

AI, Lobbying & Algorithmic Disclosure

AI in healthcare isn't just a tech story. It's a policy reckoning.

The era of “black box” algorithms is ending—across payers, providers, and regulators alike. Here's what July 2025 is teaching us about disclosure, lobbying, and the compliance frontier that's already reshaping care.

July 2025, AegisCipher.co, Melissa Gaffney

As artificial intelligence reshapes healthcare and public policy, 2024–2025 have delivered a tidal wave of lobbying, rulemaking, and litigation — and a critical spotlight on *algorithmic transparency*

One of the most paradigm shifting laws for AI will take effect in Minnesota:

Minnesota HF2500, effective Jan 1, 2026, will ban use of AI/algorithms in prior-authorization insurance decisions unless reviewed by humans. This is particularly important to those groups using soft denial and administrative approaches to get around current laws. So, if you use AI to determine more information is needed, arbitrarily and from AI, guess what....

What already exists:

1. **OCR's AI disclosure rule under Section 1557 (U.S.)** requires covered health care entities to disclose the use of AI-powered patient care decision support tools effective July 5, 2024.
2. **HHS & OCR (April 2024 Rule under Section 1557 of the ACA) already** requires **healthcare providers and insurers** to identify and mitigate discriminatory outcomes from AI-based decision tools. They mandate **disclosure of AI use** in patient care decisions w/in **300 days** of the rule enactment. It creates transparency around: **Data sources, Decision logic, Bias mitigation strategies**
3. **CMS (Centers for Medicare & Medicaid Services). In the ONC (Office of the National Coordinator for Health IT)< Governance is already embedded** in certified health IT systems. As of 2025, EHR vendors must disclose: Training data characteristics, Performance metrics, Known limitations or risks
4. **FDA (Food and Drug Administration) already** - Requires **Software as a Medical Device (SaMD)** developers to submit: Algorithm change protocols, Explainability documentation, Real-world performance monitoring plans
5. **U.S. Federal Court Orders (2023–2025).** Several district courts now require **disclosure of AI use in legal filings**, including Tool name, Sections generated by AI, Human verification



of content. These precedents are influencing **healthcare litigation**, especially in cases involving **denials of care** or **algorithmic bias**.

6. **AI use is ALREADY** regulated via existing civil rights, privacy, and consumer protection statutes and agency action (**FTC, DOJ, EEOC, CFPB**).
7. **State legislation: Over 1,000 AI bills** introduced in early-2025; about 20% **enacted, so there are over 200 laws to account for....and that is just AI related**.
8. **California's SB-942 (AI Transparency Act)**, in force Jan 1, 2026, mandates disclosure when users interact with AI-generated content for platforms with over 1M monthly users.

Major Health Plans & Provider Groups Lobbying on AI and Policy Reform

AI Lobbying (2024–2025): 648 companies lobbied on AI in 2024 up from 458 in 2023, a **141% increase** year-over-year.

- **Top spenders** included: **Meta**: \$24.43M in 2024 (up from \$19.3M in 2023), **Alphabet (Google)**: \$14.79M, **Microsoft**: \$10.35M, **Amazon**: ~\$20M
- **AI-focused firms**: **OpenAI**: \$1.76M in 2024 (up from \$260K in 2023), **Anthropic**: \$470K in 2024, **Cohere**: \$230K in 2024

Who's lobbying?

- AHIP, AHA, Blue Cross Blue Shield, and Better Medicare Alliance are actively shaping Medicare Advantage policy — especially for AI-driven prior authorization and claims.
- Startups like Olive AI (I know, I know, I left it in anyway), **Abridge, Truveta, and Hippocratic AI** are influencing **FDA and CMS frameworks** for clinical AI validation.

Market Influence

- AI-enabled healthcare startups capture 62% of all digital health VC funding in 2025, \$4B
- Adoption of AI scribes & clinical workflow tools reached 30–90% across health systems

AI in Life Sciences: Healthcare emerged as the largest non-tech sector in AI lobbying:

- FDA modernization for AI-based diagnostics and clinical decision tools
- HIPAA reform and patient data privacy in AI analytics
- Reimbursement models for AI-assisted care
- Ambient documentation tools (e.g., Abridge) to reduce physician burnout
- AI in clinical trials and drug discovery (e.g., real-world evidence modeling)



- **AI in Medicare Advantage:** Groups like AHIP and BMA are lobbying for:
 - Real-time electronic prior authorization using AI
 - Guardrails on AI-driven denials and appeals
 - Expansion of AI-enabled chronic care models

Provider AI Use Cases:

- AHA, FAH support AI for ambient documentation, diagnostics, predictive analytics
- Push for **FDA modernization** to streamline AI tool approvals
- Advocacy for **HIPAA updates** to accommodate AI-driven patient data use

Federal Agencies & Regulatory Bodies

HHS (Department of Health and Human Services) & OCR (Office for Civil Rights) launched 2024–2025 HIPAA audits targeting AI-related cybersecurity risks, especially ransomware and ePHI vulnerabilities. OCR has referred **>2,400 cases to DOJ** for criminal HIPAA violations since inception

Proposed **HIPAA Security Rule updates** include Mandatory **multi-factor authentication**, **network segmentation**, and **vulnerability scanning**, required **risk assessments** and **asset inventories** for AI systems handling ePHI

While CMS doesn't lobby, it's a **central target of lobbying** by AHIP, BMA, and provider groups: AI in **Medicare Advantage**: real-time prior authorization, risk adjustment, and fraud detection. CMS is evaluating **AI-driven care models** and reimbursement frameworks.

