



30th Annual Ellen P. Hermanson Memorial
Symposium—CLE Program
*A.I. [R]EVOLUTION: Artificial Intelligence in the
Diagnosis and Screening of Breast Cancer*
Tuesday, October 13, 2026

A BILL

To establish federal safety and liability standards for artificial intelligence-enabled medical devices.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “**AI Medical Device Safety and Liability Act.**”

SEC. 2. PURPOSE.

The purposes of this Act are:

1. to establish uniform federal safety and liability standards governing artificial intelligence-enabled medical devices;
2. to promote the safe development, manufacture, deployment, and use of such devices;
3. to establish clear standards governing the liability of developers and other responsible parties for injuries caused by defective or unreasonably dangerous AI-enabled medical devices; and
4. to preserve innovation in artificial intelligence and medical technology while ensuring accountability for foreseeable harms.

SEC. 3. DEFINITIONS.

In this Act:

(a) AI-enabled medical device. The term “AI-enabled medical device” means a medical device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), that incorporates an artificial intelligence system capable of generating a prediction, recommendation, diagnosis, treatment recommendation, risk assessment, or other output that may affect the diagnosis, prevention, or treatment of disease or the health of an individual.

(b) Developer. The term “developer” means a person or entity that designs, develops, trains, materially modifies, or provides an artificial intelligence system incorporated into an AI-enabled medical device.

(c) Manufacturer. The term “manufacturer” means the manufacturer of an AI-enabled medical device, including a person or entity responsible for placing the device into commercial distribution.

(d) Deployer. The term “deployer” means a health care provider, health care facility, or other person or entity that uses an AI-enabled medical device in the provision of health care.

(e) Patient. The term “patient” means an individual who receives health care through the use of an AI-enabled medical device.

(f) Substantial modification. The term “substantial modification,” with respect to a covered AI-enabled medical device means:

- 1, any deliberate change made to device by a deployer that:
 - (A) was not authorized or reasonably anticipated by the developer when the device left the control of the developer; and
 - (B) changes the purpose, use, function, design, or intended use or manner of use of the device from that for which the covered product was originally designed, tested, or intended; and
2. does not include a modification that solely reduces or mitigates a new or additional risk.

SEC. 4. SAFETY AND RISK MANAGEMENT.

(a) Duty of developer and manufacturer. A developer and manufacturer of an AI-enabled medical device shall exercise reasonable care in designing, testing, validating, monitoring, and maintaining the device.

(b) Risk assessment. Before commercially distributing an AI-enabled medical device, the manufacturer shall conduct reasonable testing and risk assessment appropriate to:

1. the intended use of the device;
2. the populations for which the device is intended;
3. reasonably foreseeable uses and misuses;
4. the consequences of erroneous, biased, incomplete, or unreliable outputs; and
5. reasonably foreseeable cybersecurity threats and failures.

(c) Post-market monitoring. A manufacturer shall maintain reasonable procedures for identifying, investigating, and addressing material safety failures, including material errors in AI-generated outputs discovered after deployment.

(d) Material changes. A material change to an AI system that may affect the safety or clinical performance of an AI-enabled medical device shall be subject to appropriate validation before implementation.

SEC. 5. LIABILITY FOR HARM.

(a) Developer and manufacturer liability. A developer or manufacturer shall be liable for harm caused by an AI-enabled medical device where:

1. the device was at the time of sale or distribution, in a defective condition dangerous when used or misused in a reasonably foreseeable manner and the defective condition was a proximate cause of the harm to the claimant;
2. the developer or manufacturer failed to exercise reasonable care in designing, testing, validating, monitoring, or maintaining the AI system; or
3. the developer or manufacturer knowingly or recklessly failed to address a material safety defect of which it had actual knowledge.

(b) Deployer liability. A deployer shall be liable for harm caused by an AI-enabled medical device where the harm resulted from:

1. use of the device outside its intended or reasonably foreseeable use;
2. failure to follow applicable instructions or warnings;
3. knowing reliance upon an output that the deployer knew or reasonably should have known was unreliable; or
4. failure to exercise reasonable clinical judgment where human review was required.

(c) Strict liability of developer for unreasonably dangerous or defective covered products. In a liability action described in subsection (a)(1) above, the developer of an AI-enabled medical device shall be strictly liable for harm caused by the defective condition of the device, notwithstanding that:

1. the developer exercised all possible care in the design or distribution of the device ; or
2. the claimant did not purchase the device from the developer or otherwise enter into a contractual relationship with the developer.

(d) Substantial modification. A developer shall not be liable under subsection (a)(1) for harm solely caused by a substantial modification.

(d) Causation. A person seeking damages under this section shall establish that the conduct, defect, or failure described in this section was a substantial factor in causing the alleged harm.

SEC. 6. PATIENT DISCLOSURE AND HUMAN OVERSIGHT.

(a) Disclosure. Except where disclosure would be inconsistent with the intended clinical use of the device, a health care provider using an AI-enabled medical device shall provide reasonable notice to a patient when the device materially contributes to a diagnosis, treatment recommendation, or other consequential clinical decision.

(b) Human oversight. An AI-enabled medical device shall not be deemed to replace the professional judgment of a licensed health care professional solely because the device generates an autonomous or substantially autonomous output.

(c) Clinical responsibility. Nothing in this section shall relieve a health care professional of an independent duty otherwise imposed by applicable law.

SEC. 7. LIMITATIONS ON CONTRACTUAL LIABILITY.

Any agreement, term of service, informed-consent form, or other contractual provision that prospectively waives or substantially limits a patient's right to recover damages under this Act shall be unenforceable to the extent that the waiver or limitation is contrary to public policy.

SEC. 8. FEDERAL CAUSE OF ACTION.

(a) Private right of action. A person injured by an AI-enabled medical device in violation of this Act may bring a civil action in an appropriate Federal or State court.

(b) Damages. A prevailing plaintiff may recover damages authorized under applicable law, including damages for bodily injury, economic loss, and other legally cognizable harm.

(c) Other remedies. Nothing in this Act shall preclude a plaintiff from pursuing any otherwise available claim under Federal or State law.

SEC. 9. RELATIONSHIP TO FEDERAL FOOD AND DRUG LAW.

(a) No implied authorization. Compliance with this Act shall not constitute approval, clearance, or authorization of a medical device under the Federal Food, Drug, and Cosmetic Act.

(b) Cumulative remedies. Except to the extent expressly preempted by Federal law, the remedies and duties established by this Act shall be in addition to remedies and duties otherwise available under Federal or State law.

SEC. 10. EFFECTIVE DATE.

This Act shall apply to AI-enabled medical devices first commercially distributed on or after the date that is 180 days after the date of enactment.