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2d Session

DISCUSSION DRAFT

Model legislation prepared by Daniel C. Pettus, a private citizen. Not introduced in Congress. Not endorsed by any Member or organization. Bracketed amounts are placeholders. Comments: dan@aimedagent.net

A BILL

To accelerate the safe adoption of artificial intelligence in health care in the United States through a staged national standard, independent certification, Federal incentives, and oversight, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE. This Act may be cited as the "Meaningful Artificial Intelligence in Health Care Act of 2026" or the "Meaningful AI Act".

(b) TABLE OF CONTENTS. Sec. 1, Short title. Sec. 2, Findings. Sec. 3, Purposes. Sec. 4, Definitions. Title I, The AI Adoption Model. Title II, Independent Certification. Title III, Incentives. Title IV, Oversight and Transparency. Title V, Enforcement and Penalties. Title VI, Implementation Without Delay. Title VII, Relationship to Other Law.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Demand for health care in the United States is growing faster than the workforce to provide it. The Association of American Medical Colleges projects a shortage of up to 86,000 physicians by 2036, while the population aged 65 and older grows by 34.1 percent. The World Health Organization projects a global shortfall of 11.1 million health workers by 2030.

(2) Artificial intelligence is entering clinical care at a pace without precedent. The Food and Drug Administration authorized 331 AI-enabled medical devices in 2025, the most in its history, and more

than 1,400 since 1995. Many AI systems used in care, including documentation, triage and prediction tools, are not regulated as devices and appear in no federal count.

(3) Congress has moved American health care through a technology transition before. Under the Health Information Technology for Economic and Clinical Health Act, hospital adoption of electronic health records rose from 9 percent with a basic record in 2008 to 99 percent with a certified record in 2024, and office-based physician adoption from 17 percent to 91 percent. Medicare and Medicaid incentive payments under that Act reached \$34.7 billion to more than 500,000 providers by May 2016, and were paired with Medicare payment reductions for providers who did not adopt.

(4) No national standard defines what safe adoption of artificial intelligence means for a hospital or a physician practice. At least seven States have enacted thirteen health care AI laws, with differing requirements. An Executive order of December 11, 2025, directed federal litigation against State AI laws, and federal preemption legislation remains unresolved.

(5) The only federal transparency requirement for AI inside certified health information technology, the 31 source attributes for predictive decision support interventions required since January 1, 2025, has been proposed for removal.

(6) Private organizations have published responsible-use guidance and a voluntary certification of AI governance, and leading health systems have adopted their own principles. These efforts are valuable, but they are voluntary, they are not linked to payment, and their results do not travel between organizations in a form that patients, payers and regulators can compare. HIMSS, whose maturity models include the widely used EMRAM, offers no AI-specific model.

(7) Validation before use and monitoring after use are distinct safety functions. A widely deployed sepsis prediction model, when tested on one academic medical center's own patients, identified about one third of sepsis cases while alerting on 18 percent of hospitalized patients. The same center later deactivated the model when a shift in its patient population caused false alerts.

(8) The Centers for Medicare & Medicaid Services has already recognized the need to capture harm attributable to AI, through an improvement activity in the Merit-based Incentive Payment System for 2026 that asks practices to add a field for AI-attributable events and near misses to their patient safety reporting systems, with a documented process to find the cause and prevent recurrence.

(9) Federal law has long relied on independent private bodies to verify compliance with federal standards, including accrediting organizations granted deeming authority under section 1865 of the Social Security Act and certification bodies authorized under the ONC Health IT Certification Program.

(10) Health care adopts new technology slowly without a forcing function. A national staged standard, independently verified and tied to payment, will accelerate adoption rather than slow it, because it tells every organization what is required at each step and rewards those that climb.

SEC. 3. PURPOSES.

The purposes of this Act are:

- (1) to accelerate the adoption of artificial intelligence in health care in the United States;
- (2) to establish a single national staged standard for safe adoption, measured at the level of the organization;
- (3) to require that each organization's stage be verified by an independent third party, and published;
- (4) to reward organizations and clinicians that achieve higher stages, and to apply payment consequences to those that do not achieve minimum stages after a reasonable period;
- (5) to require transparency from developers of AI systems used in care, and to prohibit contract terms that suppress safety information;
- (6) to create a national system for reporting and learning from events attributable to AI; and
- (7) to protect patients, and the clinicians who use AI, while the technology improves.

