| 118TH CONGRESS 2D SESSION | S. _ | | | |
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| To improve the quality hea | | eness, and effe | _ | nosis in |

IN THE SENATE OF THE UNITED STATES

Mr. VAN HOLLEN (for himself and Mr. Luján) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To improve the quality, appropriateness, and effectiveness of diagnosis in health care, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Improving Diagnosis
- 5 in Medicine Act of 2024".
- 6 SEC. 2. RESEARCH PROGRAM TO IMPROVE DIAGNOSTIC
- 7 SAFETY AND QUALITY.
- 8 Part B of title IX of the Public Health Service Act
- 9 (42 U.S.C. 299b et seq.) is amended by adding at the end
- 10 the following:

| 1 | "SEC. 918. RESEARCH PROGRAM TO IMPROVE DIAGNOSTIC |
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| 2 | SAFETY AND QUALITY. |
| 3 | "(a) In General.—The Director shall establish a |
| 4 | comprehensive program of research and quality improve- |
| 5 | ment to— |
| 6 | "(1) assess and understand diagnostic errors, |
| 7 | including diagnostic delays, and how to eliminate |
| 8 | common failures in the diagnostic process that lead |
| 9 | to significant patient harm; and |
| 10 | "(2) identify, develop, implement, and dissemi- |
| 11 | nate evidence-based strategies and best practices for |
| 12 | improving diagnostic quality, safety, and health care |
| 13 | value. |
| 14 | "(b) Activities.—The program established under |
| 15 | subsection (a) shall include the following: |
| 16 | "(1) Continuum of Research.—A portfolio |
| 17 | of conducted and supported activities that is con- |
| 18 | sistent with the research, implementation, and dis- |
| 19 | semination activities of the Center for Quality Im- |
| 20 | provement and Patient Safety, as described in sec- |
| 21 | tion 933, including— |
| 22 | "(A) investigator-initiated research to as- |
| 23 | sess diagnostic errors and identify improved |
| 24 | methods to prevent errors and the harm errors |
| 25 | cause; |
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| 1 | "(B) translation and synthesis of research |
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| 2 | findings and development of tools for imple- |
| 3 | menting prevention strategies into practice; |
| 4 | "(C) implementation research to refine evi- |
| 5 | dence-based tools for improving diagnostic proc- |
| 6 | esses and effectively integrate these solutions |
| 7 | into practice; and |
| 8 | "(D) dissemination to promote implemen- |
| 9 | tation of effective methods, strategies, and tools |
| 10 | for wide-scale improvement, including identi- |
| 11 | fying where digital- and artificial intelligence- |
| 12 | enabled tools could be beneficial. |
| 13 | "(2) Research centers of diagnostic ex- |
| 14 | CELLENCE.—Consistent with section 911(b), the |
| 15 | health care improvement research centers described |
| 16 | in such section shall link research directly with clin- |
| 17 | ical practice in geographically diverse locations |
| 18 | throughout the United States, and may include— |
| 19 | "(A) academic medical and institutional re- |
| 20 | search centers that combine demonstrated mul- |
| 21 | tidisciplinary expertise in diagnostic outcomes |
| 22 | or quality improvement research with linkages |
| 23 | directly or through national, State or local |
| 24 | stakeholder partner organizations to relevant |
| 25 | sites of care; and |

