

Know Which AI Tools Are Out of Compliance. Before an Auditor Does.

ClinicalGuard monitors every AI system across your organization against FDA, CMS, and HIPAA — and generates the audit report in one click.

3

FRAMEWORKS

10

RULE CODES

<1hr

FIRST SCAN

THE PROBLEM

The FDA's 2025 AI/ML SaMD guidance update makes every hospital CIO and CCO personally accountable for ensuring deployed AI tools meet compliance standards. Most hospitals have no inventory of their AI systems — let alone a compliance framework. An auditor walking in tomorrow would find violations in every department.

THE SOLUTION

ClinicalGuard is the only purpose-built AI compliance monitor for healthcare organizations. Register your AI systems in minutes. Get a live risk score. See every FDA, CMS, and HIPAA gap in real time. Generate an audit-ready PDF report in one click. No competing product exists today.

FIVE PRODUCTION MODULES

MODULE 01

AI System Registry

Centralized inventory of every AI/ML tool. FDA clearance, HIPAA BAA, CMS approval tracked per system.

MODULE 02

Compliance Monitor

Real-time findings across FDA, CMS, HIPAA. Every finding tagged with rule code, severity, and system.

MODULE 03

Audit Trail

Immutable, append-only log of every compliance event. 6-year retention. Timestamped to encounter.

MODULE 04

Regulatory Reports

One-click audit-ready PDFs for FDA, CMS, HIPAA, Joint Commission, and internal review.

MODULE 05

Risk Scoring Engine

Automated 0–100 risk score per AI system, recomputed in real time on every change.

INTEGRATION

iCare EHR Live Scan

Direct connection to iCare EHR. Scans for unsigned AI documents. CMS-AI-001 findings in 3 seconds.

REGULATORY COVERAGE

FDA

AI/ML Software as a Medical Device

- › AI/ML SaMD without 510(k) clearance
- › Missing Algorithm Change Protocol
- › No post-market surveillance plan
- › Performance metrics not defined

CMS

Medicare / Medicaid AI Billing

- › AI docs without provider co-signature
- › AI diagnosis not reviewed before billing
- › AI tool usage not disclosed in claim

HIPAA

Privacy & Security

- › AI vendor processing PHI without BAA
- › PHI access beyond minimum necessary
- › Training data audit trail missing



Exclusive: iCare EHR Live Integration — The Only Compliance Monitor That Talks to Your EHR

ClinicalGuard maintains a live read connection to the iCare EHR database. One click scans every AI-generated document for missing provider co-signatures — a CMS-AI-001 critical violation that triggers Medicare billing rejections and fines. Results in under 3 seconds. No other compliance platform has this capability.

PRICING

STARTER

\$2,500 /mo
\$25,000/yr

- ✓ Up to 5 AI systems
- ✓ 2 users
- ✓ All 5 modules
- ✓ Email support

PROFESSIONAL

\$8,000 /mo
\$80,000/yr — save \$16K

- ✓ Up to 20 AI systems
- ✓ 10 users
- ✓ iCare EHR integration
- ✓ Priority support

ENTERPRISE

Custom
Starting \$200K/yr

- ✓ Unlimited systems & users
- ✓ Dedicated onboarding
- ✓ 99.9% SLA
- ✓ Custom reporting

APMS ADD-ON

\$1,500 /mo
For existing iCare clients

- ✓ Up to 10 AI systems
- ✓ Full iCare integration
- ✓ Billed with APMS suite

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