SEC. 4. DEFINITIONS.

In this Act:

- (1) **ARTIFICIAL INTELLIGENCE SYSTEM.** The term "artificial intelligence system" has the meaning given the term "artificial intelligence" in section 5002 of the National Artificial Intelligence Initiative Act of 2020 (15 U.S.C. 9401), as applied to a system used in the delivery, management or administration of health care.
- (2) **CLINICAL AI SYSTEM.** An artificial intelligence system whose output is used to inform or carry out the diagnosis, treatment, monitoring or prevention of disease for an individual patient.
- (3) **ADMINISTRATIVE AI SYSTEM.** An artificial intelligence system used for scheduling, documentation support, coding, revenue cycle, supply, staffing or similar operational functions, and not used to make clinical decisions.
- (4) **ELIGIBLE ORGANIZATION.** A subsection (d) hospital or critical access hospital as defined in section 1886(d) and 1861(mm) of the Social Security Act, a MIPS eligible clinician or group as

defined in section 1848(q), and a Medicaid provider eligible under section 1903(t), that elects to participate.

(5) AI DEVELOPER. A person that develops, licenses or supplies an artificial intelligence system for use by an eligible organization, including a developer of certified health information technology.

(6) AI-ATTRIBUTABLE EVENT. An event or near miss in which the output, failure or unavailability of an artificial intelligence system contributed, or may have contributed, to harm or risk of harm to a patient.

(7) AUTONOMOUS FUNCTION. Completion of a task by an artificial intelligence system without contemporaneous review by a qualified individual before the task takes effect.

(8) MEANINGFUL HUMAN REVIEW. Review by a qualified individual who has the information, the time and the authority to accept, modify or reject the output of an artificial intelligence system before it takes effect.

(9) CERTIFICATION BODY. An independent organization recognized by the Secretary under section 201.

(10) OFFICE. The Office of Health AI Adoption and Safety established under section 401.

(11) STAGE. A stage of the AI Adoption Model established under section 101.

TITLE I. THE AI ADOPTION MODEL

SEC. 101. ESTABLISHMENT OF STAGES.

(a) IN GENERAL. There is established the AI Adoption Model, consisting of eight cumulative stages numbered 0 through 7. An eligible organization at a stage meets the criteria of that stage and of every lower stage.

(b) STAGE 0, UNLISTED. Artificial intelligence systems may be in use in the organization; no complete inventory exists.

(c) STAGE 1, INVENTORY AND OWNERSHIP. The organization:

- (1) maintains a complete inventory of every artificial intelligence system in use, including systems embedded in health information technology, medical devices and contracted services;
- (2) records the intended use of each system;
- (3) names an accountable executive for each system;

(4) can suspend the use of any system within 24 hours, and has a documented procedure to do so; and

(5) has an AI governance body that includes clinical, nursing, pharmacy, informatics, legal and patient safety members.

(d) STAGE 2, TRANSPARENCY. For each system in the inventory, the organization:

(1) holds model information covering, at a minimum, the source attributes set out in 45 C.F.R. 170.315(b)(11) as in effect on January 1, 2025, regardless of any later amendment of that section;

(2) makes that information available to clinicians at or near the point of use; and

(3) has a written policy on notice to patients when a clinical AI system is used in their care.

(e) STAGE 3, LOCAL VALIDATION. For each clinical AI system, the organization:

(1) evaluated performance on its own patient population before clinical use, against written acceptance criteria approved by the governance body;

(2) evaluated performance across patient subgroups, including by age, sex, race and ethnicity where data permit; and

(3) repeats validation after any material change to the system, its inputs or its intended use.

(f) STAGE 4, PRODUCTION MONITORING AND SAFETY REPORTING. The organization:

(1) monitors the performance of each clinical AI system in use, including drift, at intervals set by the governance body;

(2) defines thresholds that trigger review or suspension;

(3) records AI-attributable events in its patient safety evaluation system and reports serious events to a Patient Safety Organization under section 403; and

(4) maintains a channel for clinicians and staff to report concerns about any AI system, protected under section 404.