| 1 | (B) provider-based research networks, in- |
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| 2 | cluding plan, facility, or delivery system sites of |
| 3 | care (especially primary care), that can evaluate |
| 4 | outcomes and evaluate and promote quality im- |
| 5 | provement approaches. |
| 6 | "(3) FINANCIAL ASSISTANCE.—The Director |
| 7 | may provide financial assistance to assist in meeting |
| 8 | the costs of planning and establishing new centers, |
| 9 | as well as operating existing and new centers, pursu- |
| 10 | ant to section 902(e). |
| 11 | "(4) Stakeholder engagement.—The Di- |
| 12 | rector shall identify and enter into a supporting |
| 13 | agreement, pursuant to a grant or contract, with a |
| 14 | nonprofit entity that convenes a coalition of diverse |
| 15 | health care stakeholders for the purpose of— |
| 16 | "(A) raising attention to diagnostic safety |
| 17 | and quality concerns; |
| 18 | "(B) facilitating learning, adoption, and |
| 19 | dissemination of effective quality improvement |
| 20 | interventions; and |
| 21 | "(C) catalyzing novel actions by individual |
| 22 | member organizations to reduce harms from di- |
| 23 | agnostic error and improve patient outcomes. |
| 24 | "(c) Authorization of Appropriations.— |
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| 1 | "(1) In general.—To carry out this section, |
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| 2 | there are authorized to be appropriated \$30,000,000 |
| 3 | for fiscal year 2025, \$35,000,000 for fiscal year |
| 4 | 2026, $$40,000,000$ for fiscal year 2027 , and |
| 5 | 45,000,000 for each of fiscal years 2028 and 2029. |
| 6 | "(2) Reservation.—Of the amount appro- |
| 7 | priated under paragraph (1) for a fiscal year, |
| 8 | \$700,000 shall be allocated to carrying out the pur- |
| 9 | pose described in subsection (b)(4). |
| 10 | "(3) Availability.—Amounts appropriated |
| 11 | under this section shall remain available until ex- |
| 12 | pended.". |
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| 13 | SEC. 3. FELLOWSHIPS AND TRAINING GRANTS. |
| | SEC. 3. FELLOWSHIPS AND TRAINING GRANTS. (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of |
| 13 | |
| 13 14 | (a) Ruth Kirschstein Awards.—Section 487(a) of |
| 131415 | (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is |
| 13 14 15 16 | (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: |
| 13 14 15 16 17 | (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: "(5) For purposes of the program under this sub- |
| 13 14 15 16 17 18 | (a) Ruth Kirschstein Awards.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: "(5) For purposes of the program under this subsection, biomedical and behavioral research includes diag- |
| 13 14 15 16 17 18 | (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: "(5) For purposes of the program under this subsection, biomedical and behavioral research includes diagnostic safety and quality research.". |
| 13 14 15 16 17 18 19 20 | (a) Ruth Kirschstein Awards.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: "(5) For purposes of the program under this subsection, biomedical and behavioral research includes diagnostic safety and quality research." (b) AHRQ Programs.—Section 902(b)(1) of the |
| 13 14 15 16 17 18 19 20 21 | (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)) is amended by adding at the end the following: "(5) For purposes of the program under this subsection, biomedical and behavioral research includes diagnostic safety and quality research." (b) AHRQ PROGRAMS.—Section 902(b)(1) of the Public Health Service Act (42 U.S.C. 299a(b)(1)) is |

| 1 | (2) by striking "under section 487(d)(3)" and |
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| 2 | inserting "for purposes of carrying out section 487". |
| 3 | SEC. 4. QUALITY MEASURE DEVELOPMENT. |
| 4 | Section 931(c)(2) of the Public Health Service Act |
| 5 | (42 U.S.C. 299b–31(c)(2)) is amended— |
| 6 | (1) by redesignating subparagraphs (B) |
| 7 | through (J) as subparagraphs (C) through (K), re- |
| 8 | spectively; and |
| 9 | (2) by inserting after subparagraph (A) the fol- |
| 10 | lowing: |
| 11 | "(B) diagnostic safety and quality;". |
| 12 | SEC. 5. STANDARDIZED DATA FOR DIAGNOSIS RESEARCH |
| 13 | AND IMPROVEMENT. |
| 14 | Section 937(f) of the Public Health Service Act (42 |
| 15 | U.S.C. 299b–37(f)) is amended— |
| 16 | (1) by striking "The Secretary" and inserting |
| 17 | the following: |
| 18 | "(1) IN GENERAL.—The Secretary"; and |
| 19 | (2) adding at the end the following: |
| 20 | "(2) Consultation with expert panel.—In |
| 21 | carrying out paragraph (1), the Secretary, in coordi- |
| 22 | nation with the Director, the Administrator of the |
| 23 | Centers for Medicare & Medicaid Services, the Na- |
| 24 | tional Coordinator for Health Information Took |
| | tional Coordinator for Health Information Tech- |

