

# AI Governance in *Regulated Industries*

*Lifecycle accountability and the institutional gap in financial services and healthcare.*

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PATRON PREVIEW

PUBLIC RELEASE

SALON

FORMAT

May 13, 2026

May 20, 2026

June 10, 2026 · NYC

~30 min · 7,900 words

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### CITATION

Lovejoy, D., Chen, C., & Telang, A. (2026). *AI governance in regulated industries* (Horizon Scan No. 001). Horizon Search Institute.

*Horizon Search Institute is an independent research nonprofit operating under 501(c)(3) fiscal sponsorship through Fiscal Sponsorship Allies.*

EXECUTIVE SUMMARY

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# Deployment is outpacing accountability.

Financial services and healthcare are converging on the same AI governance expectation, continuous lifecycle oversight of deployed systems, through opposite institutional paths. Finance is adapting fifteen years of model risk infrastructure built around SR 11-7 to oversee agentic systems that recalibrate autonomously between review cycles. Healthcare has no equivalent scaffold and is improvising one in real time, largely by inserting human verification back into workflows that automation had stripped out: patient disclosure at the point of care, physician sign-off on AI-influenced coverage denials, mandatory human utilization review.

What unites the two sectors is not their regulatory architecture but the gap between it and the institutions it governs. Goldman Sachs has embedded Anthropic engineers to co-develop autonomous compliance agents while its model validation function still operates on quarterly cycles. Three in four health plans now use AI in prior authorization, with appeal overturn rates above 80% in Medicare Advantage and patient appeal rates below 1%, meaning most incorrect denials are never contested. McKinsey's 2026 survey finds only about one-third of organizations report governance maturity at level three or higher across agentic AI controls. Deployment is outpacing accountability, and the corrective signals that should pull the system back into balance are not reaching the institutions that need to act on them.

Healthcare carries a second driver that finance does not. Federal AI legislation has not passed, state legislatures filled the vacuum with more than 250 health AI bills introduced in 2025, and a federal preemption agenda is now actively challenging those state structures. A health system operating across Colorado, Texas, California, and Maryland faces four distinct compliance obligations for the same clinical workflow, on a regulatory perimeter that may shift mid-construction. Healthcare institutions are managing two governance problems simultaneously: building accountability they did not previously need, and tracking a perimeter that is fragmented and politically contested.

For institutional leaders, the practical question over the next 18 to 24 months is not which rule applies but how the organization is built to answer any rule, in any jurisdiction, at the moment a supervisor asks. Lifecycle governance cannot be satisfied by point-in-time legal compliance. It requires reporting lines, monitoring infrastructure, cross-functional authority, and documentation that operate continuously. The institutions treating AI governance as organizational design will set the template. Those treating it as legal compliance will become the case studies.

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**I • FINANCIAL SERVICES**

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# Financial Services

The governance infrastructure that U.S. and global financial institutions rely on to manage model risk was engineered for a category of system that is rapidly ceasing to exist. SR 11-7, the Federal Reserve’s 2011 guidance on model risk management, assumed that models are discrete, inventoriable, periodically validated, and stable between review cycles. Agentic AI systems—systems that autonomously parse trade data, resolve compliance exceptions, and initiate multi-step workflows with limited human direction—now entering production at major banks violate each of those assumptions simultaneously.

Regulators in the United States, the European Union, and Singapore are converging on the same structural prescription: lifecycle governance, meaning continuous post-deployment monitoring and intervention rather than point-in-time clearance. The consequential gap in financial services AI governance is therefore organizational. Compliance functions inside banks remain organized around quarterly review cadences and committee-driven validation cycles designed for the Basel II era. The regulatory expectation is moving toward real-time surveillance. The institution has yet to rebuild itself to receive it.

Understanding why this gap has opened requires examining the framework that has governed model risk in American banking for nearly fifteen years. SR 11-7, issued jointly by the Office of the Comptroller of the Currency and the Federal Reserve Board in 2011 and adopted by the FDIC in 2017, established the supervisory expectation that banks maintain strong model governance, conduct independent validation, and document model behavior throughout the lifecycle. Its foundational principles remain, as the Global Association of Risk Professionals noted in February 2026, “conceptually robust.” The stress lies in the operational tools SR 11-7 prescribed to implement those principles. Validation approaches such as conceptual soundness assessments, outcomes analysis, and benchmarking were designed for models whose structure and behavior remain stable between review cycles. For models that recalibrate autonomously or adapt based on ongoing interaction, as GARP analyst Krishan Sharma observed, “these tools may lose effectiveness, as material changes in behavior can occur without a formal redevelopment event.” The recurring debate over whether advanced AI systems should be governed as software assets or as models is a symptom of this definitional strain.

The deployment pipeline that is generating this strain is already operational. In February 2026, Goldman Sachs disclosed that it had spent six months embedding Anthropic engineers within its technology teams to co-develop autonomous AI agents for trade accounting and client onboarding. Marco Argenti, Goldman’s chief information officer, described the agents as

capable of reviewing documents, extracting entities, determining ownership structures, and triggering further compliance checks—a sequence of tasks that combines large-scale data parsing with contextual judgment. Argenti told CNBC that the bank was “surprised” by how capable Claude proved to be in accounting and compliance functions, domains where prior automation efforts had plateaued precisely because exceptions require interpretive reasoning. Goldman’s experience is representative. Accenture’s Top Banking Trends for 2026 report found that banks are turning to cloud provider platforms to build agentic AI agents aligned with compliance and service standards, and that AI agents are already improving performance in software engineering, risk management, and customer service. BCG and OpenAI jointly projected that agentic AI has the potential to increase bank profitability by thirty percent and reduce costs by thirty to forty percent by 2030. McKinsey’s 2026 AI Trust Maturity Survey, conducted across approximately five hundred organizations, found that financial services firms lead in responsible AI maturity, yet only about one-third of organizations across sectors report maturity levels of three or higher in governance and agentic AI controls.