(g) STAGE 5, BOUNDED ADMINISTRATIVE AUTONOMY. The organization may use administrative AI systems with autonomous function where:

(1) the tasks performed autonomously are listed and approved by the governance body;

(2) limits on each task are documented and enforced;

- (3) every autonomous action is logged and auditable;
- (4) a human escalation path exists for every task; and
- (5) no autonomous function makes a clinical decision.

(h) **STAGE 6, CLINICAL REASONING WITH ENGINEERED OVERSIGHT.** The organization uses clinical AI systems that reason across the patient record, where:

- (1) each finding is routed to a named qualified individual by role, with a defined response time and escalation path;
- (2) the response of the individual is recorded;
- (3) the organization has assessed that reviewers have the capacity to provide meaningful human review at the volume generated; and
- (4) findings and responses are retained as part of the audit record.

(i) **STAGE 7, BOUNDED CLINICAL AUTONOMY WITH PUBLISHED OUTCOMES.** The organization may use clinical AI systems with autonomous function for named clinical tasks where:

- (1) each task, its limits and its stop conditions are approved by the governance body, consistent with the system's status under the Federal Food, Drug, and Cosmetic Act and with State scope of practice law;
- (2) the organization publishes, at least annually, the outcomes of patients affected by autonomous clinical functions;
- (3) the certification body validated the stage by site visit; and
- (4) any autonomous clinical function can be suspended immediately.

SEC. 102. UPDATING THE CRITERIA.

(a) The Secretary may raise the criteria of any stage by rule, no more often than once every two years, with at least 12 months' notice before a raised criterion applies.

(b) The Secretary may not lower or remove a criterion set out in section 101.

(c) In updating criteria the Secretary shall consider the recommendations of the advisory committee under section 406.

SEC. 103. CRITERIA EFFECTIVE ON ENACTMENT.

The criteria in section 101 take effect on the date of enactment and apply whether or not the Secretary has issued any regulation under this Act.

TITLE II. INDEPENDENT CERTIFICATION**SEC. 201. RECOGNITION OF CERTIFICATION BODIES.**

(a) **IN GENERAL.** The Secretary shall recognize independent certification bodies to certify the stage of eligible organizations.

(b) **REQUIREMENTS.** To be recognized, a certification body shall:

- (1) be accredited by an accreditor approved by the Secretary, on the model of the ONC Health IT Certification Program;
- (2) have no ownership interest in, and receive no compensation from, any AI developer whose systems it may evaluate;
- (3) not certify any organization to which it or an affiliate provided consulting on artificial intelligence within the preceding 24 months;
- (4) conduct a site visit for certification at Stage 4 and above, and for every Stage 7 certification; and
- (5) submit each certification decision to the public registry under section 402 within 30 days.

SEC. 202. INTERIM RECOGNITION.

(a) Not later than 90 days after enactment, the Secretary shall accept applications for interim recognition from:

- (1) accrediting organizations approved by CMS under section 1865 of the Social Security Act;
- (2) ONC-Authorized Certification Bodies; and
- (3) organizations that, on the date of enactment, operate an established program validating health information technology maturity in hospitals by site visit.

(b) The Secretary shall decide each application within 30 days. An application not decided within 30 days is approved.

(c) Interim recognition is valid for 24 months and may be converted to full recognition under section 201.

SEC. 203. CERTIFICATION.

(a) An eligible organization seeking certification submits evidence to a certification body. The certification body determines the highest stage whose criteria the organization meets.

(b) Certification is valid for two years.

(c) Each certification body shall audit not fewer than 5 percent of its certified organizations each year, selected at random, and any organization that is the subject of a credible complaint.

(d) Certification fees are paid by the organization. The Secretary may set maximum fees for critical access hospitals, rural hospitals and practices of fewer than 10 clinicians.

SEC. 204. DUTIES OF AI DEVELOPERS.

(a) MODEL INFORMATION. An AI developer that supplies a system to an eligible organization shall provide, within 30 days of a request, the model information needed to meet section 101(d).

(b) VALIDATION AND MONITORING SUPPORT. An AI developer shall provide the access to outputs, inputs and performance data reasonably needed for the organization to meet sections 101(e) and 101(f).

