119TH CONGRESS
2D SESSION

S. _____

To ensure the intelligent, ethical, and transparent use of artificial intelligence in health care, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To ensure the intelligent, ethical, and transparent use of artificial intelligence in health care, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Protecting Americans Through Intelligent, Ethical, and Transparent Artificial Intelligence in Health Care Act'' or the ''PATIENT AI Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Definitions.

TITLE I—GENERAL ACTIVITIES

Sec. 101. Privacy and security protections for artificial intelligence in health care.
Sec. 102. Public meeting on liability considerations for artificial intelligence in health care.
Sec. 103. Transparency report.
Sec. 104. Expanding use of artificial intelligence within Department of Health and Human Services.
Sec. 105. Workforce development.
Sec. 106. Standardization of datasets for use in artificial intelligence-based applications.

TITLE II—FOOD AND DRUG ADMINISTRATION

Sec. 201. Review of integrated devices.
Sec. 202. Review of software-based devices.
Sec. 203. Third party review and certification.
Sec. 204. Postmarket surveillance pilot program.
Sec. 205. Rule of construction.

TITLE III—OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

Sec. 301. Cooperative agreements.
Sec. 302. Certification of clinical research technology.
Sec. 303. Certification of artificial intelligence-based health information technology.

TITLE IV—CENTERS FOR MEDICARE & MEDICAID SERVICES

Sec. 401. Coverage evaluation framework for artificial intelligence-based services.
Sec. 402. Dedicated evaluation pathway for services furnished using artificial intelligence-based applications reviewed by certified entities.
Sec. 403. Alternative payment methodologies for artificial intelligence-based services.
Sec. 404. Independent coding of artificial intelligence-based services.
Sec. 405. CMI testing of artificial intelligence coverage and payment model.

SEC. 2. DEFINITIONS.

In this Act—

(1) the term ''artificial intelligence'' has the meaning given such term in section 5002 of the National Artificial Intelligence Initiative Act of 2020 (15 U.S.C. 9401);

(2) the term ''artificial intelligence-based application'' means a system, platform, or tool that incorporates or utilizes artificial intelligence;

(3) the terms ''business associate'' and ''covered entity'' have the meanings given such terms in section 164.103 of title 45, Code of Federal Regulations (or any successor regulations);

(4) the term ''device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h));

(5) the term ''Department'' means the Department of Health and Human Services;

(6) the term ''National Coordinator'' means the National Coordinator for Health Information Technology;

(7) the term ''Secretary'' means the Secretary of Health and Human Services; and

(8) the term ''software-based device'' means a device whose intended medical purpose is achieved primarily through one or more software functions.

TITLE I—GENERAL ACTIVITIES

SEC. 101. PRIVACY AND SECURITY PROTECTIONS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE.

(a) GUIDANCE ON PRIVACY SAFEGUARDS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE.—Not later than

1 year after the date of enactment of this Act, the Secretary shall issue guidance to covered entities, business associates, and developers of artificial intelligence-based applications, on how to comply with the privacy provisions under part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or any successor regulations), and best practices for developing, deploying, and using artificial intelligence in health care, including—

(1) steps to comply with applicable minimum necessary requirements with respect to the collection, use, and disclosure of protected health information;

(2) requirements and best practices for patient consent and authorization when using identifiable data;

(3) how to structure limited data sets to comply with the requirements under section 164.514(e) of title 45, Code of Federal Regulations (or any successor regulations), when disclosing limited data sets;

(4) methods for creating, maintaining, and disclosing de-identified information and limited data sets in accordance with applicable requirements under section 164.514 of title 45, Code of Federal Regulations (or any successor regulations);

(5) safeguards to prevent the unauthorized use, disclosure, retention, or secondary use of protected health information by artificial intelligence-based applications; and

(6) contractual and governance best practices for covered entities and business associates when engaging developers or providers of artificial intelligence-based applications.

(b) GUIDANCE ON CYBERSECURITY SAFEGUARDS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE WITHIN ARTIFICIAL INTELLIGENCE-BASED APPLICATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance to covered entities, business associates, and developers of artificial intelligence-based applications on how to comply with the security provisions under part 160 and subparts A and C of part 164 of title 45, Code of Federal Regulations (or any successor regulations), including steps to expand security risk analyses to account for and assess potential cybersecurity risks associated with artificial intelligence-based applications, and best practices for developing, deploying, and using artificial intelligence in health care.

SEC. 102. PUBLIC MEETING ON LIABILITY CONSIDERATIONS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary shall seek to enter into an agreement with a nonprofit organization to convene, not later than 1 year after the date of enactment of this Act, a public meeting to examine and develop recommendations relating to liability issues for artificial intelligence-based applications used in health care settings.

