AI ACCOUNTABILITY & AUDITABILITY IN CLINICAL DECISION SOFTWARE ACT OF 2025 (AACDSA)

TITLE I — SHORT TITLE; FINDINGS; DEFINITIONS

SEC. 101. SHORT TITLE.

This Act may be cited as the **"AI Clinical Safety Act of 2025"** or, formally, as the **"AI Accountability & Auditability in Clinical Decision Software Act of 2025."**

SEC. 102. CONGRESSIONAL FINDINGS.

Congress finds the following:

1. Artificial-intelligence and machine-learning systems are increasingly embedded in United States clinical workflows.
2. Absent transparent oversight, such systems may embed or amplify bias, degrade over time, and erode patient safety and public trust.
3. A statutory framework linking transparency, continuous auditing, and proportionate incentives is necessary to safeguard patients while fostering responsible innovation.

SEC. 103. DEFINITIONS.

For purposes of this Act:

1. **Clinical Decision Software; CDS.**—The term "clinical decision software" or "CDS" means software that, whether or not so labeled, is reasonably foreseeable to influence diagnosis, triage, prognosis, or treatment decisions by a licensed health-care professional in the United States.
2. **Risk Class.**—The term "risk class" means the impact tier assigned to a CDS by the Food and Drug Administration (referred to in this Act as the "FDA") pursuant to **Schedule B**.
3. **Adaptive CDS.**—The term "adaptive CDS" means CDS that self-modifies its parameters, inference rules, or training data without manual code deployment.
4. **Explainability Summary.**—The term "explainability summary" means a document not longer than 3 pages, written in plain English and supplemented by model-interpretability graphics, that discloses primary inputs, feature-importance rankings, uncertainty bounds, and known failure modes.
5. **Independent Auditor.**—The term "independent auditor" means an organization accredited under section 301 that— (A) holds no equity stake, consulting income, or contingent-fee arrangement with the audited vendor for the 3-year period before and after an audit; and (B) maintains professional liability coverage of not less than $5,000,000.

6. **Override Event.**—The term “override event” means an instance in which a clinician disregards, delays, or meaningfully alters a CDS recommendation.
7. **Adverse Clinical Event.**—The term “adverse clinical event” means any sentinel event, as defined in section 482.70 of title 42, Code of Federal Regulations, occurring within 30 days of a CDS-guided decision.
8. **Audit Grade.**—The term “audit grade” means the Bronze, Silver, or Gold rating assigned under section 303.
9. **De-identified Log.**—The term “de-identified log” means data stripped of the identifiers enumerated in section 164.514(b)(2) of title 45, Code of Federal Regulations, and certified by an expert-deterministic review.
10. **Cyber Incident.**—The term “cyber incident” means unauthorised access to, or manipulation of, CDS model weights, inference pipelines, or associated data that could reasonably alter clinical outputs.

SEC. 104. RULE OF CONSTRUCTION.

Nothing in this Act may be construed to limit the authority of the FDA under the Federal Food, Drug, and Cosmetic Act, or to pre-empt any State law that affords more stringent protections to patients or consumers.

SEC. 105. SEVERABILITY.

If any provision of this Act, or the application of any provision to any person or circumstance, is held invalid, the remainder of this Act, and the application of that provision to other persons or circumstances, shall not be affected.

TITLE II — TRANSPARENCY AND EXPLAINABILITY

SEC. 201. MANDATORY EXPLAINABILITY SUMMARIES.

(a) **Publication Requirement.**—A CDS vendor shall make available to the public, on a freely accessible Internet website, an explainability summary before marketing or deploying the CDS.

(b) **Minimum Contents.**—Each explainability summary shall— (1) use vocabulary at or below a 12th-grade reading level; (2) list data-source origins and collection periods; (3) identify the 15 features with the highest contribution weight; (4) include at least one illustrative counter-factual example; (5) disclose performance metrics disaggregated by age, sex, race, ethnicity, and insurance status; and (6) describe known failure modes and contraindications.