(c) NO GAG CLAUSES. A contract term that prohibits or restricts an eligible organization, a clinician or a researcher from disclosing an AI-attributable event, a performance finding or a safety concern to a Patient Safety Organization, a certification body, a federal agency or the public is void and unenforceable.

(d) PERFORMANCE CLAIMS. An AI developer may not represent the performance of a system to an eligible organization in a manner that is false or misleading.

TITLE III. INCENTIVES

SEC. 301. MEDICARE INCENTIVE PAYMENTS FOR HOSPITALS.

(a) IN GENERAL. Section 1886 of the Social Security Act is amended to provide incentive payments to subsection (d) hospitals and critical access hospitals for each stage certified, as follows:

Stage certified	Base payment	Per-discharge amount	Available
Stage 2	[\$150,000]	none	E + 12 months to E + 60 months
Stage 4	[\$750,000]	[\$25] per discharge, [1,150th to 23,000th]	E + 24 months to E + 7 years
Stage 6	[\$1,000,000]	[\$25] per discharge, same range	E + 48 months to E + 7 years
Stage 7	[\$500,000]	none	E + 48 months to E + 7 years

(b) Each payment is multiplied by the hospital's Medicare share, and reduced by [25 percent] for each year after first availability in which the stage is first certified, as under section 1886(n).

(c) Each stage payment is made once.

SEC. 302. MEDICARE PAYMENT ADJUSTMENT FOR HOSPITALS.

(a) For fiscal years beginning [E + 36 months], the applicable percentage increase for a subsection (d) hospital not certified at Stage 2 or higher is reduced by [one-quarter] of the market basket update.

(b) For fiscal years beginning [E + 60 months], the reduction applies to a hospital not certified at Stage 4 or higher and is [one-half] of the market basket update.

(c) The Secretary may grant hardship exceptions for not more than five years in total, including for hospitals affected by declared disasters and for critical access hospitals demonstrating financial distress.

SEC. 303. AI ADOPTION IN THE MERIT-BASED INCENTIVE PAYMENT SYSTEM.

(a) Section 1848(q) of the Social Security Act is amended to add an AI adoption measure to the Promoting Interoperability performance category, worth up to [ten] points, beginning with the first performance year that begins at least 12 months after enactment.

(b) A MIPS eligible clinician earns credit for the stage certified for the clinician's practice, or for the eligible organization in which the clinician furnishes the majority of covered services.

(c) The measure is budget neutral within the existing MIPS payment adjustment.

SEC. 304. MEDICAID.

(a) Section 1903 of the Social Security Act is amended to provide 100 percent federal financial participation for State incentive payments to Medicaid providers for certified stages, and 90 percent federal financial participation for State administrative costs, as under section 1903(t).

(b) Participation by a State is optional.

SEC. 305. AI ADOPTION EXTENSION CENTERS.

(a) The Secretary shall award grants to establish AI Adoption Extension Centers to provide technical assistance to critical access hospitals, rural hospitals, safety-net hospitals, federally qualified health centers and practices of fewer than 10 clinicians.

(b) Grants may cover certification fees for eligible small and rural organizations.

(c) There is authorized to be appropriated [\$650,000,000] for fiscal years [E] through [E + 5].

SEC. 306. CONDITIONS.

Incentive payments under this title are conditioned on certification. Payments made on the basis of a certification later found to rest on false information shall be recouped.

TITLE IV. OVERSIGHT AND TRANSPARENCY

SEC. 401. OFFICE OF HEALTH AI ADOPTION AND SAFETY.

(a) There is established in the Office of the Secretary an Office of Health AI Adoption and Safety, headed by a Director appointed by the Secretary.

(b) The Office shall administer this Act and coordinate the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office for Civil Rights and the Office of Inspector General.

(c) There is appropriated [\$50,000,000] for each of the first two fiscal years after enactment, to remain available until expended.

SEC. 402. PUBLIC REGISTRY.

The Office shall maintain a public, searchable registry listing, for each eligible organization, its current certified stage, the certification body, and the dates of certification and expiration; and, for each AI developer, the systems supplied to eligible organizations and a link to the model information under section 204(a).

