

118TH CONGRESS
2D SESSION

S. 5613

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

IN THE SENATE OF THE UNITED STATES

DECEMBER 19 (legislative day, DECEMBER 16), 2024

Mr. VAN HOLLEN (for himself and Mr. LUJÁN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2022”.

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**
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 general, research, implementation,
19 and dissemination activities of the Center for Qual-
20 ity Improvement and Patient Safety, as described in
21 section 933, including—

22 “(A) investigator-initiated research to as-
23 sess diagnostic errors and identify improved
24 methods to prevent errors and the harm they
25 cause;

1 “(B) translation and synthesis of research
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.

11 “(2) RESEARCH CENTERS OF DIAGNOSTIC EX-
12 CELLENCE.—Consistent with section 911(b), such
13 Centers shall link research directly with clinical
14 practice in geographically diverse locations through-
15 out the United States, and may include—

16 “(A) academic medical and institutional re-
17 search centers that combine demonstrated mul-
18 tidisciplinary expertise in diagnostic outcomes
19 or quality improvement research with linkages
20 directly or through national, state or local
21 stakeholder partner organizations to relevant
22 sites of care;

23 “(B) provider-based research networks, in-
24 cluding plan, facility, or delivery system sites of
25 care (especially primary care), that can evaluate

1 outcomes and evaluate and promote quality im-
 2 provement approaches.

3 “(3) FINANCIAL ASSISTANCE.—The Director
 4 may provide financial assistance to assist in meeting
 5 the costs of planning and establishing new centers,
 6 as well as operating existing and new centers, pursu-
 7 ant to section 902(c).

8 “(4) STAKEHOLDER ENGAGEMENT.—The Di-
 9 rector shall identify and enter into a supporting
 10 agreement (grant or contract) with a nonprofit enti-
 11 ty that convenes a coalition of diverse health care
 12 stakeholders for the purpose of—

13 “(A) raising attention to diagnostic safety
 14 and quality concerns;

15 “(B) facilitating learning, adoption and
 16 spread of effective quality improvement inter-
 17 ventions; and

18 “(C) catalyzing novel actions by individual
 19 member organizations to reduce harms from di-
 20 agnostic error and improve patient outcomes.

21 “(c) AUTHORIZATION OF APPROPRIATIONS.—

22 “(1) IN GENERAL.—To carry out this section,
 23 there is authorized to be appropriated \$20,000,000
 24 for fiscal year 2023, \$25,000,000 for fiscal year

1 2024, \$30,000,000 for fiscal year 2025, and
2 \$35,000,000 for each of fiscal years 2026 and 2027.

3 “(2) RESERVATION.—Of the amount appro-
4 priated under paragraph (1) for a fiscal year,
5 \$700,000 shall be allocated to carrying out the pur-
6 pose described in subsection (b)(4).

7 “(3) AVAILABILITY.—Amounts appropriated
8 under this section shall remain available until ex-
9 pended.”.

10 **SEC. 3. FELLOWSHIPS AND TRAINING GRANTS.**

11 (a) RUTH KIRSCHSTEIN AWARDS.—Section 487(a) of
12 the Public Health Service Act (42 U.S.C. 288(a)) is
13 amended by adding at the end the following:

14 “(5) For purposes of the program under this sub-
15 section, biomedical and behavioral research includes diag-
16 nostic safety and quality research.”.

17 (b) AHRQ PROGRAMS.—Section 902(b)(1) of the
18 Public Health Service Act (42 U.S.C. 299a(b)(1)) is
19 amended—

20 (1) by inserting “and diagnostic safety and
21 quality” after “subsection (a)”; and

22 (2) by striking “under section 487(d)(3)” and
23 inserting “for purposes of carrying out section 487”.

1 **SEC. 4. QUALITY MEASURE DEVELOPMENT.**

2 Section 931(c)(2) of the Public Health Service Act
3 (42 U.S.C. 299b–31(c)(2)) is amended—

4 (1) by redesignating subparagraphs (B)
5 through (J) as subparagraphs (C) through (K), re-
6 spectively; and

7 (2) by inserting after subparagraph (A) the fol-
8 lowing:

9 “(B) diagnostic safety and quality;”.

