I

117TH CONGRESS
2D SESSION

H. R. 9377

To establish the National Patient Safety Board.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 1, 2022

Ms. BARRAGÁN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Veterans' Affairs, and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish the National Patient Safety Board.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Patient Safety Board Act of 2022".

SEC. 2. NATIONAL PATIENT SAFETY BOARD.

(a) ESTABLISHMENT.—There is hereby established an independent agency to be known at the National Patient Safety Board (in this section referred to as the

''Board'') for the purpose of preventing and reducing patient safety events.

(b) DUTIES.—

(1) IN GENERAL.—For the purpose stated in subsection (a), the Board shall—

(A) support Federal departments and agencies in monitoring and anticipating patient safety events with patient safety data surveillance technologies;

(B) provide expertise to study the context and causes of patient safety events and solutions; and

(C) formulate recommendations and solutions to prevent patient safety events from occurring.

(2) ANNUAL AUDIT.—The Board shall undergo an annual audit.

(3) ANNUAL REPORTS TO CONGRESS.—

(A) SUBMISSION.—The Chair of the Board shall submit annual reports to the Congress on the progress of the Board in achieving the purpose stated in subsection (a).

(B) CONTENTS.—Each annual report under subparagraph (A) shall include—

(i) input from the director of each division of the Board;

(ii) detailed solutions;

(iii) unaddressed needs; and

(iv) any other information determined by the Chair of the Board to be relevant to achieving the purpose stated in subsection (a).

(c) HEARINGS; REPORTS.—

(1) IN GENERAL.—The Board may, for the purpose of carrying out this Act, hold hearings, sit and act at times and places, take testimony, receive evidence, and issue such reports as the Board considers appropriate.

(2) NO INDIVIDUALLY IDENTIFIABLE INFORMATION IN PUBLICATIONS.—The Board (including any division, subdivision, or other component thereof) shall not include in any report or other publication information that can be used to identify any patient, health care provider, or health care setting.

(d) MEMBERSHIP.—

(1) IN GENERAL.—The Board shall be composed of 5 members, each nominated—

(A) by the President, by and with the advice and consent to the Senate; and

(B) for a term of 6 years.

(2) CHAIR; VICE CHAIR.—The Board shall have a Chair and Vice Chair who shall each—

(A) be designated by the President from among the members of the Board appointed under paragraph (1); and

(B) serve for a 3-year term.

(e) STAFFING.—The Chair of the Board may appoint such personnel as the Chair considers appropriate to carry out this section.

(f) ORGANIZATION.—The Board shall have—

(1) an Office of the Chair of the Board;

(2) a Patient Safety Event Monitoring Division, to be headed by a director appointed by the Board;

(3) a Study Division, to be headed by a director appointed by the Board;

(4) a Patient Safety Solutions Division, to be headed by a director appointed by the Board;

(5) an Administrative Division, to be headed by a director appointed by the Board; and

(6) regional offices.

(g) PATIENT SAFETY EVENT MONITORING DIVISION.—

(1) HEALTH CARE SAFETY TEAM.—

(A) IN GENERAL.—For the purpose stated in subsection (a), the Director of the Patient Safety Event Monitoring Division shall establish and maintain a public-private team, to be known as a Health Care Safety Team, to review, update, and prioritize patient safety event measures and data sources related to patient and provider safety in health care settings, including survey data, electronic health records data, claims data, health information exchange data, and reports of patient safety events.

(B) RECOMMENDATIONS.—The Health Care Safety Team shall recommend to public and private entities patient safety data surveillance technologies and specifications with the ability to identify and anticipate the patient safety measures.

(C) MEMBERSHIP.—The membership of the Health Care Safety Team under subparagraph (A) shall include—

(i) representatives with patient safety expertise from the following Federal agencies: the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers for Medi-

care & Medicaid, the Department of Veterans Affairs, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Office of Minority Health of the Department of Health and Human Services, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, the National Institutes of Health, and the United States Preventive Services Task Force; and

(ii) representatives of the private sector with patient safety expertise, representing providers, organized labor, health care organizations, patients, payors, suppliers, vendors, manufacturers, measurement developers, and data technology experts.

(2) OBTAINING OFFICIAL DATA.—To carry out this subsection, the Director of the Patient Safety Event Monitoring Division may secure directly from any office or agency of the Department of Health and Human Services or the Department of Veterans Affairs longitudinal, real-time, de-identified patient

data, disaggregated by race, ethnicity, gender, facility, and location, relating to patient safety event measures. Upon request of the Director of the Patient Safety Event Monitoring Division, the head of the respective office or agency shall furnish that data to the Director. The Director shall maintain and use such data consistent with applicable privacy and confidentiality law.