1 icine, the Chief Data Officer of the Department of 2 Health and Human Services, and the Chief Artificial 3 Intelligence Officer of the Department of Health and 4 Human Services, shall convene an expert panel to 5 consider and make recommendations regarding the 6 types, sources, and availability of data needed to ac-7 celerate diagnostic safety and quality research, train-8 ing, and measure development as specified in section 9 918, including— "(A) demographic data; 10 11 "(B) the specificity, interoperability, and 12 socio-technical aspects of electronic vocabularies 13 and ontologies related to presenting symptoms, 14 chief complaints, and the status of diagnosis 15 (such as tentative, working, or confirmed); and "(C) the development and use of symptom-16 17 based clinical registries. Such panel shall con-18 sider enhanced data capabilities that are nec-19 essary to support both research and improve-20 ment of diagnostic safety and quality.". 21 SEC. 6. INTERAGENCY COUNCIL ON IMPROVING DIAGNOSIS 22 IN HEALTH CARE. 23 (a) Establishment.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall establish within the Office of the Secretary

| 1 | an interagency council to be known as the Interagency |
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| 2 | Council on Improving Diagnosis in Health Care (referred |
| 3 | to in this section as the "Council"). |
| 4 | (b) Objectives.—The objectives of the Council shall |
| 5 | be the following: |
| 6 | (1) Enhance the quality, appropriateness, and |
| 7 | effectiveness of diagnosis in health care through— |
| 8 | (A) the establishment and support of a |
| 9 | broad base of scientific research; |
| 10 | (B) the dissemination and implementation |
| 11 | of the results of such research; and |
| 12 | (C) the promotion of improvements in clin- |
| 13 | ical and health system practices. |
| 14 | (2) Identify and eliminate systemic barriers to |
| 15 | supporting research in improving diagnosis in health |
| 16 | care. |
| 17 | (3) Identify knowledge gaps, research and data |
| 18 | needs, and opportunities congruent with agency mis- |
| 19 | sions to strengthen the clinical and translational re- |
| 20 | search pipeline to improve diagnostic safety and |
| 21 | quality, including potential collaborative research ini- |
| 22 | tiatives among 2 or more agencies, offices, institutes, |
| 23 | or centers within the Department of Health and |
| 24 | Human Services or other Federal agencies or offices. |
| 25 | (c) Membership.— |

| 1 | (1) CHAIRPERSON.—The Director of the Agen- |
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| 2 | cy for Healthcare Research and Quality (or the Di- |
| 3 | rector's designee) shall be the Chairperson of the |
| 4 | Council. |
| 5 | (2) Members.— |
| 6 | (A) In General.—In addition to the |
| 7 | Chairperson, the Council shall be comprised of |
| 8 | the following: |
| 9 | (i) At least 1 designee from each of |
| 10 | the following, appointed by the head of the |
| 11 | applicable department or agency: |
| 12 | (I) The Centers for Disease Con- |
| 13 | trol and Prevention. |
| 14 | (II) The Centers for Medicare & |
| 15 | Medicaid Services. |
| 16 | (III) The Department of Vet- |
| 17 | erans Affairs. |
| 18 | (IV) The Congressionally Di- |
| 19 | rected Medical Research Program of |
| 20 | the Department of Defense. |
| 21 | (V) The Office of the National |
| 22 | Coordinator for Health Information |
| 23 | Technology. |
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| 1 | (VI) The Office of the Chief |
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| 2 | Data Officer of the Department of |
| 3 | Health and Human Services. |
| 4 | (VII) The Office of the Chief Ar- |
| 5 | tificial Intelligence Officer of the De- |
| 6 | partment of Health and Human Serv- |
| 7 | ices. |
| 8 | (VIII) The Center for Devices |
| 9 | and Radiological Health of the Food |
| 10 | and Drug Administration. |
| 11 | (ii) Designees from the National Insti- |
| 12 | tutes of Health, including a least 1 des- |
| 13 | ignee from each of the following: |
| 14 | (I) The National Cancer Insti- |
| 15 | tute. |
| 16 | (II) The National Center for Ad- |
| 17 | vancing Translational Sciences. |
| 18 | (III) The National Institute of |
| 19 | Allergy and Infectious Diseases. |
| 20 | (IV) The National Heart, Lung, |
| 21 | and Blood Institute. |
| 22 | (V) The National Institute of |
| 23 | Neurological Disorders and Stroke. |
| 24 | (VI) The National Library of |
| 25 | Medicine. |