This last finding captures the structural problem. Financial institutions are deploying agentic systems at speed while the internal governance apparatus designed to oversee them operates on a fundamentally different clock. Model validation teams at most large banks conduct reviews on quarterly or semi-annual cycles. The SR 11-7 framework contemplated a world in which a model is developed, validated before deployment, and then re-examined at scheduled intervals. An agentic system that autonomously adapts its behavior in response to incoming data can undergo material behavioral drift between those intervals. U.S. banking regulators have not meaningfully updated SR 11-7 since its original issuance, even as the Government Accountability Office found in May 2025 that the guidance may not explicitly address AI models. The Consumer Bankers Association and the American Bankers Association have each acknowledged this gap in formal regulatory submissions, with the ABA describing a “complex overlay” of supervisory expectations that were designed for an earlier generation of technology. Additional federal guidance on AI accountability is expected, but it has not yet arrived.

Singapore’s approach offers the clearest picture of where lifecycle governance is heading and what it demands from institutions. The Monetary Authority of Singapore issued its consultation paper on Guidelines for AI Risk Management in November 2025, proposing requirements that apply to all financial institutions and cover oversight, AI risk management systems, lifecycle controls, and organizational capabilities. The guidelines explicitly address generative AI and AI agents. They require board-level accountability for AI risk, mandate the establishment of cross-functional oversight committees for institutions with material AI risk exposure, and prescribe continuous monitoring of fairness across credit and insurance decision systems. The toolkit includes an operationalization handbook organized around four sections—scope and oversight, risk management, lifecycle management, and enablers—each aligned with the proposed MAS guidelines. This iterative, sector-specific trajectory distinguishes Singapore from the EU’s horizontal risk classification approach and from the United States’ continued reliance on retrofitting pre-existing supervisory guidance. KPMG’s

analysis of the MAS consultation emphasized that the guidelines introduce formal requirements focused on strengthening AI risk management across the entire AI lifecycle. The EU follows a different route to the same destination: rather than issuing new sector-specific AI guidelines, the EBA's position is that the AI Act's high-risk obligations, taking effect in August 2026, can be implemented through existing financial regulatory structures and supervisory cooperation. The mechanism differs, but the expectation of continuous, lifecycle-oriented oversight does not.

K&L Gates' analysis of the AI Act's financial services implications noted that the regulation's global reach means AI providers and financial institutions interacting with EU users must comply regardless of where they are established. For U.S. institutions operating internationally, these obligations create a compliance surface that extends well beyond domestic supervisory expectations. The EU's Digital Omnibus proposal, introduced in November 2025, further consolidates rules on AI, data access, privacy, and cybersecurity for the financial sector. A parallel development is unfolding in Asia: Vietnam's Law on Artificial Intelligence, effective March 2026, is the first standalone binding AI law in Southeast Asia, with an eighteen-month transition period for the financial sector. The ASEAN Digital Economy Framework Agreement, expected by the end of 2026, will create legally binding AI governance interoperability rules across the region.

The directional convergence across these jurisdictions has a clear implication for executives: the institution's operating model, not its compliance documentation, is what determines whether it can meet the standard. MAS requires continuous monitoring and lifecycle controls. U.S. banking regulators, while operating through guidance rather than statute, have signaled through the GAO report, NIST's December 2025 Cyber AI Profile, and Congressional testimony that expectations around AI accountability are tightening. The Financial Stability Board's November 2024 report on the financial stability implications of AI identified model risk, data quality, governance, and third-party concentration as key vulnerabilities requiring regulatory attention. Georgetown CSET's October 2025 mapping of over 950 AI governance documents found that governance failure and AI system security vulnerabilities were the most heavily covered risk subdomains across the global governance landscape, a finding that confirms regulators worldwide have identified the same structural weakness. Each jurisdiction arrives at its version of lifecycle governance through a different regulatory tradition: Singapore through iterative principles, the EU through horizontal risk classification, the United States through supervisory guidance and examination.

For financial institutions, the operational implication is concrete. The compliance organizations that currently manage model risk were built for a regulatory environment that assumed stable models and bounded use cases. Agentic AI systems require monitoring infrastructure that can detect behavioral drift in production, escalate anomalies in real time, and maintain audit trails that satisfy regulators who increasingly expect lifecycle documentation. McKinsey's 2026 survey found that security and risk concerns are the top barrier to scaling agentic AI, that inaccuracy and cybersecurity remain the most frequently

cited AI risks, and that active mitigation lags behind risk awareness across nearly every AI risk category. Eighty percent of AI projects fail to deliver intended business value, according to RAND Corporation data synthesized by Pertama Partners, with governance failure a recurring cause.

