AI STRATEGY YOUR AUDITORS CAN SIGN OFF ON

Three developments that change what “ready” means for healthcare AI

Texas disclosure is in effect. The AMA has set out how clinical authority should be earned. The FDA has closed comments on generative AI devices and has not yet issued follow-on guidance.

> **How to use this briefing:** Read each section, then check it against your AI inventory, patient disclosures, and vendor contracts. Write down the gaps you find. Those gaps are the work to close.

01 - TEXAS LAW

Texas disclosure is in effect, with AG-only enforcement

TRAIGA (HB 149), Tex. Bus. and Com. Code Sec. 552.051, in effect Jan. 1, 2026 | SB 1188, in effect Sept. 1, 2025

Under Sec. 552.051(f), a provider that uses an artificial intelligence system in a health care service or treatment must disclose that use to the patient or the patient representative by the date the service is first provided. In an emergency, disclosure is due as soon as reasonably possible.

The disclosure must be clear and conspicuous, in plain language, and without dark patterns. It is required even if it would be obvious to the patient that they are interacting with AI.

SB 1188 adds clinical rules that have not changed: use AI for diagnosis only within license scope, review all AI-generated records, and disclose diagnostic AI use.

Enforcement and penalties: Enforcement rests only with the Texas Attorney General. There is no private right of action. The AG online complaint mechanism went live on September 1, 2026, so patients and competitors can now trigger inquiries. Licensing agencies may impose sanctions of up to $100,000 on the AG recommendation. Under Sec. 552.105, penalties are tiered: $10,000 to $12,000 per violation a court finds curable; $80,000 to $200,000 per violation found uncurable; plus $2,000 to $40,000 per day a violation continues.

Practical next steps

- **Inventory** every AI system that touches patient care or communication, including documentation, triage, scheduling, and billing tools.
- **Build disclosure into intake** and first-service workflows, scripts, and patient materials. Do not rely on a policy page alone.
- **Check vendor contracts** for AI-use transparency that supports your disclosure duty.
- **Document the process:** who discloses, when, in what words, and where it is recorded.

02 - AMA FRAMEWORK

The AMA framework defines how clinical authority is earned

American Medical Association, “A Governance Framework for Agentic AI Assuming Clinical Functions,” published Oct. 13, 2026. Guidance, not binding regulation.

The core principle is direct: clinical authority is earned through evidence and maintained through demonstrated performance. Authority is not a one-time approval. It changes as evidence, performance, risk, or the technology changes.

Agentic AI can inform, recommend, decide, and act. The framework gives boards, compliance teams, and clinical leaders a common set of questions for deciding what a system may do and what proof is required first.

QUESTION	WHAT YOU MUST ANSWER
1. Function	What clinical function is the AI performing? Define the task, patient population, setting, and intended use.
2. Evidence and Risk	What shows it can perform that function, and what happens if it fails? Assess performance, safety, clinical benefit, population fit, and uncertainty in proportion to the consequence.
3. Authority and Oversight	What may the AI do, and under what conditions? Place the system on this scale: inform, recommend, decide, act. Set the human or institutional oversight required at that level.
4. Accountability	Who is responsible for risks and outcomes? Allocate by authority, control, knowledge of risk, and ability to prevent or mitigate harm. Accountability is shared across developers, deployers, health systems, physicians, and payers.

Questions 2 and 3 need repeat review. The AMA expects monitoring and reassessment as conditions change, not a single sign-off at launch.

Practical next steps

- **Use the four questions** as the template for every AI governance review, for new tools and for expanded use of existing tools.
- **Name an accountable owner** for each clinical AI system before deployment.
- **Set evidence thresholds that rise** with autonomy and consequence. A documentation aid and a diagnostic agent should not clear the same bar.
- **Schedule reassessment** and record it with a date. An undated approval is not governance.

03 - FDA DISCUSSION PAPER

FDA comments are in. Guidance has not followed yet.

FDA Center for Devices and Radiological Health (CDRH), Digital Health Center of Excellence. Discussion paper issued Aug. 18, 2026. Docket FDA-2026-N-7874. Comments closed Oct. 19, 2026. The paper is nonbinding. It is not draft or final guidance.

In “Considerations for the Regulation of Generative AI-Enabled Medical Devices,” FDA asked for feedback on risk, premarket evaluation, and postmarket monitoring for generative AI devices.

Risk is assessed on two axes. The first axis is the type of activity: informational and non-directive; informational and action-directing; action-taking under healthcare professional supervision; or fully autonomous action-taking. The second axis is the severity of harm if the output is wrong.

Premarket review is competency-based. FDA describes non-clinical device benchmarking plus clinical confirmation, rather than a single test at one point in time.

Postmarket monitoring is part of the model. Options in the paper include periodic re-benchmarking, sample-based clinician review, and monitoring for drift. The paper also asks how manufacturers should detect changes to third-party foundation models used in a device.

November update: 540 stakeholders submitted comments, as reported in the Mintz November 2026 FDA newsletter. Manufacturers broadly support the risk framework. They prefer performance metrics tied to intended use and supported by statistics over a general competency score. Several commenters said postmarket monitoring should be based on risk and does not replace premarket evidence where harm could be severe or irreversible. FDA has not yet issued follow-on guidance. That guidance is the item to watch.

Practical next steps

- **Ask vendors in writing:** How do you monitor drift? How do you detect and evaluate foundation model changes, and how will you notify us?
- **Build your own monitoring now:** sampling, clinician review, and clear thresholds for escalation.
- **Track docket FDA-2026-N-7874** and update procurement language when FDA issues guidance.

What to do in the next 30 days

ACTION	DONE MEANS
1. Complete the inventory	Every AI system in clinical or patient-facing use is listed, with owner, function, and vendor.
2. Close the disclosure gap	TRAIGA and SB 1188 disclosure is live at intake and first service, in plain language, and documented.
3. Run the AMA four questions	Each clinical AI system has a written review covering function, evidence, authority, and accountability.
4. Put monitoring on the calendar	Reassessment dates, drift checks, and vendor reporting are scheduled. FDA guidance on docket FDA-2026-N-7874 is assigned to a named owner to watch.

Start with an AI readiness and governance assessment.

Malinowski Consulting helps healthcare and regulated-industry leaders inventory AI use, close disclosure and governance gaps, and produce documentation an auditor can follow. Vendor-agnostic. Compliance-focused. Principals: Nathan Malinowski (strategy and AI advisory) and Alexis Malinowski (conversion and regulatory risk).

Start the conversation at **malinowskiconsulting.com**

Note: This briefing is general information about recent regulatory and professional developments. It is not legal advice and does not create an attorney-client or advisory relationship. Consult qualified counsel for advice on your specific facts and obligations.

Sources: Texas HB 149 (TRAIGA), Tex. Bus. and Com. Code Sec. 552.051(f) and Sec. 552.105; Texas SB 1188, Tex. Health and Safety Code Ch. 183; American Medical Association, “A Governance Framework for Agentic AI Assuming Clinical Functions” (Oct. 13, 2026); FDA CDRH, “Considerations for the Regulation of Generative AI-Enabled Medical Devices” discussion paper (Aug. 18, 2026), docket FDA-2026-N-7874; Mintz, November 2026 FDA newsletter summary of comments on that docket.