SEC. 403. AI SAFETY EVENT REPORTING.

(a) An eligible organization certified at Stage 4 or higher shall report serious AI-attributable events to a Patient Safety Organization listed under the Patient Safety and Quality Improvement Act of 2005

(42 U.S.C. 299b-21 et seq.).

(b) The privilege and confidentiality protections of that Act apply to such reports.

(c) The Agency for Healthcare Research and Quality shall publish an annual report of aggregate, de-identified AI-attributable events, with lessons learned.

(d) Nothing in this section affects any obligation to report under the Federal Food, Drug, and Cosmetic Act.

SEC. 404. PROTECTION OF CLINICIANS AND STAFF.

(a) No eligible organization or AI developer may discharge, discipline or retaliate against a clinician or employee for reporting, in good faith, a concern about the safety or performance of an artificial intelligence system.

(b) No clinician may be penalized for declining, in good faith and with documentation, to follow the output of a clinical AI system.

SEC. 405. PATIENTS.

An eligible organization certified at Stage 6 or higher shall inform patients, in plain language, that clinical AI systems are used in their care, and shall provide meaningful human review of any autonomous clinical function on a patient's request.

SEC. 406. ADVISORY COMMITTEE.

The Secretary shall establish an AI Adoption Advisory Committee including physicians, nurses, pharmacists, patients, hospital and practice leaders, informaticists, standards organizations and AI developers, with AI developers holding not more than one-fifth of the seats.

SEC. 407. REPORTS AND REVIEW.

(a) The Secretary shall report to Congress annually on adoption by stage, incentive payments, penalties, and AI-attributable events.

(b) The Comptroller General shall review the program at 24 months and 48 months after enactment.

TITLE V. ENFORCEMENT AND PENALTIES

SEC. 501. FALSE ATTESTATION.

(a) An eligible organization that knowingly submits false information to obtain or maintain certification is subject to a civil money penalty of up to [\$100,000] per violation, recoupment of incentive payments, and decertification.

(b) Claims for incentive payments under title III are claims for purposes of the False Claims Act.

SEC. 502. AI DEVELOPERS.

An AI developer that violates section 204 is subject to a civil money penalty of up to \$1,000,000 per violation, imposed by the Inspector General, and may be barred from supplying systems to eligible organizations for purposes of this Act.

SEC. 503. CERTIFICATION BODIES.

The Secretary may suspend or revoke the recognition of a certification body that violates section 201, and may impose a civil money penalty of up to [\$250,000] per violation of the conflict of interest requirements.

SEC. 504. FAILURE TO REPORT.

An eligible organization that knowingly fails to report a serious AI-attributable event under section 403 is subject to a civil money penalty of up to [\$50,000] per event, and repeated failure is grounds for decertification.

SEC. 505. DUE PROCESS AND CURE.

Before imposing a penalty under this title on an eligible organization acting in good faith, the Secretary shall provide notice and not less than 60 days to cure. Penalties are subject to the procedures of section 1128A of the Social Security Act.

TITLE VI. IMPLEMENTATION WITHOUT DELAY

SEC. 601. DEADLINES.

The Secretary shall meet the deadlines in this Act. Where the Secretary does not, the following defaults apply.

SEC. 602. INTERIM FINAL RULES.

The Secretary may implement this Act by interim final rule. Chapter 35 of title 44, United States Code (the Paperwork Reduction Act), does not apply to information collected under this Act during the first three years after enactment.

SEC. 603. SELF-EXECUTING DEFAULT.

If the Secretary has not issued certification procedures within 180 days of enactment, certification bodies holding interim recognition may certify eligible organizations using the statutory criteria in section 101, and such certifications are valid for all purposes of this Act.

SEC. 604. CREDIT FOR EXISTING WORK.

An eligible organization that, on the date of enactment, holds a certification of responsible AI governance from an accrediting organization approved under section 1865 of the Social Security Act is provisionally certified at Stage 2 for 12 months, pending full certification.

TITLE VII. RELATIONSHIP TO OTHER LAW**SEC. 701. FOOD AND DRUG ADMINISTRATION.**

Nothing in this Act alters the authority of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. Certification under this Act is not clearance or approval of any device.

