Protecting Americans Through Intelligent, Ethical, and Transparent Artificial Intelligence in Health Care Act

Section 1. Short title; table of contents.
This section states that the Act may be cited as the "Protecting Americans Through Intelligent, Ethical, and Transparent Artificial Intelligence in Health Care Act" or PATIENT AI Act.

Section 2. Definitions.
This section defines the following terms: 1) "artificial intelligence," 2) "artificial intelligence-based application," 3) "business associate and covered entity," 4) "device," 5) "Department," 6) "National Coordinator," 7) "Secretary," and 8) "software-based device."

Title I – General Activities

Section 101. Privacy and security protections for artificial intelligence in health care.
This section directs the Secretary of Health and Human Services (HHS) to issue guidance to entities subject to the Health Insurance Portability and Accountability Act (HIPAA) on how to comply with applicable privacy and security requirements when using artificial intelligence-based applications.

Section 102. Public meeting on liability considerations for artificial intelligence in health care.
This section directs the Secretary of HHS to enter into an agreement with a nonprofit organization to examine and develop recommendations relating to liability issues for artificial intelligence-based applications used in health care settings and publish a report summarizing the issues and providing recommendations.

Section 103. Transparency report.
This section directs the Comptroller General to conduct and publish a report to examine public and private sector proposals for establishing transparency and explainability measures for the development, validation, use, and deployment of artificial intelligence-based applications in health care.

Section 104. Expanding use of artificial intelligence within the Department of Health and Human Services.
This section directs the Secretary of HHS to develop use cases for deploying and using artificial intelligence to improve internal operations and to improve health care outcomes.

Section 105. Workforce Development.
This section directs the Secretary, in coordination with the Director of the National Institute of Standards and Technology (NIST) and private sector stakeholders, to develop materials to support training to health care and public health sector entities on how to best use artificial intelligence-based applications in health care settings.

Section 106. Standardization of datasets for use in artificial intelligence-based applications.
This section directs the Chief Information Officer (CIO) of HHS to build datasets to be used to support health care research using artificial intelligence-based applications.

Title II – Food and Drug Administration

Section 201. Review of integrated devices.
This section establishes a voluntary process to review integrated devices.

Section 202. Review of software-based devices.
This section establishes a risk-based approach to review software-based devices, including the ability for the Food and Drug Administration (FDA) to accept premarket software changes.

Section 203. Third party review and certification.
This section directs the Secretary of HHS to publish guidance establishing the qualifications for certification bodies and certify those bodies to conduct review of low- to moderate-risk software.

Section 204. Postmarket surveillance pilot program.
This section directs FDA to establish a voluntary pilot program to evaluate methods to improve and modernize postmarket surveillance for integrated and software-based devices.

Section 205. Rule of construction.
This section reiterates existing federal preemption of state product liability laws for medical devices to apply to integrated and software-based devices.

Title III – Office of the National Coordinator for Health Information Technology

Section 301. Cooperative agreements.
This section directs the Office of the National Coordinator for Health Information Technology (ONC) to enter into cooperative agreements with agencies within HHS to offer technical assistance on implementing artificial intelligence within the framework of each applicable agency.

Section 302. Certification of clinical research technology.
This section expands the definition of Certified Health Information Technology to include clinical research technology.

Section 303. Certification of artificial intelligence-based health information technology.
This section expands the definition of Certified Health Information Technology to include artificial intelligence-based applications not considered to be an FDA-regulated device.

Title IV – Centers for Medicare & Medicaid Services

Section 401. Coverage Evaluation Framework for Artificial Intelligence-Based Services.
This section directs the Secretary of HHS to create a coverage evaluation framework for artificial intelligence-based services.

Section 402. Dedicated Evaluation Pathway for Services Furnished Using Artificial Intelligence-Based Applications Reviewed by Certified Entities.
This section directs the Secretary of HHS to create a coverage evaluation pathway for artificial intelligence-based applications reviewed by certified entities.

Section 403. Alternative Payment Methodologies for Artificial Intelligence-Based Services.
This section directs the Secretary of HHS to develop proposed payment methodologies to reimburse for artificial intelligence-based services.

Section 404. Independent Coding of Artificial Intelligence-Based Services.
This section directs the Secretary of HHS to establish a process to use Healthcare Common Procedure Coding System Level (HCPCS) Level II codes for artificial intelligence-based services.

Section 405. CMI Testing of Artificial Intelligence Coverage and Payment.
This section directs the Secretary of HHS to establish a payment model through the Center for Medicare and Medicaid Innovation (CMMI) on how to reimburse for use of artificial intelligence-based applications that deliver care autonomously.