

Table 2.			
U.S. Healthcare Sector			
Market Regulation (1996-2026)			
Market Sectors	Government Agencies/Laws	Rules & Requirements	
Electronic Health Records (acute care hospitals)	HHS OCR	HIPAA (1996) Compliance	
	HITECH Act (2009)	CEHRT (2011) Standards/Certification	
	CMS	EHR Incentives (Meaningful Use)	
	21st Century Cures Act (2015)	Promoting Interoperability (PI)	
	ONC for HIT Final Rule (2020)	CEHRT Certification (by 2023)	
Cloud Infrastructure	HHS OCR	HIPAA (1996) for PHI data privacy	
	FTC	GLBA (1999) Safeguards	
	FFIEC and SEC	FedRAMP for cloud products	
	CISA	Cybersecurity, SOC-2 Compliance	
	FDA PCCP (2024)	Cloud-based traceability of AI's continuous learning capabilities	
Generative Artificial Intelligence (GenAI)	NIST	Measurent standards, governance	
	FDA	SaMD risks, post-market monitoring	
	National AI Initiative Act (2020)	Federal strategy setting (and office)	
NONE of these laws, regulations & standards currently apply to GenAI tech for medical use (i.e., chatbots, scribes, etc.)	NIST AI RMF (2023)	Federal risk management framework	
	EU AI Act (2024)	Data privacy (per EU GDPR), quality,	
	HIPAA (1996)	transparency, post-market monitoring	
	U.S. State Legislatures (2024-26)	Laws/Acts (CO, CA, TX, IL, CT, etc.)	
Abbreviations			
Health Insurance Portability & Accountability Act	HIPAA	General Data Protection Regulation (per EU)	GDPR
Office of National Coordinator	ONC	Federal Financial Institutions Exam'n Council	FFIEC
Centers for Medicare & Medicaid Services	CMS	Securities & Exchange Commission	SEC
Health & Human Services	HHS	Cybersecurity & Infrastructure Security Agency	CISA
Office for Civil Rights (of HHS)	OCR	Gramm-Leach-Bliley Act	GLBA
Certified EHR Technology	CEHRT	National Institute of Standards & Technology	NIST
Federal Trade Commission	FTC	Food and Drug Administration	FDA
Personal Health Information	PHI	Software as a Medical Device (per FDA)	SaMD
System and Organization Controls	SOC-2	Predetermined Change Control Plan (per FDA)	PCCP