SEC. 702. HIPAA.

Nothing in this Act modifies the HIPAA privacy, security or breach notification rules. Activities required by this Act are health care operations.

SEC. 703. PRACTICE OF MEDICINE.

Nothing in this Act authorizes an artificial intelligence system to practice medicine, nursing, pharmacy or any other licensed profession, or preempts State licensure or scope of practice law.

SEC. 704. RELATIONSHIP TO STATE LAW.

(a) **FEDERAL STANDARD CONTROLS.** This Act, and regulations issued under it, supersede any provision of State law to the extent that the provision is contrary to this Act. A provision of State law is contrary to this Act if compliance with both is impossible, or if the State provision stands as an obstacle to accomplishing the purposes of this Act.

(b) STATES MAY ADD. Nothing in this Act prevents a State from enacting or enforcing requirements for the use of artificial intelligence in health care that are in addition to, and not contrary to, the requirements of this Act, including requirements that provide greater protection to patients.

(c) PROTECTION FOR COMPLIANCE. No State or political subdivision may prohibit, or impose any liability or penalty for, an act that this Act requires, including reporting to a Patient Safety Organization, disclosure of model information, publication in the registry under section 402, or certification under title II.

(d) SAVINGS. Nothing in this section preempts State law governing licensure and scope of practice, professional discipline, tort liability, or insurance coverage determinations.

SEC. 705. INSURANCE COVERAGE DETERMINATIONS.

This Act does not govern the use of artificial intelligence by health plans or Medicare Advantage organizations to make coverage or utilization review determinations.

SEC. 706. SUNSET OF INCENTIVES.

Incentive payments under title III end seven years after enactment. Certification, penalties and reporting continue unless Congress provides otherwise.

SOURCES FOR THE FINDINGS IN SECTION 2

- **Finding (1).** AAMC. New AAMC report shows continuing projected physician shortage. Press release, 21 March 2024. Shortage of up to 86,000 physicians by 2036; population aged 65 and older to grow 34.1 percent. <https://www.aamc.org/news/press-releases/new-aamc-report-shows-continuing-projected-physician-shortage> World Health Organization. Health workforce: projected shortfall of 11.1 million health workers by 2030. <https://www.who.int/teams/health-workforce/about/30>
- **Finding (2).** MedTech Dive. Tracking the FDA's AI-enabled device authorizations. Updated 27 May 2026, from the FDA list current to 30 December 2025: 331 authorizations in 2025, the most in the agency's history; more than 1,400 since 1995. <https://www.medtechdive.com/news/ai-medtech-track-new-devices-fda/748397/>
- **Finding (3).** ASTP/ONC. National trends in hospital and physician adoption of electronic health records. Hospitals 9 percent (basic EHR) in 2008 to 99 percent (certified EHR) in 2024; office-based physicians 17 percent to 91 percent. <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records> Rajiv Leventhal. Report: Meaningful Use payments total \$34.7 billion. Healthcare Innovation, 27 June 2016. \$34,698,047,312 through May 2016 to more than 500,000 unique providers. <https://hcinnovationgroup.com/policy-value-based-care/news/13027074/report-meaningful-use-payments-total-347-billion> CMS. Medicare and Medicaid Health Information Technology: Title IV of the

American Recovery and Reinvestment Act. Fact sheet, 16 June 2009. Hospital market basket reductions of one-quarter, one-half and three-quarters for non-meaningful users from 2015; physician reductions of 1, 2 and 3 percent; 100 percent federal financial participation for Medicaid incentives and 90 percent for State administration; hospital incentive as initial amount times Medicare share times transition factor.