(b) TOPICS.—The public meeting under subsection (a) shall include an examination of issues relating to apportioning liability between individual health care providers, health care facilities, health insurance issuers, developers, manufacturers, and other entities, as appropriate, in cases in where the dispute involves a medical product or intervention that uses an artificial intelligence-based application.

(c) PARTICIPATION.—The public meeting under subsection (a) shall include, to the maximum extent practicable, the participation of representatives of the Department of Health and Human Services, State governments, academia, industry, medical professional societies, patient advocacy organizations, and other stakeholders, as appropriate.

(d) REPORT.—Not later than 90 days after the date on which the public meeting under subsection (a) concludes, the organization with which the Secretary contracts under such subsection shall publish a report that—

(1) summarizes the issues discussed at the meeting; and

(2) includes recommendations for Federal and State policymakers to address liability issues for medical products that incorporate artificial intelligence, including with respect to issues that arise under laws relating to medical malpractice, clinical practice licensure, product liability, and health insurance coverage and reimbursement.

SEC. 103. TRANSPARENCY REPORT.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall conduct, and publish a report describing the results of, a study 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.

(b) CONTENTS.—The study required under subsection (a) shall include an examination of—

(1) intellectual property, trade secret, or other legal considerations that may limit the public release of proprietary information relating to artificial intelligence-based applications;

(2) current private sector initiatives for establishing transparency and explainability measures for the development, validation, and use of artificial intelligence-based applications in health care;

(3) methods for communicating information regarding the development, validation, performance, limitations, and intended use of artificial intelligence-based applications to health care providers, patients, regulators, and other stakeholders; and

(4) recommendations for how transparency and explainability measures may lead to improvement in the clinical use of artificial intelligence-based applications in health care.

SEC. 104. EXPANDING USE OF ARTIFICIAL INTELLIGENCE WITHIN DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall develop use cases for deploying and using artificial intelligence to improve internal operations of the Department and to im-

prove health care outcomes. In developing such use cases, the Secretary shall consider—

(1) the mission of the Department;

(2) any long-term benefit additional use cases could provide; and

(3) factors that would limit the progress the private sector could make with respect to the selected use cases.

(b) NON-DUPLICATION.—Nothing in this section shall be construed to require the Secretary to engage in activities under this section that would duplicate efforts pursuant to other authorities of law.

(c) REPORT TO CONGRESS.—Not later than 18 months after the conclusion of the activities under subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report identifying—

(1) use cases successfully developed;

(2) any long-term benefit additional use cases could provide; and

(3) factors that would limit the progress the private sector could make with respect to the selected use cases.

SEC. 105. WORKFORCE DEVELOPMENT.

The Secretary, in coordination with the Director of the National Institute of Standards and Technology and, as appropriate, private sector stakeholders, shall develop materials to support training to health care and public health sector entities on—

(1) expanded use of artificial intelligence-based applications in health care settings, including clinical and administrative functions;

(2) steps to review new artificial intelligence-based applications and iterative updates to such applications to improve familiarity with the applications; and

(3) best practices to leverage artificial intelligence to support cybersecurity preparedness.

SEC. 106. STANDARDIZATION OF DATASETS FOR USE IN ARTIFICIAL INTELLIGENCE-BASED APPLICATIONS.

(a) CREATION OF DATASETS.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Chief Information Officer of the Department of Health and Human Services, in cooperation with the heads of any agencies the Secretary determines appropriate, shall build datasets to be used to support health care research using artificial intelligence-based applications.

(b) GUIDANCE.—As part of any datasets released under subsection (a), the developing agency shall provide accompanying information, including—

(1) how such datasets were curated;

(2) what validation was conducted to characterize data quality, including accuracy, completeness, and traceability, for the identified use cases; and

(3) appropriate use of such datasets, including any additional validation requirements and use for commercial applications.

(c) LIMITATIONS ON DATASETS.—The datasets built under subsection (a) shall include only information already available for public use.

TITLE II—FOOD AND DRUG ADMINISTRATION

SEC. 201. REVIEW OF INTEGRATED DEVICES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515C (21 U.S.C. 360e–4) the following:

"SEC. 515D. REVIEW OF INTEGRATED DEVICES.

''(a) ESTABLISHMENT OF INTEGRATED REVIEW PROCESS.—The Secretary shall establish a voluntary process for premarket review of devices that incorporate software functions and other components (referred to in this section as 'integrated devices'), under which such de-

vices may undergo review with a focus on such software functions and other components, supplemental to the premarket review of such device under section 510(k), 513(f)(2), or 515, as applicable.