(3) WEBSITE OR SYSTEM.—The Director of the Patient Safety Event Monitoring Division shall create and maintain a website or system, to be known as the Patient Safety Reporting System, that can be used by patients, health care providers, non-clinical staff, or any other person to report patient safety events to the Division.

(4) DATA ACCESS PORTAL.—The Director of the Patient Safety Event Monitoring Division shall—

(A) enter into agreements with public and private entities, including at the State and local levels, to opt into allowing the Division to access the entity's longitudinal, real-time, de-identified patient data, disaggregated by race, ethnicity, gender, facility, and location, relating to patient safety event measures;

(B) maintain a data access portal to enable such entities to submit such data to the Division; and

(C) maintain and use such data consistent with applicable privacy and confidentiality law.

(5) REPORTING.—The Director of the Patient Safety Event Monitoring Division shall—

(A) submit to the Health Care Safety Team maintained under paragraph (1) regular reports on patient safety event surveillance; and

(B) prompt the Study Division when any of the following types of findings are identified in a geographic area or health care organization:

(i) The most frequently occurring major sources of patient safety events.

(ii) Abnormal patterns of patient safety events.

(iii) Unexpectedly low numbers of patient safety events.

(iv) Racial, ethnic, social, gender, or geographic disparities.

(v) Unaddressed reoccurring patient safety events.

(h) STUDY DIVISION.—

(1) IN GENERAL.—The Director of the Study Division may conduct or support studies with respect to patient safety events, including to understand the—

(A) circumstances, context, and conditions that enable patient safety events; and

(B) causes or probable causes of the high or low number of patient safety events.

(2) DATA SHARING.—

(A) REQUEST.—In conducting or supporting a study under paragraph (1), the Director of the Study Division may request from the Director of the Patient Safety Event Monitoring Division such information as may be collected by the Patient Safety Event Monitoring Division and relevant to the study.

(B) SHARING.—Upon receipt of such a request, the Director of the Patient Safety Event Monitoring Division shall share such information with the Director of the Study Division.

(3) STUDY REQUIREMENTS.—In conducting or supporting a study under paragraph (1):

(A) STUDY LEAD.—The Director of the Study Division shall—

(i) appoint an individual to serve as the person in charge of the study (in this paragraph referred to as the ''Study Lead''); and

(ii) vest such person with authority to determine the appropriate type of study, assemble a study team of experts, identify the study site or sites, and ask any health care organization that experienced the unexpectedly high or low numbers of patient safety events for permission to conduct the study based on prompts from the Patient Safety Event Monitoring Division.

(B) STUDY TEAM.—The Study Lead shall—

(i) assemble a team of multidisciplinary experts to improve the understanding of high or low numbers of patient safety events in the context of the study, including by gathering qualitative and quantitative information to understand—

(I) the circumstances, context, and conditions that enable the patient safety events; and

(II) the causes or probable causes of the high or low number patient safety events;

(ii) include in such team individuals with the ability to study and understand the interaction of human abilities, expectations, and limitations with work environments, technologies, and system design and other appropriate experts from the public and private sectors;

(iii) prohibit such team from releasing information obtained during the study prior to the public release of such information by the National Patient Safety Board; and

(iv) ensure that such team receives permission from each health care organization involved to—

(I) enter health care facilities participating in the study; and

(II) communicate with staff, health care providers, patients, vendors, suppliers, contractors, equipment manufacturers, and members of the Board.

(C) APPROPRIATE TYPE OF STUDY.—The Director of the Study Division shall—

(i) create guidelines and criteria to determine the appropriate type of study to be conducted or supported, including whether the study should be virtual, in-person, or a special board of inquiry; and

(ii) in creating such guidelines and criteria, take into account the impact of the patient safety events to be studied, whether such patient safety events may indicate a systemic risk, and what may potentially be learned from the study.

(D) NOVEL INFECTION AND EMERGENCY PANDEMIC.—In the case of a novel infection and emerging pandemic, the Director of the Study Division may establish a special board of inquiry—

(i) to provide independent recommendations on a coordinated national preparedness and response plan;

(ii) to independently monitor the implementation of the preparedness and response plan; and

(iii) to recommend technologies to support logistics and autonomous real-time research to inform evidence-based treatment options and decisions.