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| 1 | (VII) The National Institute or |
| 2 | Minority Health and Health Dispari- |
| 3 | ties. |
| 4 | (VIII) The National Institute of |
| 5 | Nursing Research. |
| 6 | (IX) The Eunice Kennedy Shriv- |
| 7 | er National Institute of Child Health |
| 8 | and Human Development. |
| 9 | (iii) Designees from such other na- |
| 10 | tional research institutes and national cen- |
| 11 | ters as may be appropriate, as determined |
| 12 | by the Director of the National Institutes |
| 13 | of Health. |
| 14 | (B) Additional members.—In addition |
| 15 | to the designees under subparagraph (A), the |
| 16 | Council may include such other designees from |
| 17 | Federal departments or agencies as the Chair- |
| 18 | person of the Council determines appropriate. |
| 19 | (C) Designation.—A person appointed to |
| 20 | the Council as a designee shall be a senior offi- |
| 21 | cial or employee of the department or agency |
| 22 | whose responsibilities and subject matter exper- |
| 23 | tise are relevant to the Council's objectives list |
| 24 | ed in subsection (b), as determined by the des- |
| 25 | ignating official. |

| (d) | STRATEGIC | PLAN: | Reports.— |
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(1) STRATEGIC FEDERAL PLAN TO IMPROVE DIAGNOSIS IN HEALTH CARE.—Not later than 18
months after the date of enactment of this Act, the
Council shall develop, submit to the Secretary and
Congress, and make publicly available a strategic
plan, to be known as the Strategic Federal Plan to
Improve Diagnosis, that, consistent with the objectives listed in subsection (b)—

- (A) identifies coordinated opportunities to enhance scientific research and reduce systemic barriers in order to improve diagnosis in health care; and
- (B) includes legislative and administrative policy recommendations, including opportunities to remove barriers to, and enhance, inter-agency coordination in the planning, conduct, and funding of, such research.
- (2) Reports to congress.—Not later than July 31 of every odd-numbered year beginning with the first such year after the date of submission of the first Strategic Federal Plan to Improve Diagnosis under paragraph (1), the Council shall prepare, submit to the Secretary and Congress, and

| 1 | make publicly available an updated Strategic Fed- |
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| 2 | eral Plan to Improve Diagnosis that includes— |
| 3 | (A) such updates as the Council deter- |
| 4 | mines to be appropriate; |
| 5 | (B) information on the overall progress of |
| 6 | the Federal Government in reducing barriers to |
| 7 | research on, and supporting projects to im- |
| 8 | prove, diagnosis in health care; and |
| 9 | (C) legislative and administrative policy |
| 10 | recommendations, including addressing any |
| 11 | needs for greater legislative authority to meet |
| 12 | the objectives listed in subsection (b). |
| 13 | (e) Authorization of Appropriations.—To carry |
| 14 | out this section, there are authorized to be appropriated |
| 15 | \$1,500,000 for each of fiscal years 2025 through 2029. |
| 16 | SEC. 7. NATIONAL ACADEMIES REPORT. |
| 17 | (a) In General.—The Director of the Agency for |
| 18 | Healthcare Research and Quality shall seek to enter into |
| 19 | a contract with the National Academies of Sciences, Engi- |
| 20 | neering, and Medicine under which such National Acad- |
| 21 | emies conducts a study and issues a report on disparities |
| 22 | in diagnostic safety and quality that— |
| 23 | (1) identifies what is known about the burden |
| 24 | and causes of such disparities, including racial, eth- |

| 1 | nic, socioeconomic, age, gender, geography, language |
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| 2 | proficiency, and intersectional interactions; and |
| 3 | (2) includes recommendations on specific ac- |
| 4 | tions that policymakers, researchers, clinicians, and |
| 5 | other stakeholders can take to eliminate such bur- |
| 6 | dens. |
| 7 | (b) Authorization of Appropriations.—To carry |
| 8 | out this section, there is authorized to be appropriated |
| 9 | \$1,500,000 for fiscal year 2025, to remain available until |
| 0 | expended. |