''(b) REVIEW OF SOFTWARE FUNCTIONS AND OTHER COMPONENTS.—

''(1) IN GENERAL.—In conducting a review described in subsection (a), the Secretary shall provide for the independent evaluation of each of the software functions and other components of an integrated device, including—

''(A) inputs, including sensors, data sources, and other mechanisms through which information is received;

''(B) software functions, including artificial intelligence-based applications; and

''(C) outputs, including information, recommendations, or actions generated by the device.

''(2) EVIDENCE OF CONFORMITY.—In evaluating a software function or other component under paragraph (1), the Secretary may consider—

''(A) the extent to which the software function or other component conforms with applicable consensus standards; and

"(B) evidence derived from—

"(i) automated testing and validation;

"(ii) evaluations conducted by qualified third parties; and

"(iii) previous reviews or determinations by the Secretary relating to the software function or other component.

"(3) RELIANCE ON PRIOR REVIEW.—In reviewing a software function or other component previously evaluated under this section, the Secretary shall, to the maximum extent practicable, rely on such prior evaluation to the extent applicable to the intended use of the component in the integrated device.

"(c) INTEGRATED DEVICE REVIEW.—Following the review of each software function or other component under subsection (b), the Secretary shall evaluate the integrated device as a whole, including—

"(1) the interaction and interoperability of the components;

"(2) the safety and effectiveness of the device when its components are used together;

"(3) risks arising from the integration of components that may not be identified through independent component review; and

''(4) the intended use, clinical context, and human factors associated with the device.

''(d) GUIDANCE.—Not later than 180 days after the date of enactment of the PATIENT AI Act, the Secretary shall issue guidance regarding implementation of review under this section, including—

''(1) the identification and evaluation of components;

''(2) the documentation and evidence necessary to support component review;

''(3) procedures for relying on previously reviewed components; and

''(4) the standards and procedures applicable to integrated device review.''.

SEC. 202. REVIEW OF SOFTWARE-BASED DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515D, as added by section 201, the following:

''SEC. 515E. RISK-BASED REVIEW OF SOFTWARE-BASED DEVICES.

''(a) IN GENERAL.—The Secretary shall establish a risk-based approach to the premarket review of software-based devices pursuant to section 510(k), 513(f)(2), or 515 under which the level of review is commensurate with

the risk presented by the device and the level of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device.

''(b) LOW- TO MODERATE-RISK SOFTWARE-BASED DEVICES.—

''(1) IN GENERAL.—For purposes of this section, a software-based device shall be considered a low- to moderate-risk software-based device if the Secretary determines that—

''(A) the device presents low to moderate risk; and

''(B) general controls, or general and special controls, are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

''(2) REVIEW OF LOW- TO MODERATE-RISK SOFTWARE-BASED DEVICES.—In conducting premarket review of a device described in paragraph (1), the Secretary shall—

''(A) apply the least burdensome means of evaluating the safety and effectiveness of the device consistent with the protection of the public health; and

''(B) take into account the nature of the software function, the intended use of the de-

vice, and the risk presented by such intended use.

''(c) OTHER SOFTWARE-BASED DEVICES.—A software-based device that does not meet the criteria under subsection (b)(1) shall not be eligible for review under this section.

''(d) GUIDANCE.—Not later than 180 days after the date of enactment of the PATIENT AI Act, the Secretary shall issue guidance regarding implementation of this subsection, including the factors the Secretary will consider in determining whether a software-based device meets the criteria under subsection (b)(1).

''(e) DEFINITION.—In this section, the term 'software-based device' has the meaning given such term in section 2 of the PATIENT AI Act.''.

(b) PREMARKET SOFTWARE CHANGES.—

(1) IN GENERAL.—Section 515C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–4) is amended—

(A) in subsection (a)—

(i) in paragraph (1), by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(ii) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(iii) by inserting after paragraph (1) the following:

''(2) PREMARKET SOFTWARE CHANGES.—

''(A) IN GENERAL.—In the case of an application under section 515 for a device that includes a software function, the applicant may submit a predetermined change control plan describing changes to such software function that the applicant may make during the review of such application.

''(B) CONTINUED REVIEW.—A change to a software function that is consistent with a predetermined change control plan accepted by the Secretary shall not, solely by reason of such change, require—

''(i) the submission of a new application;

''(ii) the withdrawal and resubmission of the pending application; or

''(iii) the recommencement of the applicable review period.