FDA is under pressure to **modernize its regulatory pathways** for AI/ML-based Software as a Medical Device (SaMD). Lobbying focuses: **Pre-certification programs** for adaptive AI tools, **Transparency in algorithm updates**, **Real-world evidence** for AI validation

DOJ (Department of Justice) is involved in **HIPAA criminal enforcement** and **AI bias investigations** and Increasing scrutiny of **algorithmic discrimination** in healthcare and insurance U/W. **Ethical & Legal Tensions:**

- **Trade Secrets vs. Transparency:** Courts and regulators are balancing IP protection with patients' rights to understand how decisions are made.
- **Bias & Disparate Impact:** Disclosure is increasingly tied to **civil rights compliance**, especially under HIPAA, Section 1557, and state AI laws.

What Is Algorithmic Transparency?



When advanced analytics surged with meaningful use and in **healthcare, insurance, and public benefits**, opaque algorithms became a common debate in discussion of policy, disclosure and legality. As a lesson learned, agencies are getting ahead of it for policy making and AI.

At its core, it's the principle that organizations using AI or automated decision-making systems (ADMs) must disclose **when** and **how** algorithms are used, **what data** they rely on, **how decisions are made or influenced, and what risks or biases** may be embedded. Specific focus includes:

- AI in utilization management, guardrails on AI-driven denials, HIPAA modernization and interoperability standards.
- Automation Bias: Over-reliance on AI tools without understanding their logic has led to clinical drift and reduced diagnostic testing in some systems

How that translates:

- **OCR (HHS)** is pushing for **HIPAA updates** to address AI-driven decision-making
- **CMS** is under pressure to ensure **transparency in AI-based prior authorization**
- **FDA** is being lobbied to require **explainability** for AI/ML-based medical devices
- **Civil society** (e.g., Mozilla Foundation, Center for AI Safety) is advocating for **mandatory disclosures** and **auditability** of AI systems

Regulatory Requirements for AI Disclosure in Healthcare

<i>Tool</i>	<i>Purpose</i>
AI Facts Labels	Patient-facing summaries of AI use, modeled after Drug Facts Labels
Model Cards	Technical disclosures of model purpose, data, and limitations
Algorithm Registries	Public databases of government-used AI systems (e.g., UK, Chile)
Audit Trails	Logs of AI decision-making steps for retrospective review

Who to look to: AI-healthcare regulations and best practice

Kuwait: I first became interested in what Kuwait was doing was based on Microsoft Kuwait, UAE from a peer and friend in my Wharton AI program. What struck me the most was how intuitive, heartfelt and foundational it was. I was not surprised; it was just so inspiring.

Two top areas to start with:

- Development is underway under the **Kuwait National AI Strategy (2025-2028)**, aligning with public-private data, risk-assessment, transparency and human-centric AI principles law-middleeast.com+4digital.nemko.com+4cait.gov.kw+4.



- AI compliance elements include **data protection, human oversight, risk assessments, and transparency obligations**—but no specific disclosure mandate in care delivery yet [legalnodes.com+2twobirds.com+2worldhealthexpo.com+2](#).

United Arab Emirates (UAE)

- **The UAE regulates AI in healthcare via Federal Law No. 2 of 2019** on ICT in Health Fields, and the DOH Policy on AI in Healthcare, which mandates transparency, accountability, patient-rights protection and disclosure of AI-enabled functions, validation process, datasets used, and roles of professionals in decisions (including appeals) [healthcareworld.com+1twobirds.com+1](#).
- **More general AI governance through UAE AI Charter (2024)** with ethics principles (ACCESS) and the National Strategy framework but again, no regulation exactly mirroring U.S. Section 1557 disclosure rule, transparency and accountability provisions overlap .

United Kingdom: UK was a focus in my AI program as well as the undeniable presence and voice of Andy Meiner and OpenEHR in the single patient record and response to UK's 10 year plan.

- **AI in healthcare is regulated via: Data Protection Act 2018** / UK GDPR (restricting automated decisions); **Medical Device Regulations 2002** and MHRA guidance on Software as a Medical Device (SaMD) and AI as a Medical Device (AIaMD) [practiceguides.chambers.com+1gov.uk+1](#).
- **UK launched AI Airlock regulatory** sandbox in Spring 2024—a pilot environment for AI medical device innovators with oversight and pre-market testing; cohort 2 running June-July 2025 [gov.uk+1gov.uk+1](#).
- **Cross-sector AI White Paper principles** (transparency, fairness, contestability, safety) guide future regulation; new Regulatory Innovation Office launched Oct 2024 to accelerate innovation in sectors including healthcare AI [Xenoss+1en.wikipedia.org+1](#).

Transparency is no longer optional. Algorithmic logic, training data, and auditability are mandatory disclosures, not only for clinical tools, but for any decision system affecting care.

- Lobbying dollars on AI in healthcare has skyrocketed 150% year over year....
- Minnesota HF2500 banning algorithm-only prior auth
- OCR's 1557 AI disclosure rule is now in effect
- FDA and CMS under pressure from industry to modernize
- Over 1,000 AI bills introduced in 2025 across the U.S.
- Massive lobbying surge: 648 companies in 2024 (up 141%)
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