STATE OF OKLAHOMA

1st Session of the 60th Legislature (2025)

HOUSE BILL 1915 By: Alonso-Sandoval

AS INTRODUCED

An Act relating to artificial intelligence (AI); providing definitions; mandating that AI devices in health care be deployed and utilized in accordance with certain regulations; requiring exclusive use by qualified end-user; directing deployers to implement Quality Assurance Program; requiring device-generated data be reviewed; authorizing qualified end-users to amend or overrule outputs; requiring performance evaluations; mandating all documentation comply with certain record-keeping requirements; directing deployers establish an AI governance group; requiring deployers to maintain updated inventory; directing the State Department of Health to enforce act; requiring diligent review and selection process for deployed AI device; requiring documentation of use case and user training procedure; directing deployers to monitor the performance of deployed AI devices continuously; requiring deployers participate in national specialty society-administered AI assessment registries when feasible; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5501 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in this act:

1. "Artificial intelligence (AI) device" or "machine learning-enabled device" means a medical device as defined by Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that includes a machine-based function that, based on training data, infers from the input it receives how to generate outputs that enhance or support a medical diagnosis, prognosis, or treatment;

2. "Deployer" means a hospital, physician practice, or other health care facility responsible for implementing an AI device for patient care purposes; and

3. "Qualified end-user" means a user of an AI device that is a licensed physician with the necessary qualifications and training to independently provide the same diagnostic, prognostic, or therapeutic procedure without the aid of the AI device, and who possesses specific qualifications and training in the use of the AI device, including the ability to assess the validity of its output.

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5502 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. All artificial intelligence (AI) devices or machine learning-enabled devices used in health care settings that meet the definition of a medical device under Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) shall be deployed and utilized in accordance with federal regulations established by the U.S. Food and Drug Administration (FDA) and other federal

agencies, including relevant guidance on AI or machine learning-enabled software medical devices.

B. An AI device shall be used exclusively by a qualified end-user.

C. Deployers shall implement and maintain a Quality Assurance Program, as outlined in Section 4 of this act, to ensure the safe, effective, and compliant use of AI devices in patient care.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5503 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. All relevant artificial intelligence (AI) device-generated data shall be reviewed for accuracy and validated by a qualified end-user in accordance with deployer-documented policies and procedures before patient care decisions are rendered.

B. The qualified end-user of the AI device shall retain authority to amend or overrule outputs from the device based on their professional judgment, and without pressure from the deployer or any other entity to ignore or alter professional judgement.

C. Deployers of an AI device shall conduct and document regular performance evaluations and risk assessments of the device. Such evaluations and assessments should be informed by invited feedback from qualified end-users and, when applicable, participation in national specialty society-administered AI assessment registries. Whenever AI device performance concerns are identified, deployers

shall implement appropriate corrective actions to mitigate risk to patients.

D. All documentation shall comply with state and federal medical record-keeping requirements and be accessible for regulatory review. Documentation of relevant instances where a qualified end-user overrides or disagrees with AI device-generated outputs must be maintained through a summary report indicating the frequency and nature of overrides. Deployers shall document the percentage or number of such overrides or disagreements.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5504 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Deployers of any artificial intelligence (AI) device shall establish an AI governance group with representation from qualified end-users. This governance group is responsible for overseeing compliance with this act.

B. Deployers shall maintain an updated inventory of deployed AI devices, with device instructions for use and any relevant safety and effectiveness documentation made accessible to all qualified end-users of the device.

C. Deployers of AI devices shall ensure compliance with all requirements herein, as well as with applicable federal and state security, privacy, and nondiscrimination regulations. Noncompliance will result in penalties set by the State Department of Health,

which shall have the authority to enforce and make rules to enforce this act.

D. Deployers shall have a diligent review and selection process for the deployed AI device.

E. Deployers shall document the use case and user training procedure for the AI device.

F. Deployers shall continuously monitor the performance of all deployed AI devices, including assessing any impact on patient safety or the quality of patient care.

G. In conducting performance monitoring described in subsection F of this section, deployers must participate in national specialty society-administered artificial intelligence assessment registries when feasible.

SECTION 5. This act shall become effective November 1, 2025.

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