The institutions that will navigate this transition successfully are those treating AI governance as organizational design. They will restructure reporting lines, build continuous monitoring capabilities, and invest in the cross-functional expertise that MAS, the EBA, and the Federal Reserve's supervisory posture all increasingly demand. The window for treating this as a future compliance consideration is closing. By August 2026, the EU AI Act's high-risk obligations will be enforceable. MAS has proposed a twelve-month transition period following finalization of its guidelines. U.S. banking regulators are expected to issue additional guidance on AI accountability. The regulatory expectation of lifecycle governance is arriving. Institutions that still run AI governance on quarterly review cycles by August 2026 will face enforcement risk under the AI Act and supervisory scrutiny from the Fed with no grace period for organizational redesign.

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## **Actionable Strategies: What Financial Institutions Should Do Now**

The strategies that follow apply to financial institutions specifically. Healthcare-specific actions appear in the next chapter; cross-sector postures appear in Implications for Institutional Leaders.

### **Build a Living AI Inventory That Catches Shadow Deployments**

The Treasury's Financial Services AI Risk Management Framework, released February 2026, opens with the AI Adoption Stage Questionnaire for a reason: institutions cannot govern what they cannot see. Automated discovery is now the baseline. Scanning tools maintained by the second line of defense should sweep API endpoints, embedded LLM prompts, vendor integrations, end-user computing files, and notebook environments on a scheduled cadence, populating a central repository with risk tier, owner, intended use, data lineage, and change history. SR 11-7's foundational expectation of complete model inventory has been reinforced by the GAO's May 2025 findings on AI oversight gaps: incomplete or fragmented inventories remain a recurring examination concern, compounded by shadow deployments that accumulate outside the second-line view. A monthly reconciliation between procurement records, cloud spend, and the central inventory catches the drift between what the enterprise has authorized and what is actually running in production.

## **Operate a Tiered Validation Cadence Calibrated to Agentic Behavior**

SR 11-7's validation rhythm works for static models. Agentic systems require a different frequency. Building on SR 11-7's framework and MAS's proposed lifecycle controls, institutions should assign every agentic system a validation frequency tied to its autonomy level, the reversibility of its actions, and its exposure to non-stationary data, with shorter cycles for systems that recalibrate autonomously between reviews. Credit decisioning agents that adjust weighting in response to new application data warrant quarterly validation. Trade reconciliation agents operating on structured ledger data may sustain annual cycles. Champion-challenger testing, where a candidate model runs in parallel with the production model on live data, is a core SR 11-7 technique that should be standard practice for any system that recalibrates autonomously, and is increasingly expected under continuous-monitoring supervisory regimes.

## **Engineer Continuous Monitoring Into the Production Stack**

Continuous monitoring is the lifecycle governance expectation that MAS, the EU AI Act, and the Treasury's FS AI RMF all converge on. Implementation requires three layers. The first is statistical: automated drift detection on input distributions, output distributions, and population stability indices, with thresholds that trigger automatic alerts to the second line. The second is behavioral: telemetry that records every agent action, tool call, memory state, and decision rationale, stored in tamper-evident audit logs. The third is fairness: ongoing disparate-impact testing across protected classes for any model that influences credit access, pricing, or claims adjudication, consistent with the Consumer Financial Protection Bureau's dynamic monitoring expectations under the Equal Credit Opportunity Act. Integrated governance platforms that consolidate these three layers produce the examination-ready documentation supervisors increasingly expect on short notice, in line with the MAS, Treasury FS AI RMF, and SR 11-7 documentation standards.

## **Install Kill Switches, Circuit Breakers, and Graduated Autonomy Ramps**

Agentic systems fail faster than human operators can respond. Infrastructure-level safety controls become essential. Building on NIST AI RMF GOVERN function guidance and the Treasury FS AI RMF's incident response expectations, institutions should design a global hard stop that revokes tool permissions and halts queues in seconds, paired with per-agent circuit breakers for high-cost actions and objective-based breakers for repetitive patterns. Spend and rate governors cap tokens, API calls, and per-task budgets. The AWS Prescriptive Guidance on incident response for agentic AI adds a critical operational layer: business continuity plans that assume the agent is offline, with staff trained to handle the workload manually during the degradation window. New agents should return to production through a graduated autonomy ramp: full human-in-the-loop mode at launch, graduating to human-on-the-loop after a defined confidence period with zero anomalies.

## **Extend Third-Party Oversight to Foundation Model Providers**

Goldman Sachs's Anthropic partnership illustrates a new category of vendor risk: institutions depending on foundation models whose training, fine-tuning, and update cadence they do not control. The Treasury FS AI RMF includes explicit control objectives for vendor evaluation, service-level agreements, and incident response coordination with AI providers. Contracts should include right-to-audit clauses, change notification requirements, performance guarantees tied to the institution's actual token volume, and exit strategies that address data portability. MAS's consultation paper requires compensatory testing of third-party AI to verify robustness and detect bias, plus contingency plans for vendor discontinuation. A standing quarterly review of every third-party AI contract against the FS AI RMF vendor control objectives prevents the accumulation of unpriced risk.

## **Rebuild the Three Lines of Defense Around Agentic Accountability**

The structural problem in agentic AI accountability is diffuse ownership: product owns the model, engineering owns the infrastructure, compliance owns the policy, and when a decision is challenged each team points elsewhere. The remedy is explicit accountability mapped to specific action categories and documented in writing before the system enters production. A named senior manager should own each material agentic system with authority to pause, modify, or decommission it. The first line deploys and operates. The second line validates independently, monitors in production, and challenges. The third line provides assurance to the board risk committee. The BIS Consultative Group on Risk Management's 2025 report on AI governance recommends adapting this existing model to cover AI-specific threats and vulnerabilities, which preserves governance coherence as the institution scales.