10 **SEC. 5. DATA FOR RESEARCH AND IMPROVEMENT.**

11 Section 937(f) of the Public Health Service Act (42
12 U.S.C. 299b–37(f)) is amended—

13 (1) by striking “The Secretary” and inserting
14 the following:

15 “(1) IN GENERAL.—The Secretary”; and

16 (2) adding at the end the following:

17 “(2) CONSULTATION WITH EXPERT PANEL.—In
18 carrying out paragraph (1), the Secretary, in coordi-
19 nation with the Director, the Director of the Centers
20 for Medicare & Medicaid Services, the National Co-
21 ordinator for Health Information Technology, and
22 the National Library of Medicine, shall convene an
23 expert panel to consider and make recommendations
24 regarding the types, sources, and availability of data
25 needed to accelerate diagnostic safety and quality re-
26 search, training, and measure development as speci-

1 fied in section 918, including data related to racial,
 2 ethnic, and language attributes; gender, age, geog-
 3 raphy, and socioeconomic conditions; the specificity,
 4 interoperability, and socio-technical aspects of elec-
 5 tronic vocabularies and ontologies related to pre-
 6 senting symptoms and diagnostic certainty; and the
 7 development and use of symptom-based clinical reg-
 8 istries. Such panel shall consider enhanced data ca-
 9 pabilities that are necessary to support both re-
 10 search and improvement of diagnostic safety and
 11 quality.”.

12 **SEC. 6. INTERAGENCY COUNCIL ON IMPROVING DIAGNOSIS**
 13 **IN HEALTH CARE.**

14 (a) **ESTABLISHMENT.**—The Secretary of Health and
 15 Human Services (in this section referred to as the “Sec-
 16 retary”) shall establish within the Office of the Secretary
 17 an interagency council to be known as the Interagency
 18 Council on Improving Diagnosis in Health Care (referred
 19 to in this section as the “Council”).

20 (b) **OBJECTIVES.**—The objectives of the Council shall
 21 be the following:

22 (1) Enhance the quality, appropriateness, and
 23 effectiveness of diagnosis in health care through—

24 (A) the establishment and support of a
 25 broad base of scientific research;

1 (B) the dissemination and implementation
2 of the results of such research; and

3 (C) the promotion of improvements in clin-
4 ical and health system practices.

5 (2) Identify and eliminate systemic barriers to
6 supporting research in improving diagnosis in health
7 care.

8 (3) Identify knowledge gaps, research and data
9 needs, and opportunities congruent with agency mis-
10 sions to strengthen the clinical and translational re-
11 search pipeline to improve diagnostic safety and
12 quality, including potential collaborative research ini-
13 tiatives among 2 or more agencies, offices, institutes,
14 or centers within the Department of Health and
15 Human Services or other Federal agencies or offices.

16 (c) MEMBERSHIP.—

17 (1) CHAIRPERSON.—The Director of the Agen-
18 cy for Healthcare Research and Quality (or the Di-
19 rector's designee) shall be the Chairperson of the
20 Council.

21 (2) MEMBERS.—

22 (A) IN GENERAL.—In addition to the
23 Chairperson, the Council shall be comprised of
24 the following:

1 (i) At least 1 designee from each of
2 the following, appointed by the head of the
3 applicable department or agency:

4 (I) The Centers for Disease Con-
5 trol and Prevention.

6 (II) The Centers for Medicare &
7 Medicaid Services.

8 (III) The Department of Vet-
9 erans Affairs.

10 (IV) The Congressionally Di-
11 rected Medical Research Program of
12 the Department of Defense.

13 (V) The Office of the National
14 Coordinator for Health Information
15 Technology.

16 (ii) Designees from the National Insti-
17 tutes of Health, including a least 1 des-
18 ignee from each of the following:

19 (I) The National Cancer Insti-
20 tute.