''(C) REVIEW OF CHANGES.—The applicant shall submit such information as the Secretary determines necessary to demonstrate that a change made pursuant to the plan does not materially alter the safety or effectiveness of the device.''; and

(B) in subsection (b)—

(i) in paragraph (1), by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(ii) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(iii) by inserting after paragraph (1) the following:

''(2) PREMARKET SOFTWARE CHANGES.—

''(A) IN GENERAL.—In the case of a premarket notification under section 510(k) for a device that includes a software function, the person submitting such notification may submit a predetermined change control plan describing changes to such software function that may be made during the review of such notification.

''(B) CONTINUED REVIEW.—A change to a software function that is consistent with a pre-

determined change control plan accepted by the Secretary shall not, solely by reason of such change, require—

"(i) the submission of a new premarket notification;

"(ii) the withdrawal and resubmission of the pending premarket notification; or

"(iii) the recommencement of the applicable review period.

"(C) REVIEW OF CHANGES.—The person submitting the premarket notification shall submit such information as the Secretary determines necessary to demonstrate that a change made pursuant to the plan does not materially alter the safety or effectiveness of the device.".

SEC. 203. THIRD PARTY REVIEW AND CERTIFICATION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515E, as added by section 202, the following:

"SEC. 515F. THIRD PARTY REVIEW AND CERTIFICATION.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the PATIENT AI Act, the Secretary shall publish guidance establishing the qualifications for certification bodies to conduct review of low- to

moderate-risk software described in section 515E(b). Such guidance shall include the following:

''(1) The qualifications and technical expertise necessary to conduct review of low- to moderate-risk software.

''(2) Standards for evaluating the independence, competence, and capacity of third-party review organizations.

''(3) Procedures for submitting and evaluating applications for accreditation.

''(b) CERTIFICATION OF THIRD-PARTY REVIEW ORGANIZATIONS.—

''(1) IN GENERAL.—Not later than 180 days after the finalization of the guidance in subsection (a), the Secretary shall certify not fewer than 3 organizations that meet the requirements of this section.

''(2) ADDITIONAL ORGANIZATIONS.—The Secretary may accredit additional third-party review organizations that satisfy the requirements of this section.

''(3) QUALIFICATIONS.—A third-party review organization accredited by the Secretary under this section shall, at a minimum, meet the following requirements:

"(A) Not be an employee or agency of the Federal Government.

"(B) Be an independent organization that is not owned or controlled by, and has no organizational, material, or financial affiliation with, a manufacturer, supplier, or vendor of devices.

"(C) Be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

"(D) Not engage in the design, manufacture, promotion, or sale of devices.

"(E) Conduct its operations in accordance with generally accepted professional and ethical business practices.

"(F) Agree, at the time of accreditation and at any time it conducts a review under this section, to—

"(i) certify that reported information accurately reflects the data reviewed;

"(ii) limit its work to matters for which it has appropriate competence and capacity;

"(iii) treat information received, records, reports, and recommendations as proprietary information;

"(iv) promptly respond to and attempt to resolve complaints regarding activities for which it is accredited; and

"(v) maintain procedures to prevent any officer or employee with a financial conflict of interest relating to a device from participating in the review of such device and make appropriate disclosures regarding compliance with such requirements.

"(c) THIRD PARTY REVIEW.—

"(1) ELIGIBLE DEVICES.—A device that meets the definition of a low- to moderate-risk software-based device under section 515E(b) may be reviewed by a third-party review organization accredited under subsection (b) for purposes of making recommendations to the Secretary concerning premarket approval or clearance of the device under section 510(k), 513(f)(2), or 515.

"(2) REQUIREMENTS REGARDING REVIEW.—

"(A) IN GENERAL.—In making a recommendation to the Secretary, a third-party review organization shall notify the Secretary in writing of the reasons for the recommendation.

"(B) SUBMISSION TO THE SECRETARY.—Upon completion of a review under this subsection, the third-party review organization shall submit to the Secretary—

"(i) a recommendation concerning the safety and efficacy with respect to the device;

"(ii) the reasons for such recommendation; and

"(iii) such supporting documentation as the Secretary may require pursuant to guidance issued under subsection (d)(4).

"(d) FDA REVIEW OF THIRD-PARTY REVIEW ORGANIZATION RECOMMENDATIONS.—

"(1) IN GENERAL.—Not later than 30 days after the determination and supporting documentation from a third-party review organization under subsection (c), the Secretary shall accept such determination or determine that additional review by the Secretary is appropriate.

"(2) RELIANCE ON THIRD PARTY REVIEW.—In making a determination under paragraph (1), the Secretary shall, to the maximum extent practicable, rely on the review conducted by the third-party re-

view organization and shall not routinely re-review matters adequately addressed in such review.