(c) **Updates.**—A vendor shall update an explainability summary not later than 30 days after any model change that materially affects outputs.

SEC. 202. DATA-PROVENANCE DISCLOSURE.

A CDS vendor shall publish a machine-readable schema detailing dataset origins, geographic and demographic composition, and preprocessing steps. Proprietary weighting formulas may be redacted, but every variable category, including learned embeddings, shall be enumerated.

SEC. 203. CLINICIAN-FACING TRANSPARENCY.

A hospital shall embed, within its electronic health-record system, a single-click hyperlink to the explainability summary applicable to any CDS output displayed to a clinician.

SEC. 204. PATIENT RIGHT TO KNOW.

Upon written request, a patient shall receive, not later than 7 calendar days after such request, a concise explanation of not more than 250 words describing how CDS contributed to that patient's care.

SEC. 205. PENALTIES FOR NON-DISCLOSURE.

A violation of sections 201 through 204 is a prohibited act under section 331 of title 21, United States Code, and is subject to a civil monetary penalty of not more than $75,000 for each day of non-compliance.

SEC. 206. INTERNATIONAL ALIGNMENT.

The FDA and the National Institute of Standards and Technology (in this Act referred to as "NIST") shall, to the maximum extent practicable, align audit metrics and reporting templates under this Act with Annex VIII of the European Union Artificial Intelligence Act and comparable international standards.

TITLE III — INDEPENDENT ASSESSMENT AND CONTINUOUS MONITORING

SEC. 301. NIST ACCREDITATION AND AUDITOR INTEGRITY.

(a) **Accreditation Standards.**—Not later than 180 days after the date of enactment of this Act, NIST shall publish accreditation standards for independent auditors addressing statistical rigor, machine-learning interpretability, cybersecurity, and conflict-of-interest controls.

(b) **Conflicts of Interest.**—An accredited auditor may not provide consulting, lobbying, or investment services to a CDS vendor during the 3-year period preceding or following an audit engagement with that vendor.

SEC. 302. RISK-SCALED AUDIT CADENCE.

(a) **Class I.**—A Class I CDS shall undergo a bias, performance, and security audit every 24 months.

(b) **Class II.**—A Class II CDS shall undergo such audit annually.

(c) **Class III.**—A Class III CDS shall undergo such audit semi-annually and maintain a continuous drift-monitoring dashboard accessible to the FDA.

(d) **Adaptive CDS.**—If a CDS is adaptive, the audit cadence applicable to the next higher risk class shall apply.

SEC. 303. AUDIT GRADING SCALE.

Audit outcomes shall be graded as follows: (1) **Bronze**—Meets minimum statutory thresholds. (2) **Silver**—Exceeds thresholds by not less than 10 percent across all protected sub-groups. (3) **Gold**—Meets Silver criteria and shows no material deficiencies for three consecutive audits.

SEC. 304. PUBLIC REPORTING PORTAL.

The FDA shall maintain a searchable public portal and shall post each audit report, with bona fide trade secrets redacted, not later than 30 days after submission. Each posting shall include a machine-readable model card summarizing metrics.

SEC. 305. RANDOMISED AND TRIGGERED SPOT AUDITS.

(a) **Randomised Audits.**—The FDA shall annually select at least 25 percent of CDS products for spot audits, with selection weighted toward Class III tools.

(b) **Triggered Audits.**—The FDA may initiate an immediate audit upon detection of override spikes, adverse-event clusters, cybersecurity incidents, or credible whistle-blower tips.

SEC. 306. AUDIT FAILURE REMEDIES.

If a CDS receives two consecutive Bronze grades, fails a spot audit, or materially misrepresents information, the FDA may— (1) suspend or revoke marketing clearance; (2) require a corrective-action plan with time-bound milestones; and (3) assess a civil penalty of not more than $3,000,000 for each violation.

SEC. 307. WHISTLE-BLOWER BOUNTY.

An individual who provides original information leading to the collection of a civil penalty under this title shall receive an award of not less than 10 percent and not more than 30 percent of the amount collected.

