

HIPAA

VS

HITRUST

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Introduced in 1996, a U.S. federal law that mandates privacy and security standards for certain health data.

INTRODUCED & NATURE

Introduced in 2007, a private framework established by the HITRUST Alliance, integrating multiple security standards (NIST, PCI, ISO, etc.).

Enforced by the U.S. Department of Health and Human Services (HHS), specifically the Office for Civil Rights (OCR).

GOVERNING BODY

Developed and maintained by the HITRUST Alliance, a non-governmental, industry-led organization.

Applies to covered entities (healthcare providers, health plans, clearinghouses) and business associates handling Protected Health Information (PHI).

SCOPE

Can be adopted by any organization handling sensitive data (commonly used in healthcare to demonstrate compliance with HIPAA and other frameworks).

Mandatory for U.S. healthcare entities and their business associates under federal law.

LEGAL REQUIREMENT

Voluntary adoption but widely recognized; often pursued to demonstrate higher-level compliance and security rigor in healthcare and related fields.

Requires risk analysis and ongoing risk management under the HIPAA Security Rule; controls are broadly stated.

RISK ASSESSMENT & CONTROLS

Utilizes detailed, prescriptive controls referencing recognized standards, offering a formal process to either accept, transfer or mitigate.

No official government "HIPAA Certification"; compliance is monitored via complaints or random HHS audits.

CERTIFICATION & AUDIT

Offers HITRUST CSF Certification after a formal assessment by accredited CSF assessors; typically i1 and e1 certification lasts for 1 yr and for r2 for 2 years.

Non-compliance can lead to civil penalties ranging from \$100 to \$50,000 per violation (capped at \$1.5 million annually for repeated violations), and criminal penalties of up to \$250,000 and/or 10 years in jail for willful neglect or malicious intent.

PENALTIES

No direct financial penalties for non-compliance; however, lack of certification can affect business partnerships, trust, and market competitiveness.

Compliance is continuous, as there is no fixed start-to-finish certification pathway.

IMPLEMENTATION TIMELINE

Typically 6-12 months to implement and prepare for a HITRUST audit, depending on organizational size and complexity.

U.S. centric regulation focused on protecting health data of U.S. individuals.

COVERAGE & MARKET

Recognized primarily in the U.S. healthcare market but can be leveraged globally to showcase a robust security and compliance posture.