<https://cms.gov/newsroom/fact-sheets/medicare-and-medicaid-health-information-technology-title-iv-american-recovery-and-reinvestment-act>

- **Finding (4).** Naomi Diaz. 13 state healthcare AI laws to know. Becker's Hospital Review, 9 October 2026. Laws in California (4), Rhode Island (3), Texas (2), Hawaii, Iowa, Maine and Illinois. <https://www.beckershospitalreview.com/healthcare-information-technology/ai/13-state-healthcare-ai-laws-to-know/> Executive Order 14365, Ensuring a National Policy Framework for Artificial Intelligence, 11 December 2025, 90 Fed. Reg. 58499, <https://www.federalregister.gov/documents/2025/12/16/2025-23092/ensuring-a-national-policy-framework-for-artificial-intelligence>. Status summary: CASRAI, Federal AI preemption fight: where it stands, 20 September 2026. Executive Order 14365, 11 December 2025; Senate vote of 99 to 1 in July 2025 removing a State AI moratorium; House preemption draft not introduced as a bill. <https://casrai.org/news/federal-ai-moratorium-state-preemption-fight-2026>
- **Finding (5).** ASTP/ONC. Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5), proposed rule. Federal Register, 29 December 2025. <https://www.federalregister.gov/documents/2025/12/29/2025-23896/health-data-technology-and-interoperability-astponc-deregulatory-actions-to-unleash-prosperity>. On the 31 source attributes at 45 C.F.R. 170.315(b)(11), effective 1 January 2025, and their proposed removal: MedAI Directory, The AI model card in your EHR, 21 September 2026, <https://medaidirectory.com/blog/ehr-ai-model-card-hti-5-dsi-transparency-2026> ASTP/ONC. HTI Rules page, last updated 29 April 2026, lists HTI-5 as a proposed rule: <https://healthit.gov/regulations/hti-rules>. Ruth Reader, Second Opinion, 10 September 2026, reported the final rule at the Office of Management and Budget: <https://www.secondopinion.media/scoop-interoperability-final-rule-drops-info-blocking-fixes/>. No final rule had been found as of 25 October 2026; check before publication.
- **Finding (6).** Digital Health Insights. Joint Commission launches Responsible Use of AI in Healthcare certification. 18 June 2026. Voluntary; evaluates governance, data management, risk and bias, validation, and transparency; certifies organizations, not products. <https://dhinsights.org/news/joint-commission-launches-responsible-ai-use-certification> Coalition for Health AI. Joint Commission and CHAI release initial guidance to support responsible AI adoption across U.S. health systems. 17 September 2025. <https://www.chai.org/news/joint-commission-and-coalition-for-health-ai-chai-release-initial-guidance> Daniel Yang, MD. AI in health care: 7 principles of responsible use. Kaiser Permanente, 25 March 2025. <https://about.kaiserpermanente.org/news/ai-in-health-care-7-principles-of-responsible-use> HIMSS. Digital maturity models: EMRAM, AMAM, INFRAM, C-COMM, DIAM and CCMM; none is specific to AI. <https://www.himss.org/maturity-models/>
- **Finding (7).** Wong A, et al. External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. JAMA Internal Medicine. 2021;181(8):1065-1070. Summary: Fierce Healthcare, 22 June 2021, <https://www.fiercehealthcare.com/tech/epic-s-widely-used-sepsis-prediction-model-falls-short-among-michigan-medicine-patients> Finlayson SG, et al. The clinician and dataset shift in artificial intelligence. New England Journal of Medicine. 2021;385:283-286. doi:10.1056/NEJMc2104626.

Summary of the April 2020 deactivation: Digital Health Insights, 28 June 2022,
<https://dhinsights.org/news/predictive-models-need-monitoring-to-avoid-dataset-shifts>

- **Finding (8).** CMS Quality Payment Program, 2026 improvement activity IA_PSPA_34, Patient Safety in Use of Artificial Intelligence (AI). Text via MDinteractive: https://mdinteractive.com/mips_ia/2026-mips-IA_PSPA_34-patient-safety-in-use%20of-artificial-intelligence-ai
- **Finding (9).** CMS. Accrediting Organizations: deemed status under section 1865(a) of the Social Security Act. <https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/accrediting-organizations-aos> HHS. How is the ONC Health IT Certification Program structured? ONC-Approved Accreditor, ONC-Authorized Certification Bodies, ONC-Authorized Testing Laboratories. <https://www.hhs.gov/guidance/document/a1-how-onc-health-it-certification-program-structured>

DISCLOSURE

The author holds pending patent applications on a method for AI-assisted medication oversight, is co-inventor on two issued US patents in connected health, and offers executive advisory services in medical device interoperability and AI in health care. No organization paid for, reviewed or endorsed this draft. It is not legal advice.