## **Elevate AI Risk to the Board Risk Committee**

GARP's February 2026 analysis argues that AI oversight belongs with the board risk committee because AI risk now cuts across credit, market, operational, and compliance domains. The board should approve the institution's AI risk appetite, set boundaries on automated decisioning, review material deployments before launch, receive quarterly AI risk reporting with defined KRIs, and review model incidents and failures. The CFA Institute's 2026 bank risk framework recommends board-level engagement specifically to reduce ambiguity in decision rights and signal to regulators that AI governance is treated as a core risk discipline. Board materials should include the institution's current FS AI RMF adoption stage, the gap to the next stage, incident counts and remediation status, and cross-jurisdictional compliance posture for MAS, EU AI Act, and U.S. supervisory expectations.

## **Red-Team Before Deployment and Continuously After**

The Cloud Security Alliance's Agentic AI Red Teaming Guide details specific test categories: permission escalation, hallucination, orchestration flaws, memory manipulation, and supply chain risks. Gray Swan AI's 2025 benchmark pitted 22 frontier AI agents against 44 realistic deployment scenarios and observed nearly two million prompt injection attacks, with over 60,000 successful. Institutions should conduct structured red-team exercises before every material deployment, mapping findings to the OWASP Top 10 for Agentic Applications. The red team should sit in the second line of defense, report independently to the chief risk officer, and rerun test suites after every material model update. HackerOne's 2026 agentic taxonomy provides a mapped weakness framework that translates red-team findings into compliance reporting, closing the loop between testing and remediation.

## **Document Everything for Examination Readiness**

Regulators across jurisdictions are converging on the same documentation expectation: institutions should be able to produce, on short notice, the full lifecycle record of any material AI system. This includes the intended use statement, training data lineage and quality assessment, architecture description, validation evidence, production monitoring logs, incident history, change management records, and third-party documentation. Following SR 11-7's model documentation expectations, on which MAS, the EU AI Act, and Treasury FS AI RMF all build, effective documentation demonstrates rationale (why this model over alternatives), assumptions (underlying principles, data sources, methodologies), testing performed (pre-implementation and ongoing), and decision-making (why validation and deployment choices were made). Examination-ready documentation is the tangible output of every other strategy on this list, and it is the artifact regulators evaluate first.

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**II • HEALTHCARE INDUSTRY**

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# Healthcare Industry

The U.S. healthcare AI regulatory environment presents a structurally different version of the same problem. The institutions deploying AI, including health systems, insurance payers, and clinical software vendors, are outpacing both the regulators supposed to oversee them and their own internal governance capacity. By pulling back at the center, the federal government has pushed compliance accountability down to the state level and, ultimately, inside the organizations themselves. The following sections map the redistribution across four state legislative lanes and argue that the central risk in 2026 is not regulatory uncertainty but the gap between what these organizations are deploying and what they have built the internal infrastructure to govern.

The clearest signal of the federal government’s current posture came on January 6, 2026, when the FDA issued revised final guidance on Clinical Decision Support Software, superseding its 2022 version. The guidance draws a line between clinical decision support tools that are regulated as medical devices and those that are not. Under the updated guidance, FDA will now exercise enforcement discretion for CDS tools that provide a singular output, including, for example, software that recommends a specific FDA-approved drug based on a patient’s symptoms and medical history, as long as the tool meets the other non-device CDS criteria. This was a meaningful shift from the 2022 guidance, which had excluded software providing a “specific preventative, diagnostic, or treatment output or directive” from the non-device category. FDA Commissioner Marty Makary framed the changes at CES as intended to “cut unnecessary regulation and promote innovation” and said the agency needed to move “at Silicon Valley speed.” Legal analysts noted that while the guidance provides helpful clarifications, it does not represent a fundamental deregulatory shift. FDA oversight still applies fully to tools that analyze medical images or make recommendations that are not independently reviewable by a clinician.

The CDS guidance is the most substantive federal healthcare AI action of 2026, and its practical effect is to expand the category of AI-enabled clinical software that can reach the market without premarket FDA review. For health system procurement teams, this creates a gap: software that previously required FDA clearance as a condition of vendor due diligence may no longer carry that signal. The accountability structure changes while clinical risk stays the same. No federal legislation directly governing health AI has passed, and the Trump administration has signaled it may challenge state-level AI laws through DOJ litigation as incompatible with its “minimally burdensome” national policy framework. The result is a federal posture that is simultaneously deregulatory on AI tools and adversarial toward the state-level structures attempting to govern the consequences.

As a response, states have moved with unusual speed and specificity. In 2025, 47 states introduced more than 250 health AI bills, with 33 becoming law across 21 states, and roughly 200 more have already been filed in 2026. The result is a fragmented national framework: disclosure requirements vary in threshold and timing, mental health chatbot rules differ in scope, and payer mandates impose different standards of human review depending on the state. A health system operating across Colorado, Texas, California, and Maryland faces four distinct compliance obligations for the same AI-enabled workflow, with no federal floor to unify them. Health system leaders have publicly described the operational difficulty of deploying AI tools when state requirements diverge, citing the resources required to maintain different workflows for the same clinical use case across multiple jurisdictions. State legislative activity in 2026 is concentrating in four areas: mental health chatbots, patient disclosure and consent, preventing AI tools from presenting as clinical providers, and payer use of AI in coverage decisions. Each area reflects a different institutional failure that legislators are trying to correct from the outside, without coordination across jurisdictions.

