Model Legislative Language – AI Qualified End-User
American College of Radiology
Working Draft v1.0 (updated: 10/18/2024)

Sections:

1. **Definitions (*imaging AI device, qualified end-user, deployer*)**
2. **Consistency with Federal Law**
3. **Requirements for Human Oversight of Imaging AI Device Uses**
4. **Quality Assurance by Deployers**

1: Definitions

(a) **Imaging AI device** refers to 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 and support the interpretation of medical imaging data.

(b) A **qualified end-user** of an "imaging AI device" is a licensed physician with the necessary qualifications and training to independently interpret medical images without the aid of the imaging AI device, and who possesses specific qualifications and training in the use of the imaging AI device, including the ability to assess the validity of its output.

(c) A **deployer** of an "imaging AI device" is a hospital, physician practice, or other healthcare facility responsible for implementing the imaging AI device for patient care purposes.

2: Consistent with Federal Laws and Regulations

(a) All AI/ML-enabled devices used in healthcare 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/ML-enabled software medical devices.

(b) An imaging AI device as defined in Section 1(a) must be used exclusively by a qualified end-user as defined in Section 1(b).

(c) Deployers as defined in Section 1(c) must implement and maintain a Quality Assurance Program, as outlined in Section 4, to ensure the safe, effective, and compliant use of imaging AI devices in patient care.

3: Requirements for Human Oversight of Imaging AI Device Uses

(a) All relevant imaging AI device-generated data must 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 imaging AI device must 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 imaging AI device must 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, if/when applicable, participation in national specialty

society-administered AI assessment registries. Whenever imaging AI device performance concerns are identified, deployers must implement appropriate corrective actions to mitigate risk to patients.

(d) All documentation must 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 imaging AI device-generated outputs must be maintained through a summary report indicating the frequency and nature of overrides. At minimum, deployers must document the percentage or number of such overrides or disagreements.

Section 4: Quality Assurance by Deployers

(a) AI Governance Group: Deployers of any imaging AI device must establish an AI governance group with representation from qualified end-users. This governance group is responsible for overseeing compliance with Sections 2, 3, and 4.

(b) Inventory of Imaging AI Devices: Deployers must maintain an updated inventory of deployed imaging 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) Security and Compliance: Deployers of imaging AI devices must ensure compliance with all requirements herein, as well as with applicable federal and state security, privacy, and nondiscrimination regulations. Noncompliance will result in penalties as defined by the appropriate regulatory authority.

(d) Selection and Review of AI Algorithms: Deployers must have a diligent review and selection process for the deployed imaging AI device.

(e) Training and Use Case Documentation: Deployers must document the use case and user training procedure for the imaging AI device.

(f) Performance Monitoring: Deployers must continuously monitor the performance of all deployed imaging AI devices, including assessing any impact on patient safety or the quality patient care.

(g) Participation in National Registries: In conducting performance monitoring described in 4(f), deployers must participate in national specialty society-administered AI assessment registries if/when feasible.

Alternative Option for Broader Applicability (i.e., not limited to imaging)

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1: Definitions

a) **AI device** refers to 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.

b) A **qualified end-user** of an "AI device" 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.

c) A **deployer** of an "AI device" is a hospital, physician practice, or other healthcare facility responsible for implementing the AI device for patient care purposes.

2: Consistent with Federal Laws and Regulations

a) All AI/ML-enabled devices used in healthcare 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/ML-enabled software medical devices.

b) An AI device as defined in Section 1(a) must be used exclusively by a qualified end-user as defined in Section 1(b).

c) Deployers as defined in Section 1(c) must implement and maintain a Quality Assurance Program, as outlined in Section 4, to ensure the safe, effective, and compliant use of AI devices in patient care.

3: Requirements for Human Oversight of AI Device Uses

a) All relevant AI device-generated data must 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 must 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 must 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, if/when applicable, participation in national specialty society-administered AI assessment registries. Whenever AI device performance concerns are identified, deployers must implement appropriate corrective actions to mitigate risk to patients.

d) All documentation must 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. At minimum, deployers must document the percentage or number of such overrides or disagreements.

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