



# Healthcare Regulatory & Compliance Quick Reference

## HIPAA

- Applies when a solution **creates, stores, processes, or transmits PHI**
- Often requires a **Business Associate Agreement (BAA)**

## HITRUST

- A **certifiable security framework** commonly requested by health systems
- Maps to HIPAA, NIST, ISO, SOC 2
- Often used to streamline vendor risk reviews, but it is not a legal requirement.

## FDA

- Applies when software or hardware:
  - Supports diagnosis
  - Influences clinical decisions
  - Functions as a medical device (SaMD)

## SOC 2 / ISO / NIST

- Security and risk frameworks used to evaluate:
  - Data protection
  - Access controls
  - Operational resilience
- Often required during **vendor security reviews**

## Data Residency & Sovereignty

- Governs **where healthcare data is stored and processed**
- Increasingly relevant for:
  - Cloud platforms
  - Global SaaS vendors
  - AI/ML training data

Technology Category	HIPAA	HITRUST	FDA	SOC 2 / NIST	Data Residency
Cloud Platforms & SaaS	✓	✓		✓	✓
Digital Engagement & Virtual Care	✓	✓	✓	✓	✓
Mobile Health Applications	✓	✓	✓	✓	✓
AI/ML & Clinical Decision Support	✓	✓	✓	✓	
Data Interoperability & Analytics	✓	✓		✓	✓
Cybersecurity & Infrastructure	✓	✓		✓	✓
Clinical & Point-of-Care Devices	✓	✓	✓	✓	

✓ May apply depending on the solution’s functionality, data handled, and deployment model

**FOR MORE INFORMATION**

Visit our website: <https://www.tdsynnex.com/na/us/td-synnex-public-sector/healthcare-resource-center/>

For additional information and questions, email: [healthcare@tdsynnex.com](mailto:healthcare@tdsynnex.com)

\* For general guidance only; not legal or compliance advice. Applicability depends on solution, data, customer, and deployment.