''(3) ADDITIONAL REVIEW.—The Secretary may conduct an additional review of all or any portion of a determination submitted under subsection (c) if the Secretary determines such review is appropriate. If the Secretary conducts such additional review, the Secretary shall provide the applicant and the third-party review organization a written statement identifying the matters subject to additional review and the reasons such additional review is necessary.

''(4) GUIDANCE.—Not later than 180 days after the date of enactment of the PATIENT AI Act, the Secretary shall issue guidance describing—

''(A) the standards and procedures the Secretary will use in reviewing determinations submitted by third-party review organizations;

''(B) the circumstances under which the Secretary may conduct an additional review under paragraph (3);

''(C) the scope of any such additional review; and

''(D) the information a third-party review organization shall submit to facilitate review by the Secretary.

''(e) OVERSIGHT OF CERTIFICATION BODIES.—

''(1) ACCREDITATION CRITERIA.—Not later than 180 days after the date of enactment of the PATIENT AI Act, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to certification bodies seeking to perform reviews under this section. The Secretary shall approve or deny a request for accreditation not later than 60 days after receipt of such request. The accreditation of a certification body shall specify the particular activities and categories of devices for which such body is accredited.

''(2) SUSPENSION OR WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any certification body accredited under this section, after providing notice and an opportunity for an informal hearing, if such body—

''(A) is substantially not in compliance with the requirements of this section;

''(B) poses a threat to public health; or

''(C) fails to act in a manner consistent with the purposes of this section.

''(3) PERFORMANCE AUDITING.—To ensure that certification bodies accredited under this section

continue to meet the standards of accreditation, the Secretary shall—

"(A) make onsite visits on a periodic basis to each accredited certification body to audit the performance of such body; and

"(B) take such additional measures as the Secretary determines appropriate.

"(4) PERIODIC REACCREDITATION.—

"(A) PERIOD.—Subject to suspension or withdrawal under paragraph (2), any accreditation under this section shall be valid for a period of 3 years after issuance.

"(B) RESPONSE TO REACCREDITATION REQUEST.—Upon submission of a request for reaccreditation, the Secretary shall approve or deny such request not later than 60 days after receipt.

"(C) CRITERIA.—The Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to certification bodies under this section. Reaccreditation shall specify the particular activities and categories of devices for which the certification body is reaccredited.".

SEC. 204. POSTMARKET SURVEILLANCE PILOT PROGRAM.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall establish a voluntary pilot program to evaluate methods to improve and modernize postmarket surveillance for integrated and software-based devices.

(b) STRUCTURE OF PILOT PROGRAM.—In carrying out the pilot program under subsection (a), the Secretary shall consider—

(1) how to leverage data generated through the use of integrated and software-based devices gathered through the course of health care delivery as well as any real-world evidence that may be collected;

(2) methods to automate and standardize the collection and transmission of postmarket data;

(3) methods to reduce the cost and administrative challenges associated with generating postmarket evidence; and

(4) coordination with the Centers for Medicare & Medicaid Services to consider reimbursement and payment associated with postmarket surveillance.

(c) REPORT.—Not later than 2 years after the establishment of the pilot program under subsection (a), the Secretary shall submit to the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report detailing the implementation of the postmarket pilot under subsection (a), including any challenges or additional authorities needed to implement on a permanent basis.

SEC. 205. RULE OF CONSTRUCTION.

Nothing in this title shall be construed to alter or otherwise affect any liability arising under Federal or State law, including any law governing product liability or medical malpractice or the application of section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k).

TITLE III—OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

SEC. 301. COOPERATIVE AGREEMENTS.

(a) IN GENERAL.—The Secretary, acting through the National Coordinator, shall enter into formal cooperative agreements with agencies within the Department, as appropriate, to offer technical assistance on implementing artificial intelligence within the framework of each applicable agency.

(b) SCOPE.—The coordination under subsection (a) shall include—

(1) leveraging existing programs within the Department to facilitate artificial intelligence adoption;

(2) sharing information on best practices related to artificial intelligence adoption; and

(3) steps to improve and maximize information sharing between agencies of the Department and private sector entities, as appropriate, in a way that protects the privacy and security of such data.

SEC. 302. CERTIFICATION OF CLINICAL RESEARCH TECHNOLOGY.

