DocuSign’s anti-tampering controls ensure the integrity of customer documents, both in process and completed.
- With near real-time, secure data replication and uptime of 99.99%, customers can count on the availability of DocuSign’s service to complete critical document processes.
- Through DocuSign’s multi-faceted verification of signing events, customers can rely on the authenticity of signers.

- DocuSign provides unique features for non-repudiation, including digital audit trail and chain of custody.

Learn more about DocuSign’s industry leading [security](#) and [legality](#), and [view the latest information on system performance and availability](#).

Has DocuSign signed HIPAA Business Associate Agreements (BAAs) with customers to date?

- Yes, DocuSign has signed BAAs with healthcare and life sciences customers.
- To the extent DocuSign receives or possesses access to Protected Health Information, DocuSign complies in full with the privacy and security requirements of HIPAA applicable to DocuSign as a Business Associate of our customer.
- DocuSign has BAAs in place with customers who have Enterprise accounts and want to be HIPAA compliant. A signed BAA should be in place between DocuSign and the customer prior to transmitting any Protected Health Information (PHI) through DocuSign.

Using eSignatures in Healthcare and Life Sciences

Are electronic signatures on medical forms legally enforceable?

- Medical forms are one type of document that can be signed electronically.
- [Electronic signatures](#) are legally binding in the United States. There are two primary Acts that establish this legality of electronic signatures — [the U.S. Electronic Signatures in Global and National Commerce Act \(ESIGN, 2000\)](#) and the [Uniform Electronic Transactions Act \(UETA, 1999\)](#), which has been adopted by most state legislatures. Both ESIGN and UETA establish that electronic records and signatures carry the same weight and legal effect as traditional paper documents and handwritten signatures. The ESIGN Act states: A document or signature cannot be denied legal effect or enforceability solely because it is in electronic form.
- Not all eSignature solutions are created equal. DocuSign warrants federal ESIGN and UETA Act compliance and was the first digital transaction company to meet this standard. [Learn more about ESIGN and UETA here.](#)

Are electronic signatures HIPAA compliant?

- HIPAA does not mandate the way documents are signed, so an electronic signature does not conflict with the law, but it does not constitute compliance on its own; HIPAA governs the use and transmission of Protected Health Information (PHI) which may or may not be contained in signed documents.
- DocuSign's anti-tampering controls ensure the integrity of customer documents, both in process and completed.

How do I update patient information through DocuSign?

- It is important to note that DocuSign is not an EMR system — it is not designed to be the source of current information about patients. DocuSign is used to complete and sign documents, which represent the information available at a given time. Once a document sent via DocuSign has been completed and signed, it cannot be altered. However, DocuSign can be used to obtain updated information for use in an EMR system. This process can be streamlined by creating templates with set recipient roles, signing tags and information fields for standard forms and documents that you frequently need to complete.
- DocuSign does not have access to information that customers send through its platform. Once all parties have completed a document, information is considered at rest.
- DocuSign employs strong anti-tamper controls to prevent any alteration of your signature or your documents. Our SHA-1 hashing verifies documents have not been modified, and for those who require X.509 digital signatures, our PKI digital certificate technology secures documents and signatures with tamper-evident seals. DocuSign offers DocuSign Express Digital Signatures and also integrates with SAFE-BioPharma to provide digital certificates.

Can I integrate DocuSign into my existing EMR system?

- Yes. A leading children's hospital has integrated DocuSign into their EMR for surgery e-consents. In addition, DocuSign has partnered with SureScripts, a leading healthcare solutions company that purchased Kryptiq whose patient onboarding product integrates DocuSign into patient intake workflows. Kryptiq's product is integrated into several leading EMR systems with other integrations currently in development.

- DocuSign offers an open API that can be used to integrate DocuSign into almost any app, website, or system. However, most EMRs currently operate as closed loop systems, so DocuSign cannot integrate with them unless they choose to work with us and integrate our technology into their solution.

Healthcare Use Cases and Customers

Among healthcare providers, what are the most common use cases for electronically completing documents?

DocuSign healthcare customers are providing high quality, efficient care and spending more time with patients by reducing the time and costs associated with paper-based transactions. Use cases include:

- Patient onboarding
- Hospital intake forms
- Provider agreements
- Consent forms
- Transition of care documents
- Notice of privacy practices
- Vendor/supplier contracts
- Insurance claims processing
- Drug prescriptions
- Lab reports

Call +1.877.720.2040 to learn more about DocuSign solutions that meet your organization's needs.

What types of healthcare organizations are using DocuSign? Who else is using DocuSign?

- Healthcare providers such as New York-Presbyterian are DocuSigning to onboard and treat patients faster, and health plans such as Blue Cross Blue Shield and UnitedHealth Group have increased efficiencies in agent/broker onboarding and member enrollment.
- Boston Scientific, Medtronic, AstraZeneca, and Novartis are among the medical device and pharmaceutical companies DocuSigning to accelerate clinical trials, manage KOL agreements, and streamline supply chain contracts.



- Millions of users have DocuSigned hundreds of millions of documents in 188 countries, including employees at 90% of the Fortune 500.
- Customers across industries and departments are DocuSigning every day, including 14 of the top 15 global pharmaceutical companies, 11 of the top 15 medical device manufacturers, and over 100 hospitals.

Visit our [Healthcare](#) and [Life Sciences](#) solution pages on [docusign.com](#) to learn more about [Digital Transaction Management](#) for your business and read about customer success stories.

Where can I learn more?

- Visit www.docusign.com/healthcare
- Consult HHS resources
 - [Understanding HIPAA Privacy for Covered Entities and Business Associates.](#)
 - [Summary of the HIPAA Privacy Rule](#)



About DocuSign

DocuSign is changing how business gets done by empowering anyone to transact anytime, anywhere, on any device with trust and confidence. DocuSign keeps life moving forward.

For U.S. inquiries: toll free 866.219.4318 | [docusign.com](#)

For EMEA inquiries: phone +44 203 714 4800 | email emea@docusign.com | [docusign.co.uk](#)

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