The mental health chatbot lane is driven by documented harm: California's law, effective January 1, 2026, bans chatbot deployment without protocols to prevent the production of suicidal ideation content and imposes stricter requirements when the user is a minor. Illinois, effective August 2025, prohibits AI from making independent therapeutic decisions or generating treatment plans without licensed professional review. These statutes are not precautionary but responses to specific documented incidents of consumer-facing AI products causing therapeutic harm to vulnerable users, including minors.

The patient disclosure and consent lane is the most organizationally demanding because it requires operational changes at the point of care. Texas, effective January 1, 2026, requires written disclosure to patients before any AI system is used in their treatment or services. Ohio has introduced legislation requiring written informed consent. The practical implication for health systems, particularly those that have embedded AI scribes, diagnostic aids, or decision support into clinical workflows, is that disclosure obligations now sit with the provider at the point of service, not with the software vendor. This creates a governance and training problem, on top of the legal aspect.

The most consequential regulatory action in 2026 is playing out in the payer lane, and it is driven by documented evidence of harm at scale. Research published in Health Affairs this January found that roughly three in four health plans now use AI for prior authorization approvals, which is a process that determines whether patients receive covered care before it is delivered. The governance concern is not theoretical. Stanford researchers examining AI use in insurance utilization review found that an appeal overturn rate of nearly 82% in Medicare Advantage plans indicates these systems are frequently wrong, yet fewer than 1% of patients appeal their denials. This means most incorrect denials result in care not being delivered, with no formal challenge and no institutional accountability.

The researchers identified structural reasons why internal governance has not corrected this: human reviewers at insurers may lack the clinical expertise to meaningfully evaluate

AI-generated recommendations; the opacity of algorithmic determinations makes errors hard to detect and harder to challenge; and training data drawn from insurers' historical decisions repeats the biases and flaws of those decisions. The technology deployed at scale inside these institutions is making consequential decisions that the organizations themselves cannot adequately audit or explain, and the incentive structure, where incorrect denials are financially beneficial and rarely challenged, explains why there is no internal pressure to fix it.

States have responded by trying to impose accountability structures from outside. California's SB 1120, effective January 2025, prohibits health plans from basing medical necessity determinations solely on AI and requires human clinical review. Maryland, Arizona, Connecticut, Nebraska, and Texas have enacted comparable requirements. The legislative frontier is now moving further. Louisiana SB 246, introduced by Senator Jay Luneau, goes further than any currently enacted law. Under the bill, AI could not be used to delay, deny, or modify healthcare services on its own; any adverse determination would require independent judgment from a human utilization reviewer, and a physician who personally reviewed the medical record would be required to sign off on each denial. The bill's most structurally significant provision is its burden-shifting rule: any adverse determination in which AI materially contributed would be presumed invalid unless the insurer could demonstrate the decision was independently reached through documented clinical judgment without reliance on algorithmic output. Additionally, if a denial is appealed on AI grounds, the insurer could not use AI in any subsequent review of that claim. This inverts the current default. Rather than patients having to prove algorithmic error, insurers would have to prove human independence. Louisiana SB 246 represents the direction the legislation is moving, even if this specific bill does not pass in its current form.

What connects these four legislative lanes is a common problem: the institutions deploying AI in healthcare have not built the internal governance infrastructure proportionate to the risk of what they are deploying. The FDA's CDS guidance expansion means more software will reach clinical environments without premarket review, shifting validation responsibility to health systems and payers at the point of procurement and deployment. State disclosure mandates mean frontline clinical workflows now carry legal obligations that require training, documentation, and oversight infrastructure that most organizations have not yet built. Payer AI mandates mean that prior authorization workflows, which have been heavily automated with AI for efficiency gains, now require documented physician-level review at scale, a requirement that is operationally expensive and organizationally complex precisely because automation was adopted to avoid it.

There is a common mechanism underneath these four lanes, and it is worth naming directly. Each is, in effect, legislating humans back into workflows that automation had stripped out. Patient disclosure mandates require a clinician to name the AI's role at the point of care. Mental health chatbot rules require licensed professional review of any therapeutic decision. Payer AI mandates require physician sign-off on adverse determinations, and Louisiana SB 246 goes further by presuming any AI-influenced denial invalid unless human independence

can be documented. The corrective is not new technical oversight infrastructure but the legislated reinsertion of human judgment, supported by training, documentation, and workflow redesign. This matters for how institutions should plan. The compliance investment is not principally a model risk platform or a monitoring stack. It is the operational capacity to route AI-influenced decisions through qualified humans at scale, in workflows that were redesigned over the past decade to avoid exactly that step.

Tim Hwang, General Counsel at AI scribe company Abridge, has argued that regulatory clarity would actually accelerate AI adoption in healthcare. His argument understates the near-term organizational challenge. Clarity about what the rules are is not the same as organizational capacity to comply with them. Health systems operating across multiple states now face disclosure requirements that vary by jurisdiction, payer AI mandates that differ in threshold and scope, and a federal regulatory boundary for clinical software that has just been redrawn. The compliance question is whether these organizations have the governance structures, the trained personnel, and the documented processes to demonstrate accountability to multiple regulators simultaneously.

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## **Three Converging Pressures and the Institutional Gap They Expose**

The regulatory trajectory in healthcare AI is determined less by any single law or court ruling than by the interaction of three converging pressures: state mandates tightening around payer accountability, a federal preemption agenda with specific enforcement deadlines, and an FDA whose published governance ambitions for AI-enabled devices now exceed its demonstrated institutional capacity to enforce them. Each puts pressure on the same institutional weakness, which the chapter closes on.