SEC. 308. CYBER-INCIDENT DISCLOSURE.

A CDS vendor shall, not later than 72 hours after confirming a cyber incident, notify the FDA, affected hospitals, and any patient whose protected health information may have been exposed or whose care may have been impacted.

SEC. 309. CLINICAL HARDSHIP WAIVER.

If the FDA suspends a CDS, a hospital may request a waiver, for a period not to exceed 90 days, to continue use of the CDS when necessary to prevent disruption of patient care. The waiver and supporting justification shall be made public.

SEC. 310. MALPRACTICE-INSURER INTEROPERABILITY.

An independent auditor shall provide, upon request, a redacted audit summary to a licensed malpractice insurer for actuarial use, except that such data shall not be used to deny coverage or implement discriminatory pricing unrelated to AI-specific risk.

TITLE IV — INCENTIVES AND SAFE HARBOR

SEC. 401. GRADUATED SAFE HARBOR.

(a) **Bronze-grade CDS.**—No liability shield; standard FDA review timelines apply.

(b) **Silver-grade CDS.**—The FDA shall complete any 510(k) review of a Silver-grade CDS not later than 90 days after submission. A Silver-grade CDS shall be subject to a cap on punitive damages of $500,000 in any civil action arising from its use, unless willful misconduct is proven.

(c) **Gold-grade CDS.**—The FDA shall complete any 510(k) review of a Gold-grade CDS not later than 60 days after submission. A Gold-grade CDS shall be immune from punitive damages in any civil action arising from its use, unless willful misconduct is proven. If a Gold-grade CDS is downgraded to Silver or Bronze, the enhanced protections under this subsection shall terminate on the date of the downgrade.

SEC. 402. HOSPITAL QUALITY BONUS.

A hospital whose deployed CDS fleet maintains an average audit grade of Silver or higher for a fiscal year shall receive a 0.25-percentage-point positive adjustment under the Medicare Hospital Value-Based Purchasing program for that fiscal year.

SEC. 403. STARTUP COMPLIANCE CREDIT.

A CDS vendor with annual revenue of less than $25,000,000 may apply to the FDA for a rebate covering not more than 80 percent of first-year audit fees assessed under this Act.

SEC. 404. SUNSET OF INCENTIVES.

The incentives authorised under this title shall expire in accordance with section 601 unless reauthorised by an Act of Congress.

TITLE V — OVERSIGHT; ANTI-GAMING; DATA GOVERNANCE

SEC. 501. STANDARDISED LOGGING AND TRANSMISSION.

Hospitals shall collect override and adverse-event logs using the HL7 FHIR “cds-audit” profile and shall transmit de-identified logs to the FDA not less often than quarterly.

SEC. 502. DE-IDENTIFICATION STANDARD.

Logs transmitted under section 501 shall satisfy the HIPAA Safe Harbor standard and an expert-determination de-identification review, to balance privacy with analytic utility.

SEC. 503. FREEDOM OF INFORMATION ACT TIMELINES AND TRADE-SECRET BALANCING.

(a) **Presumptive Release.**—Audit reports and aggregated override statistics are presumed releasable under section 552 of title 5, United States Code, not later than 60 days after receipt by the FDA.

(b) **Protective Order.**—A vendor may seek a protective order to withhold specific content only upon demonstrating that release would substantially harm competitive standing; the burden of proof rests with the vendor.

SEC. 504. REGULATORY CAPTURE GUARDRAIL.

An officer or employee of the FDA who has supervisory or decision-making authority over CDS approvals or audits shall be ineligible, during the 3-year period beginning on the date on which the officer or employee leaves government service, to receive compensation from any CDS vendor.

SEC. 505. USER-FEE FUNDING.

(a) **Authority.**—The FDA may assess an annual user fee, not to exceed $350 per licensed hospital bed (indexed to the Consumer Price Index for All Urban Consumers), to fund implementation and enforcement of this Act.