(a) CLERICAL AMENDMENTS.—

(1) IN GENERAL.—Section 4003 of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in subsection (a)—

(i) by redesignating paragraph (2) as paragraph (3);

(ii) by striking paragraph (1) and inserting the following:

''(1) by striking paragraphs (7) and (8);

''(2) by redesignating paragraph (9) as paragraph (8); and''; and

(iii) in paragraph (3), as so redesignated—

(I) by striking ''paragraph (9)'' and inserting ''paragraph (8), as so redesignated by paragraph (2) of this subsection,''; and

(II) by striking ''(10) INTEROPERABILITY'' and inserting ''(9) INTEROPERABILITY''; and

(B) in subsection (e)(2)(B), by striking ''(42 U.S.C. 300jj)—'' and all that follows through ''by inserting'' in clause (ii) and inserting ''(42 U.S.C. 300jj), by inserting''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255).

(b) CLINICAL RESEARCH.—

(1) IN GENERAL.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(A) by redesignating paragraphs (2) through (14) as paragraphs (3) through (15), respectively;

(B) by inserting after paragraph (1) the following:

''(2) CLINICAL RESEARCH.—The term 'clinical research' has the meaning given such term in section 409(b).''; and

(C) in paragraph (6), as so redesignated, by striking ''health care entities or patients for the electronic creation, maintenance, access, or exchange of health information'' and inserting ''health care entities, patients, or persons conducting, supporting, or participating in clinical research for the electronic creation, collection, maintenance, access, use, or exchange of health information or information collected, generated, or used in clinical research.''.

(2) CONFORMING AMENDMENT.—Section 3009(b) of the Public Health Service Act (42 U.S.C. 300jj–19(b)) is amended by striking ''section 3000(3)'' and inserting ''section 3000''.

SEC. 303. CERTIFICATION OF ARTIFICIAL INTELLIGENCE-BASED HEALTH INFORMATION TECHNOLOGY.

(1) IN GENERAL.—The National Coordinator shall, under the voluntary certification program maintained or recognized under section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)), provide for the voluntary certification of artificial intelligence-based applications that—

(A) constitute health information technology, as defined in section 3000 of such Act (42 U.S.C. 300jj); and

(B) do not constitute a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(2) CLARIFICATION OF REGULATION OF NON-DEVICE SOFTWARE FUNCTIONS.—

(A) IN GENERAL.—Nothing in this section shall be construed to alter the exclusion from the definition of ''device'' under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) of a software function described in section 520(o)(1) of such Act.

(B) ARTIFICIAL INTELLIGENCE.—The incorporation or use of artificial intelligence by a software function shall not, by itself, cause such software function to constitute a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act if such software function is otherwise excluded from the definition of device pursuant to section 520(o)(1) of such Act.

(C) EXISTING AUTHORITY.—Nothing in this subsection shall be construed to alter the authority of the Secretary under section

520(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)(3)).

(3) EFFECT OF CERTIFICATION.—The certification of an artificial intelligence-based application under paragraph (1) shall not cause such application to constitute a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

TITLE IV—CENTERS FOR MEDICARE & MEDICAID SERVICES

SEC. 401. COVERAGE EVALUATION FRAMEWORK FOR ARTIFICIAL INTELLIGENCE-BASED SERVICES.

Section 1869 of the Social Security Act (42 U.S.C. 1395ff) is amended by adding at the end the following new subsection:

''(j) COVERAGE EVALUATION FRAMEWORK FOR ARTIFICIAL INTELLIGENCE-BASED SERVICES.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of this subsection, the Secretary shall establish and publish a framework for evaluating a request for coverage under this title of an artificial intelligence-based service.

''(2) EXISTING MEDICARE REQUIREMENTS.—In applying the framework established under this subsection, the Secretary shall determine, as applicable,

with respect to a request for coverage of an artificial intelligence-based service—

''(A) whether the service falls within a benefit category covered under this title;

''(B) whether the service meets the requirements for coverage under section 1862(a)(1)(A) and other applicable requirements for coverage under this title; and

''(C) whether requirements with respect to the provider of services or supplier furnishing the service, the setting in which the service is furnished, supervision, ordering, and any other requirements for coverage and payment under this title are met.

''(3) EVALUATION FACTORS.—Under the framework, with respect to a request for coverage of an artificial intelligence-based service, the Secretary—

''(A) shall provide for consideration of clinical validity and utility, patient safety, comparative clinical outcomes, intended population and setting, performance across relevant patient subgroups, appropriate human oversight or escalation, ongoing performance monitoring, and material changes to the application;

"(B) may consider evidence generated in clinical practice subject to appropriate methodological safeguards;

"(C) may not determine that the item or service lacks clinical utility solely because the artificial intelligence-based application which the item or service is furnished through or with the substantial use of performs a clinical function without contemporaneous physician interpretation or other physician work; and

"(D) shall not base any decision regarding coverage or payment under this title solely on authorization, clearance, or approval by the Food and Drug Administration, review conducted by an entity certified under section 515F of the Federal Food, Drug, and Cosmetic Act, or the assignment of a billing code.

