117TH CONGRESS 2D Session

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

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 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:

"SEC. 918. RESEARCH PROGRAM TO IMPROVE DIAGNOSTIC SAFETY AND QUALITY.

3 "(a) IN GENERAL.—The Director shall establish a
4 comprehensive program of research and quality improve5 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

"(2) identify, develop, implement, and disseminate evidence-based strategies and best practices for
improving diagnostic quality, safety, and health care
value.

14 "(b) ACTIVITIES.—The program established under15 subsection (a) shall include the following:

"(1) CONTINUUM OF RESEARCH.—A portfolio
of conducted and supported activities that is consistent with the general, research, implementation,
and dissemination activities of the Center for Quality Improvement and Patient Safety, as described in
section 933, including—

"(A) investigator-initiated research to assess diagnostic errors and identify improved
methods to prevent errors and the harm they
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

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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
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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".
	inserting for purposes of carrying out section 107.

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	
20	needed to accelerate diagnostic safety and quality re-

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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.

(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
an interagency council to be known as the Interagency
Council on Improving Diagnosis in Health Care (referred
to in this section as the "Council").

20 (b) OBJECTIVES.—The objectives of the Council shall21 be the following:

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

24 (A) the establishment and support of a25 broad base of scientific research;

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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.

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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

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-

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

4 (1) identifies what is known about the burden
5 and causes of such disparities, including racial, eth6 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.

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