### **1. June 30, 2026: Colorado's AI Act Takes Effect**

Colorado's AI Act requires high-risk AI deployers in healthcare to adopt risk management policies, perform impact assessments, and issue consumer notices. The Act takes effect June 30, and the DOJ AI Litigation Task Force, established in January 2026 with the sole mission of challenging state AI laws, could file suit before that date. Actual preemption requires either congressional legislation or a court ruling, neither of which will be resolved before June 30, and legal analysts at White & Case advise continued compliance with state AI laws until there is greater clarity.

## **2. June 9, 2026: FCC Rulemaking Deadline**

The executive order's June 9 deadline directs the FCC to initiate rulemaking on federal AI reporting and disclosure standards specifically designed to preempt conflicting state laws. Unlike DOJ litigation, which challenges statutes case by case, an FCC standard would establish affirmative federal requirements, a structurally more durable preemption mechanism that poses a direct threat to patient disclosure mandates now embedded in clinical workflows across Texas, California, and Maryland.

## **3. The FDA's Two-Track Posture and Capacity Gap**

The January 2026 CDS guidance pulling back on clinical decision support oversight should be read alongside the FDA's January 2025 draft guidance proposing a Total Product Lifecycle framework for AI-enabled medical devices. The agency is deregulating one category while building more structured controls for another, and the boundary between them is where the most contested healthcare AI products sit. That boundary question is complicated by institutional capacity: CDRH approved only nine new or substantially changed high-risk medical devices in the quarter following 2025 DOGE staffing cuts, down from 13 the prior year, even as pending applications increased. An agency publishing more sophisticated governance standards while losing specialized reviewers creates a gap that health system procurement teams should factor into vendor due diligence.

### **The Institutional Gap These Pressures Expose**

The Health Affairs research documents that institutional governance by insurers has not kept pace with AI adoption in utilization review, and state disclosure mandates impose compliance obligations at the point of clinical care that require training and workflow infrastructure that most organizations have not yet built. The FDA's lifecycle guidance, when finalized, will add post-market monitoring obligations, including model drift detection and performance documentation, that go well beyond what most health system IT and procurement functions currently handle. The organizations best positioned are those treating AI governance as an operational infrastructure problem, not a legal compliance deadline.

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## **Actionable Strategies: What Healthcare Institutions Should Do Now**

The strategies that follow apply to health systems and payer organizations operating in the U.S. regulatory environment. They translate the four legislative lanes and the three converging pressures into operational priorities for the next twelve to eighteen months. Cross-sector postures appear in Implications for Institutional Leaders.

### **Build Multi-State Disclosure Infrastructure at the Point of Care**

Texas's January 2026 disclosure requirement, California's mental health chatbot law, and pending Ohio consent legislation share a common operational implication: the disclosure obligation lives with the clinician or provider, not the software vendor. Health systems operating across state lines need workflow infrastructure that scales with the strictest applicable standard rather than maintaining different processes for the same clinical use case across jurisdictions. EHR-integrated disclosure prompts, captured patient acknowledgment, and clinician training programs are the operational components. Building once to the highest common denominator is more durable than rebuilding per state as the legislative map shifts under the federal preemption agenda.

### **Restructure Prior Authorization for Documented Physician-Level Review at Scale**

California SB 1120 already prohibits AI-only medical necessity determinations, with comparable requirements in Maryland, Arizona, Connecticut, Nebraska, and Texas. Louisiana SB 246 signals the direction of travel: burden-shifting that presumes AI-influenced denials invalid absent documented human independence. Payer organizations should redesign utilization review workflows so every adverse determination flows through, and is documented as flowing through, qualified clinical review. The infrastructure question is staffing, audit trails, and case management, not algorithmic improvement. The 82% Medicare Advantage appeal overturn rate identified by Stanford researchers indicates the magnitude of the corrective work required.

## **Establish a Governed AI Inventory Across Clinical and Operational Environments**

The FDA's narrowed CDS guidance shifts validation responsibility from premarket review to procurement and operations teams at the point of deployment. Health systems need a central registry of every AI-enabled tool in clinical use, including EHR scribes, decision support, imaging, prior authorization tools, and scheduling algorithms, with risk tier, validation evidence, vendor documentation, and post-deployment monitoring linked to each. Without this inventory, an institution cannot answer the basic supervisory question of where AI is operating inside its walls. With it, the institution has the foundation for the post-market obligations that the FDA's Total Product Lifecycle framework will eventually impose.

## **Prepare for FDA Total Product Lifecycle Obligations Before They Finalize**

The FDA's January 2025 draft guidance on AI-enabled device lifecycle management proposes post-market monitoring obligations, including model drift detection, performance documentation, and predetermined change control plans. Most health system IT and procurement functions are not currently structured to handle these. Building drift monitoring, performance dashboards, and incident reporting infrastructure now, even before finalization, produces examination-ready capability when the guidance lands. CDRH's reduced reviewer capacity following 2025 staffing cuts means that, when finalization comes, supervisory expectations will likely outpace the agency's bandwidth to provide guidance during transition.

## **Stand Up Cross-Functional AI Governance with Clinical Authority**

Most health systems hold IT, clinical leadership, legal, compliance, and quality in separate reporting lines. Lifecycle AI governance routes through all five. The structure that works is a named senior owner per material AI deployment, a cross-functional oversight body with authority to pause or modify deployments on demand, and clinical leadership with explicit decision rights, not a committee that only reviews. Payer organizations need the equivalent structure for utilization review AI, with accountability anchored at the level of the chief medical officer rather than distributed across operations and information technology.