"(4) COORDINATION AND TRANSPARENCY.—The Secretary shall—

"(A) coordinate with the Food and Drug Administration and the Office of the National Coordinator for Health Information Technology, as appropriate, in establishing and implementing the framework under this subsection;

''(B) publish guidance for—

''(i) submission of a request for coverage under such framework; and

''(ii) requirements with respect to the submission of evidence relating to such request; and

''(C) publish an explanation of how the framework interacts with national and local coverage determinations under subsection (f).

''(5) DEFINITIONS.—In this subsection:

''(A) ARTIFICIAL INTELLIGENCE-BASED APPLICATION.—The term 'artificial intelligence-based application' has the meaning given that term in section 2 of the PATIENT AI Act.

''(B) ARTIFICIAL INTELLIGENCE-BASED SERVICE.—The term 'artificial intelligence-based service' means an item or service furnished through or with the substantial use of an artificial intelligence-based application.

''(6) RULE OF CONSTRUCTION.—Nothing in this subsection may be construed to—

''(A) waive requirements applicable under this title with respect to coverage of benefits, providers of services or suppliers, supervision, or any other requirements relating to coverage

of, or payment for, items or services under this title; or

''(B) alter the process for making a national or local coverage determination as those terms are defined in paragraph (1)(B) and (2)(B), respectively, of section 1869(f).''.

SEC. 402. DEDICATED EVALUATION PATHWAY FOR SERVICES FURNISHED USING ARTIFICIAL INTELLIGENCE-BASED APPLICATIONS REVIEWED BY CERTIFIED ENTITIES.

Section 1869(j) of the Social Security Act, as added by section 401, is amended—

(1) by redesignating paragraph (6) as paragraph (7); and

(2) by inserting after paragraph (5) the following new paragraph:

''(6) DEDICATED EVALUATION PATHWAY FOR SERVICES FURNISHED USING ARTIFICIAL INTELLIGENCE-BASED APPLICATIONS REVIEWED BY CERTIFIED ENTITIES.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall establish within the framework under this subsection a dedicated pathway to evaluate a request for cov-

erage of an artificial intelligence-based service that is furnished through or with the substantial use of an artificial intelligence-based application that has been reviewed by an entity certified under section 515F of the Federal Food, Drug, and Cosmetic Act.

''(B) SUBMISSION AND REVIEW.—

''(i) SUBMISSION.—The pathway shall permit a developer, provider of services, supplier, or other interested person specified by the Secretary to submit evidence regarding an artificial intelligence-based service described in subparagraph (A) and its intended beneficiary population.

''(ii) REVIEW.—Upon review of such evidence with respect to the service, the Secretary shall—

''(I) identify applicable benefit categories, evidence gaps, and appropriate existing national or local coverage processes; and

''(II) provide a written disposition or referral to the applicable coverage process.

"(C) CLINICAL SAFEGUARDS.—The Secretary shall specify, as appropriate, expectations under the pathway for clinical validation, safety monitoring, transparency to patients and clinicians, mechanisms for escalation and correction, and reporting of material performance changes, without duplicating requirements applicable under other Federal law.".

SEC. 403. ALTERNATIVE PAYMENT METHODOLOGIES FOR ARTIFICIAL INTELLIGENCE-BASED SERVICES.

(a) DEVELOPMENT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall develop and publish proposed payment methodologies for covered items and services furnished under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) through artificial intelligence-based applications, taking into account the distinct resource costs and modes of delivery of such items and services.

(b) REQUIRED CONSIDERATIONS.—Such methodologies shall consider—

(1) per-service payment, per-beneficiary or episode-based payment, and payments conditioned in whole or in part on measured clinical outcomes, or quality;

(2) software licensing, compute, maintenance, validation, cybersecurity, integration, monitoring, and necessary human oversight costs, to the extent appropriate and not otherwise paid;

(3) reductions in physician or other practitioner work, including items or services for which such work is absent;

(4) avoidance of duplicative payment, inappropriate utilization incentives, and adverse selection; and

(5) beneficiary access, health outcomes, fiscal effects, and administrative feasibility.

(c) APPLICATION OF EXISTING AUTHORITIES.—The Secretary may implement a methodology developed under this section only to the extent authorized under otherwise applicable provisions of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including relevant prospective payment, fee schedule, and other payment authorities. The Secretary shall identify in the report under subsection (e) any legislative changes needed to implement a methodology not otherwise authorized.

