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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To better coordinate Federal efforts to utilize advance technologies, such as artificial intelligence, to improve diagnoses, treatments, cures, and prevention strategies for pediatric cancer, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCCAUL introduced the following bill; which was referred to the Committee on _____

A BILL

To better coordinate Federal efforts to utilize advance technologies, such as artificial intelligence, to improve diagnoses, treatments, cures, and prevention strategies for pediatric cancer, 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 ''Ailani Myers Accelerating Innovation in Medicine to Cure Kids with Cancer Act'' or the ''Ailani Myers AIM to Cure Kids with Cancer Act''.

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

TITLE I—FEDERAL GOVERNMENT EFFORTS

SEC. 101. COORDINATION OF FEDERAL EFFORTS.

(a) IN GENERAL.—The President shall designate an officer or employee of the Federal Government, or an office, council, or commission of the executive branch, to coordinate Federal efforts to use advanced technologies, including artificial intelligence, to improve the diagnosis, treatment, and prevention of, and the development of cures for, pediatric cancer. The officer, employee, office, council, or commission so designated shall be known as the Coordinator of AI Innovation (in this Act referred to as the ''Coordinator'').

(b) NOTIFICATION.—Not later than 30 days after making a designation under subsection (a), the President shall notify the appropriate committees of Congress of the designation.

(c) DUTIES.—The Coordinator shall—

(1) coordinate and align the activities of relevant Federal departments and agencies, in support of the purposes specified in subsection (a), including—

(A) the Department of Health and Human Services, and the agencies and offices thereof, including—

(i) the National Institutes of Health;

(ii) the Food and Drug Administration;

(iii) the Centers for Medicare & Medicaid Services;

(iv) the Advanced Research Projects Agency for Health; and

(v) the Office of the National Coordinator for Health Information Technology;

(B) the Department of Defense, including the Defense Health Agency and the Congressionally Directed Medical Research Programs;

(C) the Department of Energy;

(D) the Department of Veterans Affairs;

(E) the National Science Foundation;

(F) the National Institute of Standards and Technology;

(G) the Office of Science and Technology Policy; and

(H) such other Federal departments and agencies as the Coordinator determines appropriate;

(2) facilitate, with respect to the Federal efforts relating to pediatric cancer specified in subsection (a), interagency coordination and collaboration among Federal and non-Federal entities, such as patients, survivors, families, caregivers, researchers, and entities funding research on pediatric cancer;

(3) align Federal data and artificial intelligence policies affecting pediatric cancer research and care;

(4) consult with the Director of the National Cancer Institute on matters affecting the CCDI; and

(5) support the Federal activities that advance the purposes of this Act, including the activities of the CCDI.

TITLE II—DEPARTMENT OF HEALTH AND HUMAN SERVICES EFFORTS

SEC. 201. CHILDHOOD CANCER DATA INITIATIVE.

(a) IN GENERAL.—The NCI Director shall carry out the CCDI to collect, generate, standardize, link, and share data with respect to individuals who are diagnosed with cancer as a child, adolescent, or young adult in the United States, regardless of the age of the individual on the date such data is collected, regardless of where such individual receives care, in order to improve outcomes for individuals with such cancers, including with respect to prevention, diagnosis, treatment, quality of life, and survivorship.

(b) COMPONENTS.—In carrying out subsection (a), the NCI Director—

(1) shall support, at a minimum—

(A) molecular characterization of pediatric cancers, including through the initiative known as the Molecular Characterization Initiative of the CCDI, and the sharing of the results of such characterization to inform diagnosis and treatment;

(B) the generation, analysis, and sharing of data produced by non-invasive clinically validated technologies, software, and artificial intel-

ligence tools, including molecular testing and functional precision medicine approaches, to inform diagnosis and treatment;

(C) data platforms, catalogs, and tools that enable researchers and clinicians to find, access, integrate, analyze, and share pediatric cancer data, including the network of such platforms and tools known as the CCDI Data Ecosystem;

(D) the collection and study of data on pediatric cancers, including rare pediatric cancers;

(E) the aggregation and linkage of clinical, research, and population-based data for secondary use, including through the registry known as the National Childhood Cancer Registry; and

(F) the development of data standards and infrastructure necessary to carry out subparagraphs (A) through (D); and

(2) may support such other activities as the NCI Director determines appropriate to carry out subsection (a).

(c) DIRECTOR OF THE CCDI.—The Secretary, on the recommendation of the NCI Director, shall designate a Director of the Childhood Cancer Data Initiative (in this Act referred to as the ''CCDI Director''), who shall—

(1) be an individual with demonstrated scientific expertise in pediatric oncology, biomedical data science, or a related field;

(2) provide scientific and programmatic leadership for the CCDI, including the components described in subsection (b) and the artificial intelligence activities described in section 202;

(3) coordinate the activities of the CCDI with other Federal departments and agencies and with non-Federal partners; and

(4) report to the NCI Director.

SEC. 202. HARNESSING INNOVATION IN ARTIFICIAL INTELLIGENCE.

(a) IN GENERAL.—The NCI Director shall support, in coordination with the Coordinator, the development and application of artificial intelligence to accelerate progress in pediatric cancer research and care, including through the CCDI.