(4) REPORTING.—The Director of the Study Division shall—

(A) provide for the submission to the Board and the Patient Safety Solutions Division of—

(i) at least one progress report on each study under this subsection over the course of the study; and

(ii) a final report upon the conclusion of the study;

(B) include in a final report under subparagraph (A)(ii) factual information and analysis regarding the probable causes of the high or low numbers of patient safety events being studied and the recommendations of the Patient Safety Solutions Division; and

(C) make such final report publicly available.

(5) RESPONSE BY BOARD.—Upon receipt of a final report under paragraph (4)(A)(ii), the Board may elect to—

(A) adopt the report;

(B) work with the Study Division to make changes to the report prior to adoption; or

(C) require the Study Division to conduct or support further studies or revisions.

(6) TIMING.—The Director of the Study Division shall ensure that, not later than 1 year after the commencement of a study under this section—

(A) the study is completed; and

(B) the final report is made publicly available pursuant to paragraph (4)(C).

(7) LIMITATION ON AUTHORITY.—The Study Division and any study team established under this subsection shall not have authority to determine the rights or liabilities of any person with respect to adverse patient safety events.

(i) PATIENT SAFETY SOLUTIONS DIVISION.—

(1) ANALYSIS.—Whenever the Director of the Study Division provides a final report on a study pursuant to subsection (h)(4), the Director of the Patient Safety Solutions Division shall—

(A) analyze such report; and

(B) formulate recommendations (including solutions) to prevent the patient safety events that were studied from occurring.

(2) WORKING WITH HEALTH CARE SAFETY TEAM.—In formulating recommendations (including solutions) under paragraph (1), the Director of the Patient Safety Event Monitoring Division shall—

(A) in consultation with the Health Care Safety Team under subsection (g)(1), identify or develop solutions based on the causes of the patient safety events that were studied; and

(B) include such solutions in the recommendations.

(3) RESPONSE BY SECRETARY.—Not later than 90 days after the submission of the final report under subsection (h)(4)(A)(ii), the Secretary of Health and Human Services and the Secretary of Veterans Affairs shall publish a response to the recommendations.

(j) ADMINISTRATIVE DIVISION.—

(1) IN GENERAL.—The Director of the Administrative Division shall support the day-to-day activities of the Board, including with respect to communications, facility coordination, shipping and receiving, supply inventory, labor relations, and human resource management.

(2) SUBDIVISION.—The Administrative Division shall have a Safety and Equity Subdivision which shall—

(A) advise on, analyze, and publish proper safety guidelines to ensure safe working conditions at the Federal, State, and local levels;

(B) create an equity plan to ensure that the Board's programs and operations take into consideration the implications of, and remedies to address, discrimination and disparities; and

(C) provide training to enhance employee safety competence.

(k) PROHIBITION AGAINST ADMISSIBILITY AS EVIDENCE.—Any report or other publication of the Board (including any division, subdivision, or other component thereof) shall not be admissible as evidence, or used for any purpose, in any Federal or State action, suit, or other judicial, legislative, or administrative proceeding.

(l) PROTECTIONS FOR EMPLOYEES.—

(1) PROHIBITION.—No employer shall discharge or in any manner discriminate against any employee with respect to compensation, terms, conditions, or other privileges of employment because the employee (or an individual acting at the request of the employee)—

(A) has cooperated, or is perceived as being about to cooperate, with a study of the Board; or

(B) has submitted a report to the Patient Safety Reporting System of the Patient Safety Event Monitoring Division.

(2) COMPLAINT PROCEDURE.—

(A) IN GENERAL.—An employee who believes that he or she has been discharged or otherwise discriminated against by any employer in violation of this subsection may seek relief in accordance with the procedures, notifications, burdens of proof, remedies, and statutes of limitation set forth in section 2087(b) of title 15, United States Code.

(B) NO LIMITATION ON RIGHTS.—Nothing in this subsection shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this subsection may not be waived by any agreement, policy, form, or condition of employment.

(3) DEFINITION.—In this subsection, the term ''employer'' has the meaning given to such term in

section 3 of the Fair Labor Standards Act of 1938 (29 U.S.C. 203).

(m) DEFINITIONS.—In this section:

(1) The term ''health care setting'' means a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or other health care practitioner's office, long-term care facility, mental health treatment facility, substance use disorder treatment facility, clinical laboratory, or health center.

(2) The term ''patient safety event'' means an action or inaction that—

(A) led to patient injury or harm in a health care setting;

(B) could lead to patient injury or harm as a precursor to injury or harm in a health care setting; or

(C) could have caused injury or harm to the patient but did not cause injury or harm in a health care setting as a result of chance, prevention, or mitigation.

(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $110,000,000 for each of fiscal years 2023 and 2024.

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