(d) NO PHYSICIAN WORK FLOOR.—To the extent consistent with applicable law, the Secretary shall not assign positive physician work relative value units solely to accommodate an item or service furnished without physi-

cian work, nor shall the absence of physician work, by itself, preclude consideration of an otherwise lawful payment methodology.

(e) REPORT.—Not later than 36 months after the date of enactment of this Act, the Secretary shall submit to Congress a report describing methodologies evaluated, administrative actions taken, and statutory impediments identified, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 404. INDEPENDENT CODING OF ARTIFICIAL INTELLIGENCE-BASED SERVICES.

(a) EXPEDITED PROCESS.—Not later than 12 months after the date of enactment of this Act, the Secretary shall establish a process to receive and decide requests for the establishment, revision, or use of Healthcare Common Procedure Coding System Level II codes to identify items and services furnished through or with the use of artificial intelligence-based applications.

(b) DECISION PROCESS.—

(1) PERIOD.—Under such process, the Secretary shall issue a written determination not later than 180 days after receipt of a complete request, which may establish a new code, revise an existing code, determine that an existing code adequately de-

scribes the item or service, or deny the request with reasons. Such 180-day period shall begin with respect to a request upon written notice that the request is complete.

(2) COMPLETENESS.—The Secretary shall publish criteria for when a request is considered complete and may request additional information as needed with respect to a request that is not complete.

(3) AUTHORITY.—Where appropriate for claims processing under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Secretary may establish a G-code or other appropriate HCPCS Level II code.

(c) COORDINATION.—The process established under this section shall accommodate requests involving professional services, autonomous services, and other items or services, while preserving requirements applicable under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including requirements applicable to clinical diagnostic laboratory tests. The Secretary shall coordinate effective dates and claims-processing implementation with existing coding updates where practicable.

(d) CLARIFICATION.—The establishment or assignment of a code under this section shall not constitute a

determination of Medicare coverage, payment amount, provider of services or supplier eligibility, or compliance with any other condition of coverage or payment under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

SEC. 405. CMI TESTING OF ARTIFICIAL INTELLIGENCE COVERAGE AND PAYMENT MODEL.

Section 1115A of the Social Security Act (42 U.S.C. 1315a) is amended—

(1) in subsection (b)(2)(A), by adding at the end the following new sentence: ''The models selected under this subparagraph shall include the model described in subsection (h).''; and

(2) by adding at the end the following new subsection:

''(h) ARTIFICIAL INTELLIGENCE COVERAGE AND PAYMENT MODEL.—

''(1) ESTABLISHMENT.—The Secretary shall establish a model to evaluate coverage and payment for selected clinical items and services furnished through—

''(A) artificial intelligence-based applications capable of performing a clinical function autonomously; and

"(B) artificial intelligence-based applications reviewed by an entity certified under section 515F of the Federal Food, Drug, and Cosmetic Act.

"(2) DURATION.—The model shall be implemented for a 5–year period, beginning not later than 24 months after the date of enactment of this subsection.

"(3) SELECTION AND DESIGN.—Under the model, the Secretary shall select artificial intelligence-based applications and providers of services or suppliers for participation using published criteria addressing clinical promise, patient safety, evidence gaps, potential benefit under title XVIII, operational readiness, and diversity of patient populations and care settings. The model shall test one or more per-service, per-beneficiary, episode-based, or outcomes-based payment arrangements and include appropriate comparison groups or other rigorous evaluation designs.

"(4) SAFEGUARDS.—The Secretary shall require informed beneficiary notice, appropriate clinical accountability and escalation arrangements, safety monitoring, reporting of material incidents and changes in performance, protections for bene-

ficiary data, and mechanisms for suspension or termination when patient safety or program integrity so requires. Participation in the model shall not diminish beneficiary appeal rights otherwise available under title XVIII or other applicable law.

''(5) FDA COORDINATION.—The Secretary shall coordinate, as appropriate and consistent with applicable confidentiality and data-sharing requirements, with the postmarket surveillance pilot program under section 204 of the PATIENT AI Act, including alignment of relevant safety and performance measures, without conditioning participation in the model on enrollment in such pilot.

''(6) EVALUATION.—As part of the evaluation of the model under subsection (b)(4), the Secretary shall evaluate the impact of the model on patient outcomes, safety, access, beneficiary experience, performance across relevant populations, utilization, provider and supplier behavior, expenditures under title XVIII, administrative costs, and the extent to which payment is linked to measurable value.''.