## III • CROSS-SECTOR SYNTHESIS

# Cross-Sector Synthesis

Financial services and healthcare operate under fundamentally different regulatory traditions, yet they are converging on a common governance expectation from opposite directions. The dominant supervisory posture in both sectors is shifting from point-in-time review to lifecycle accountability. The Monetary Authority of Singapore's November 2025 consultation paper, the FDA's January 2025 draft guidance on AI-enabled medical device lifecycle management, the EU AI Act's August 2026 high-risk obligations, and the directional updating of the fifteen-year-old SR 11-7 tradition differ substantially in form, but each imposes the same underlying requirement: continuous monitoring, post-deployment intervention, and documented behavioral oversight across the operational life of a deployed system.

What has not shifted at comparable speed is the organizational architecture of the institutions these instruments govern. Compliance functions at most large banks still operate on quarterly or semi-annual validation cycles. Most health systems and payers have not yet built the monitoring infrastructure or cross-functional accountability structures their own AI deployments now require. Regulators are writing rules for 2026. Most institutions are still running governance on a 2018 operating model.

The asymmetry has two layers, and they need to be held separately. The first is organizational: in both sectors, deployment is moving faster than governance capacity, and the resulting gap is structurally identical regardless of which industry the institution sits in. The second is regulatory. Finance operates inside a coherent supervisory perimeter. SR 11-7, the EU AI Act, the MAS guidelines, and BIS expectations are different instruments, but they are issued by recognizable bodies and apply across the institution's footprint with reasonable predictability. Healthcare does not have that. With federal AI legislation absent and a federal preemption agenda actively challenging state structures, the regulatory perimeter itself is fragmented and contested. The organizational driver is shared across sectors. The regulatory driver is not.

Even with the organizational driver shared, the institutional starting point differs. Financial services carries the weight of fifteen years of institutional model risk infrastructure. SR 11-7 established in 2011 a jointly supervised expectation that banks document model lineage, conduct independent validation, and maintain governance artifacts regulators can examine. The question confronting the sector now is whether that infrastructure, engineered for stable and periodically validated models, can be adapted to oversee agentic systems that recalibrate autonomously between review cycles.

Healthcare arrives at the same point with no comparable scaffold, and what it is being asked to build looks structurally different from what finance is adapting. The state-level mandates already in force or pending (patient disclosure at the point of care, physician sign-off on AI-influenced coverage denials, mandatory human utilization review) bolt human verification back into workflows that automation had largely displaced. Louisiana SB 246 makes the pattern explicit: any AI-influenced adverse determination is presumed invalid unless the insurer can document independent human clinical judgment. This is less the construction of novel technical infrastructure than the legislated reinsertion of human review into automated processes, supported by training, documentation, and workflow redesign that most organizations have not yet built at scale. Finance is adapting model risk infrastructure to a new class of system. Healthcare is operationalizing human-in-the-loop accountability that the deployment curve had bypassed.

The mechanism connecting the two sectors is institutional deployment outpacing institutional accountability, not regulatory ambition outpacing institutional capacity. Goldman Sachs has embedded Anthropic engineers inside its technology organization to co-develop agentic systems capable of extracting entities from complex documents, determining ownership structures, and triggering downstream compliance checks. The bank's model validation functions continue to operate on quarterly cycles designed for an earlier paradigm, even as production behavior adapts continuously between those cycles.

The same pattern, reframed, describes the payer lane in healthcare. Roughly three in four health plans now use AI in prior authorization, the process that determines whether patients receive covered care. Appeal overturn rates in Medicare Advantage plans exceed 80%, while fewer than 1% of patients appeal their denials. Deployment has scaled faster than the organizational structures required to audit, challenge, or explain algorithmic determinations, which means most incorrect denials are never contested and the denial rate itself carries no corrective signal back into the system.

McKinsey's 2026 AI Trust Maturity Survey, conducted across approximately 500 organizations, found that only about one-third report governance maturity levels of three or higher across agentic AI controls. The finding generalizes: any regulated industry deploying AI at operational speed while governance capacity lags its deployment curve is exposed to the same structural risk, and the one-third data point is the best current proxy for how unevenly that risk is distributed across the sectoral landscape.

The distinction this pattern reveals for the next 18 to 24 months is not a compliance timetable but a split between two kinds of institution: those treating AI governance as organizational design, and those treating it as legal compliance. The difference is not semantic. Legal compliance functions are oriented toward demonstrating adherence to a specified rule at a specified moment. Organizational design builds the reporting lines, monitoring infrastructure, cross-functional authority, and documented lifecycle posture that allow an institution to answer any rule, in any jurisdiction, at the moment it is asked.

The gap between regulatory expectation and organizational reality will close in one of two ways: because institutions rebuild themselves, or because supervisors force them to. The first path is governance. The second is enforcement. The institutions that recognize the distinction will lead the sector through the transition; the institutions that miss it will be led through it.

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**IV • IMPLICATIONS**

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# Implications for Institutional Leaders

The synthesis names the pattern. The institutions best positioned to navigate it are acting on four postures now, before the regulatory expectations fully arrive. All four are achievable inside the existing supervisory environment without waiting for federal clarity. Each reflects a decision about what AI governance is inside the institution, and which functions are accountable for it.