21 (II) The National Center for Ad-
22 vancing Translational Sciences.

23 (III) The National Institute of
24 Allergy and Infectious Diseases.

1 (IV) The National Heart, Lung,
2 and Blood Institute.

3 (V) The National Institute of
4 Neurological Disorders and Stroke.

5 (VI) The National Library of
6 Medicine.

7 (VII) The National Institute on
8 Minority Health and Health Dispari-
9 ties.

10 (VIII) The National Institute of
11 Nursing Research.

12 (IX) The Eunice Kennedy Shriv-
13 er National Institute of Child Health
14 and Human Development.

15 (iii) Designees from such other na-
16 tional research institutes and national cen-
17 ters as may be appropriate, as determined
18 by the Director of the National Institutes
19 of Health.

20 (B) ADDITIONAL MEMBERS.—In addition
21 to the designees under subparagraph (A), the
22 Council may include such other designees from
23 Federal departments or agencies as the Chair-
24 person of the Council deems appropriate.

1 (C) DESIGNATION.—A person appointed to
2 the Council as a designee shall be a senior offi-
3 cial or employee of the department or agency
4 whose responsibilities and subject matter exper-
5 tise are relevant to the Council’s objectives list-
6 ed in subsection (b), as determined by the des-
7 ignating official.

8 (d) STRATEGIC PLAN; REPORTS.—

9 (1) STRATEGIC FEDERAL PLAN TO IMPROVE DI-
10 AGNOSIS IN HEALTH CARE.—Not later than 18
11 months after the date of enactment of this Act, the
12 Council shall develop, submit to the Secretary and
13 Congress, and make publicly available a strategic
14 plan, to be known as the Strategic Federal Plan to
15 Improve Diagnosis, that, consistent with the objec-
16 tives listed in subsection (b)—

17 (A) identifies coordinated opportunities to
18 enhance scientific research and reduce systemic
19 barriers in order to improve diagnosis in health
20 care; and

21 (B) includes legislative and administrative
22 policy recommendations, including opportunities
23 to remove barriers to, and enhance, inter-agen-
24 cy coordination in the planning, conduct, and
25 funding of, such research.

1 (2) REPORTS TO CONGRESS.—Not later than
 2 July 31 of every odd-numbered year beginning with
 3 the first such year after the date of submission of
 4 the first Strategic Federal Plan to Improve Diag-
 5 nosis under paragraph (1), the Council shall pre-
 6 pare, submit to the Secretary and Congress, and
 7 make publicly available an updated Strategic Fed-
 8 eral Plan to Improve Diagnosis that includes—

9 (A) such updates as the Council deter-
 10 mines to be appropriate;

11 (B) information on the overall progress of
 12 the Federal Government in reducing barriers to
 13 research on, and supporting projects to im-
 14 prove, diagnosis in health care; and

15 (C) legislative and administrative policy
 16 recommendations, including addressing any
 17 needs for greater legislative authority to meet
 18 the objectives listed in subsection (b).

19 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
 20 out this section, there are authorized to be appropriated
 21 \$1,500,000 for each of fiscal years 2023 through 2027.

22 **SEC. 7. NATIONAL ACADEMIES REPORT.**

23 (a) IN GENERAL.—The Director of the Agency for
 24 Healthcare Research and Quality shall seek to enter into
 25 a contract with the National Academies of Sciences, Engi-

1 neering, and Medicine under which such National Acad-
2 emies conducts a study and issues a report on disparities
3 in diagnostic safety and quality that—

4 (1) identifies what is known about the burden
5 and causes of such disparities, including racial, eth-
6 nic, socioeconomic, age, gender, geography, language
7 proficiency, and intersectional interactions; and

8 (2) includes recommendations on specific ac-
9 tions that policymakers, researchers, clinicians, and
10 other stakeholders can take to eliminate such bur-
11 dens.

12 (b) AUTHORIZATION OF APPROPRIATIONS.—To carry
13 out this section, there is authorized to be appropriated
14 \$1,500,000 for fiscal year 2023, to remain available until
15 expended.

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