(b) DATA READINESS.—In carrying out subsection (a), the NCI Director shall—

(1) expand and improve the artificial intelligence readiness of the data platforms and tools of the CCDI Data Ecosystem;

(2) consolidate and harmonize data from multiple sources to enable such data to be analyzed using artificial intelligence; and

(3) develop data standards and technical approaches necessary for the use of artificial intelligence with the data described in paragraphs (1) and (2).

(c) RESEARCH AND ANALYSIS.—In carrying out subsection (a), the NCI Director shall support research on pediatric cancer using artificial intelligence—

(1) to improve predictive modeling of patient response, disease progression, and treatment toxicity;

(2) to derive novel diagnostic, prognostic, and therapeutic biomarkers from molecular and imaging data; and

(3) to carry out research projects, including projects carried out at cancer centers designated by the National Cancer Institute.

(d) CLINICAL TRIALS.—In carrying out subsection (a), the Secretary shall support the use of multimodal data and artificial intelligence to improve the design, participant recruitment and selection, administration, conduct, and interpretation of clinical trials for medical products

intended to diagnose, treat, prevent, or cure pediatric cancer.

(e) RELATIONSHIP TO CCDI COMPONENTS.—Activities under this section shall supplement, and not supplant, the components described in section 201(b).

(f) DISSEMINATION.—The Secretary shall make methods, tools, data standards, and technical approaches developed under this section available to other programs of the National Cancer Institute, to other Federal departments and agencies, and, as appropriate, to the public.

SEC. 203. IMPROVING THE DATA ECOSYSTEM, DATA SHARING, AND EMPOWERING PATIENTS.

(a) INTEGRATION OF ARTIFICIAL INTELLIGENCE INTO INTEROPERABILITY.—The Secretary of Health and Human Services, acting through the National Coordinator for Health Information Technology, shall ensure that artificial intelligence is appropriately integrated into interoperability activities carried out under title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), in order to improve the potential for electronic health record and claims data to inform private sector and academic research and clinical trial design, while ensuring the privacy of individually identifiable health information in accordance with regulations promulgated under section 264(c)

of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(b) INTEROPERABILITY STANDARDS.—Not later than 2 years after the date of the enactment of this Act, the Secretary, acting through the National Coordinator for Health Information Technology, shall finalize interoperability standards for patient data to be used with artificial intelligence that—

(1) appropriately account for structured and unstructured data;

(2) enable safe and privacy-compliant exchanges of data; and

(3) account for the needs of pediatric patients, including pediatric cancer patients, as a priority use case.

(c) APPLICABILITY.—The standards finalized under subsection (b) shall be developed for application throughout the Department of Health and Human Services and shall not be limited in application to the CCDI or to the National Cancer Institute.

(d) CONSULTATION AND PATIENT ENGAGEMENT.—In carrying out this section, the Secretary, acting through the National Coordinator for Health Information Technology, shall—

(1) consult with the Director, the CCDI Director, patients and their families, health care providers, researchers, and developers of health information technology;

(2) coordinate with the patient community to ensure transparency and to establish mechanisms for the sharing of data; and

(3) identify existing barriers to pediatric data sharing and interoperability, in coordination with the stakeholder community, and make recommendations to address such barriers.

SEC. 204. REPORTS.

(a) INTERIM REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that—

(1) describes the progress made in implementing this title;

(2) includes any interim findings of the Secretary with respect to that implementation; and

(3) identifies any barriers to that implementation.

(b) ANNUAL REPORTS.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter through fiscal year 2031, the Secretary of Health

and Human Services shall submit to the appropriate committees of Congress a report that includes—

(1) a description of the activities carried out under this title, including each component described in section 201(b) and the artificial intelligence activities described in section 202;

(2) the amounts expended on such activities;

(3) progress on data sharing, interoperability, and privacy protections, including the status of the interoperability standards required under section 203(b);

(4) the barriers identified in section 203(d)(3) and the recommendations made to address such barriers; and

(5) outcomes and measures of progress with respect to the diagnosis, treatment, prevention, or cure of pediatric cancer.

TITLE III—GENERAL PROVISIONS

SEC. 301. DEFINITIONS.

In this Act:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term ''appropriate committees of Congress'' means—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Science, Space, and Technology of the House of Representatives;

(C) the Committee on Health, Education, Labor, and Pensions of the Senate; and

(D) the Committee on Commerce, Science, and Transportation of the Senate.

(2) ARTIFICIAL INTELLIGENCE.—The term ''artificial intelligence'' has the meaning given such term in section 238(g) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115–232).

(3) CCDI.—The term ''CCDI'' means the initiative known as the Childhood Cancer Data Initiative.

(4) NCI DIRECTOR.—The term ''NCI Director'' means the Director of the National Cancer Institute.

SEC. 302. PRIVACY.

Activities under this Act shall be carried out in a manner consistent with applicable Federal and State laws relating to the privacy of patient information, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

SEC. 303. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to carry out this Act, other than section 201, such sums as may be necessary for each of fiscal years 2027 through 2031.

(b) CCDI.—In addition to amounts authorized to be appropriated under subsection (a), there are authorized to be appropriated to carry out section 201 $100,000,000 for each of fiscal years 2027 through 2031.

SEC. 304. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to affect the authority of the Secretary of Health and Human Services or the Director of the National Cancer Institute under any other provision of Federal law.