## **AI governance is organizational design, not legal compliance.**

The institutions that will succeed in this transition treat AI governance as a question about how the organization is structured rather than about which rule applies. Legal compliance answers whether the institution is in adherence at a specified moment; organizational design answers whether the institution is built to demonstrate adherence to expectations that have not yet been finalized, across jurisdictions that do not yet agree on the standard.

The difference matters for two reasons. First, lifecycle expectations cannot be satisfied through point-in-time attestations. MAS's lifecycle controls, the EU AI Act's post-deployment monitoring obligations, the FDA's Total Product Lifecycle framework, and the directional updating of SR 11-7 all presume an institution with continuous visibility into its AI systems, continuous authority to intervene, and continuous documentation of both. Those are organizational capabilities built into reporting lines and monitoring infrastructure, not policies the legal function can draft in isolation.

Second, the fragmentation of state-level healthcare regulation and the cross-jurisdictional scope of financial regulation make any single-rule compliance posture structurally fragile. A health system operating across Colorado, Texas, California, and Maryland faces four distinct AI compliance obligations for the same clinical workflow. A bank operating across the United States, the EU, and Singapore faces three converging but non-identical lifecycle frameworks. Building the organization to meet the highest common expectation is more durable than building the legal function to parse each jurisdiction in sequence, and the institutions best positioned are already treating governance architecture, not rule interpretation, as the primary question.

**Build continuous monitoring before the regulation demands it.**

MAS's proposed twelve-month transition period following finalization, the EU AI Act's August 2026 high-risk obligations, and state-level payer mandates already in force converge on the same operational expectation: continuous post-deployment monitoring. What that means in practice varies by system type. An agentic trading system needs drift detection and behavioral telemetry. A clinical decision support tool needs post-market performance documentation. A prior authorization model needs fairness testing across protected populations and audit trails that connect denials to documented clinical review.

Retrofitting monitoring after the deadline is meaningfully harder than building it before. The infrastructure operates in three layers, and none can be purchased as a product. Statistical monitoring requires integration with production systems. Behavioral telemetry requires instrumentation at the agent-action level. Fairness monitoring requires longitudinal data pipelines that most organizations have not built. An institution that starts the work before the deadline has time to iterate on false positives, calibrate thresholds, and produce the documentation artifacts regulators will request; one that starts after faces supervisory scrutiny on infrastructure that has not been stress-tested, with no grace period to tune it.

The question inside the institution is no longer whether a monitoring capability exists, but on which systems, at what granularity, with what escalation paths, and reviewed by whom. These are twelve-month build decisions, not twelve-week ones, and institutions that treat them as a procurement exercise typically discover mid-build that the supporting data infrastructure is the binding constraint.

**Invest in cross-functional expertise now.**

Most institutions currently hold model risk, compliance, legal, information security, and technology in separate reporting lines, each with distinct leadership, accountability, and examination posture. That structure works for a regulatory environment organized around separable compliance domains, but lifecycle AI governance routes through all five functions simultaneously and requires coordinated decisions that the existing committee architecture was never set up to produce.

The financial services chapter's treatment of the three lines of defense and the board risk committee, and the healthcare chapter's treatment of physician-level review obligations and state disclosure mandates, describe the same organizational fact in different domains. Agentic systems and clinical AI both produce consequential outputs on a continuous cadence, and the authority to pause a deployment, investigate an anomaly, or document an adverse decision therefore cannot be distributed across five committees on quarterly meeting schedules. It has to sit in a named, empowered, cross-functional structure with decision rights, which is an organizational design most large institutions have not yet built even where the component functions all exist in mature form.

The institutions best positioned are building this structure now: a named senior owner for each material AI system, a cross-functional oversight body with authority to convene on demand, and model risk, compliance, legal, and technology represented in a single governance forum rather than in parallel ones. These are not exotic organizational forms; the same patterns already exist in cybersecurity and market risk at most large institutions, and the task is transposing them onto a category the organization has not yet reorganized around.

### **Build documentation infrastructure, not documentation artifacts.**

Regulators across both sectors are converging on the same documentation expectation: institutions should be able to produce, on short notice, the full lifecycle record of any material AI system. That record includes the intended-use statement, training data lineage, validation evidence, production monitoring logs, incident history, change management records, and third-party vendor documentation. The first artifact a supervisor now requests is no longer the model itself but the record of how it was developed, validated, deployed, monitored, and updated.

An institution that treats documentation as a byproduct of its validation cycle, generated at the end of each review, cannot produce it on examination timelines; an institution that treats documentation as real-time infrastructure, generated automatically as systems run, can. The practical gap between the two is both a platform choice and an accountability choice: which governance technology sits between the AI system and the supervisor, and who inside the institution owns the freshness, completeness, and auditability of the record.

Neither choice can be delegated to a vendor, and both have roughly eighteen-month consequences. An institution making those choices in 2026 enters the 2027 examination cycle with evidence infrastructure already tested; an institution deferring them enters that cycle with a documentation project still underway, which is typically the point at which the supervisor notices. In a regime that evaluates AI governance maturity through examination-ready artifacts rather than policy statements, that lag is what distinguishes demonstrating governance from describing it.

None of these postures is novel in isolation. Each has an analog in an existing institutional discipline: model risk in finance, post-market surveillance in medical devices, three-lines-of-defense in risk management, examination-ready documentation across every regulated sector. What is new is the requirement that they operate together, continuously, across a category of system that is still in active deployment. The institutions that rebuild to meet that requirement will set the template others follow. The ones that do not will become the case studies supervisors cite.

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