(b) **Use of Funds.**—Fees collected under this section shall be available to the FDA without fiscal-year limitation for audits, portal maintenance, and compliance support.

SEC. 506. ANTI-RETALIATION PROTECTION.

A CDS vendor or hospital shall not discharge, demote, harass, or otherwise retaliate against an individual for lawful whistle-blowing related to this Act. A prevailing whistle-blower shall be entitled to treble damages and reasonable attorney's fees.

SEC. 507. WORKFLOW-BURDEN WAIVER AUTHORITY.

If override rates for a CDS remain below 1 percent for four consecutive quarters, the Secretary of Health and Human Services may grant a waiver reducing log-detail granularity or alert-frequency requirements, provided patient-safety metrics are not adversely affected.

TITLE VI — PREEMPTION; SUNSET; GAO REVIEW; EFFECTIVE DATE; RESEARCH CARVE-OUT

SEC. 601. SUNSET.

All authorities granted under this Act shall terminate 5 years after the effective date, unless renewed by an Act of Congress.

SEC. 602. GAO EVALUATION.

Not later than 48 months after the effective date, the Comptroller General of the United States shall submit to Congress a report evaluating— (1) the accuracy and utility of independent audits; (2) the impact of this Act on patient safety and health equity; (3) the effects of this Act on innovation, particularly with respect to small vendors; (4) administrative and compliance burdens; and (5) the effectiveness of the risk-class framework in allocating audit resources.

SEC. 603. EFFECTIVE DATE.

Except as otherwise provided, this Act shall take effect 12 months after the date of enactment.

SEC. 604. TRANSITION PROVISION.

A CDS marketed before the effective date of this Act shall attain Bronze compliance not later than 12 months after such date and Silver compliance not later than 24 months after such date. Failure to meet either deadline shall render the CDS an adulterated device under section 351 of the Federal Food, Drug, and Cosmetic Act.

SEC. 605. PUBLIC-SECTOR RESEARCH CARVE-OUT.

A non-commercial academic or governmental CDS research deployment involving fewer than 1,000 patients per year and operating under an Institutional Review Board approval shall be exempt from sections 301 through 307, but shall— (1) file a registry entry with the FDA; and (2) display a conspicuous "Research Use Only — Not for Standard Care" disclaimer within the user interface.

SCHEDULE A — POTENTIAL ABUSES AND MITIGATIONS

Potential Abuse	Actor	Mitigation
Relabeling CDS as "informational only"	Vendor	Secs. 103(1); 305
Glossy but vacuous explainability	Vendor	Sec. 201; 303
Hiding bias in latent embeddings	Vendor	Sec. 202; 302
Audit shopping or self-review	Vendor/Auditor	Sec. 301(b); 305
Hospitals suppressing overrides	Hospital	Secs. 501; 306
FOIA stall tactics	Vendor/FDA	Sec. 503
Retaliation against whistle-blowers	Vendor/Hospital	Secs. 506; 307
Revolving-door influence	FDA Staff	Sec. 504
Innovation chill for startups	Systemic	Sec. 403; 605
Over-auditing low-risk tools	Systemic	Sec. 302
Undisclosed cyber breach	Vendor	Sec. 308
Care disruption on suspension	Hospital	Sec. 309
Insurer misuse of audit data	Insurer	Sec. 310
Alert fatigue	Hospital/Vendor	Sec. 507

SCHEDULE B — RISK CLASS FRAMEWORK (INFORMATIVE)

Class I (Minimal Risk).—Tools offering non-patient-specific reference information or low-stakes dose calculators where erroneous output is unlikely to cause more than minimal harm.

Class II (Moderate Risk).—Tools influencing differential diagnosis or treatment plans where erroneous output may cause moderate, reversible harm.

Class III (High Risk).—Tools autonomously triaging emergent conditions or directing life-sustaining interventions where erroneous output may cause serious injury or death.

The FDA shall, not later than 180 days after the date of enactment of this Act, publish detailed criteria and illustrative examples for each risk class.