

117TH CONGRESS  
2D SESSION

# H. R. 9377

To establish the National Patient Safety Board.

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## 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.

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 “National Patient Safe-  
5       ty Board Act of 2022”.

**6 SEC. 2. NATIONAL PATIENT SAFETY BOARD.**

7       (a) ESTABLISHMENT.—There is hereby established  
8       an independent agency to be known at the National Pa-  
9       tient Safety Board (in this section referred to as the

1   “Board”) for the purpose of preventing and reducing pa-  
2   tient safety events.

3                 (b) DUTIES.—

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

6                             (A) support Federal departments and  
7                     agencies in monitoring and anticipating patient  
8                     safety events with patient safety data surveil-  
9                     lance technologies;

10                             (B) provide expertise to study the context  
11                     and causes of patient safety events and solu-  
12                     tions; and

13                             (C) formulate recommendations and solu-  
14                     tions to prevent patient safety events from oc-  
15                     curring.

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

18                     (3) ANNUAL REPORTS TO CONGRESS.—

19                             (A) SUBMISSION.—The Chair of the Board  
20                     shall submit annual reports to the Congress on  
21                     the progress of the Board in achieving the pur-  
22                     pose stated in subsection (a).

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

1                             (i) input from the director of each di-  
2                             vision of the Board;  
3                             (ii) detailed solutions;  
4                             (iii) unaddressed needs; and  
5                             (iv) any other information determined  
6                             by the Chair of the Board to be relevant  
7                             to achieving the purpose stated in sub-  
8                             section (a).

9                             (c) HEARINGS; REPORTS.—

10                             (1) IN GENERAL.—The Board may, for the pur-  
11                             pose of carrying out this Act, hold hearings, sit and  
12                             act at times and places, take testimony, receive evi-  
13                             dence, and issue such reports as the Board considers  
14                             appropriate.

15                             (2) NO INDIVIDUALLY IDENTIFIABLE INFORMA-  
16                             TION IN PUBLICATIONS.—The Board (including any  
17                             division, subdivision, or other component thereof)  
18                             shall not include in any report or other publication  
19                             information that can be used to identify any patient,  
20                             health care provider, or health care setting.

21                             (d) MEMBERSHIP.—

22                             (1) IN GENERAL.—The Board shall be com-  
23                             posed of 5 members, each nominated—

24                                 (A) by the President, by and with the ad-  
25                             vice and consent to the Senate; and

1                         (B) for a term of 6 years.

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

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

7                         (B) serve for a 3-year term.

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

11                         (f) ORGANIZATION.—The Board shall have—

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

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

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

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

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

21                         (6) regional offices.

22                         (g) PATIENT SAFETY EVENT MONITORING DIVI-  
23                         SION.—

24                         (1) HEALTH CARE SAFETY TEAM.—

1                             (A) IN GENERAL.—For the purpose stated  
2                             in subsection (a), the Director of the Patient  
3                             Safety Event Monitoring Division shall estab-  
4                             lish and maintain a public-private team, to be  
5                             known as a Health Care Safety Team, to re-  
6                             view, update, and prioritize patient safety event  
7                             measures and data sources related to patient  
8                             and provider safety in health care settings, in-  
9                             cluding survey data, electronic health records  
10                            data, claims data, health information exchange  
11                            data, and reports of patient safety events.

12                            (B) RECOMMENDATIONS.—The Health  
13                             Care Safety Team shall recommend to public  
14                             and private entities patient safety data surveil-  
15                             lance technologies and specifications with the  
16                             ability to identify and anticipate the patient  
17                             safety measures.

18                            (C) MEMBERSHIP.—The membership of  
19                             the Health Care Safety Team under subpara-  
20                             graph (A) shall include—

21                                 (i) representatives with patient safety  
22                             expertise from the following Federal agen-  
23                             cies: the Agency for Healthcare Research  
24                             and Quality, the Centers for Disease Con-  
25                             trol and Prevention, the Centers for Medi-

1                   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

13                   (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.

20                 (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

1       data, disaggregated by race, ethnicity, gender, facil-  
2       ity, and location, relating to patient safety event  
3       measures. Upon request of the Director of the Pa-  
4       tient Safety Event Monitoring Division, the head of  
5       the respective office or agency shall furnish that  
6       data to the Director. The Director shall maintain  
7       and use such data consistent with applicable privacy  
8       and confidentiality law.

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

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

19                             (A) enter into agreements with public and  
20                             private entities, including at the State and local  
21                             levels, to opt into allowing the Division to ac-  
22                             cess the entity's longitudinal, real-time, de-iden-  
23                             tified patient data, disaggregated by race, eth-  
24                             nicity, gender, facility, and location, relating to  
25                             patient safety event measures;

1                         (B) maintain a data access portal to enable  
2                         such entities to submit such data to the Divi-  
3                         sion; and

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

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

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

11                         (B) prompt the Study Division when any  
12                         of the following types of findings are identified  
13                         in a geographic area or health care organiza-  
14                         tion:

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

17                         (ii) Abnormal patterns of patient safe-  
18                         ty events.

19                         (iii) Unexpectedly low numbers of pa-  
20                         tient safety events.

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

23                         (v) Unaddressed reoccurring patient  
24                         safety events.

25                         (h) STUDY DIVISION.—

1                             (1) IN GENERAL.—The Director of the Study  
2                             Division may conduct or support studies with re-  
3                             spect to patient safety events, including to under-  
4                             stand the—

5                                 (A) circumstances, context, and conditions  
6                             that enable patient safety events; and  
7                                 (B) causes or probable causes of the high  
8                             or low number of patient safety events.

9                             (2) DATA SHARING.—

10                                 (A) REQUEST.—In conducting or sup-  
11                             porting a study under paragraph (1), the Direc-  
12                             tor of the Study Division may request from the  
13                             Director of the Patient Safety Event Moni-  
14                             toring Division such information as may be col-  
15                             lected by the Patient Safety Event Monitoring  
16                             Division and relevant to the study.

17                                 (B) SHARING.—Upon receipt of such a re-  
18                             quest, the Director of the Patient Safety Event  
19                             Monitoring Division shall share such informa-  
20                             tion with the Director of the Study Division.

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

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

1                                     (i) appoint an individual to serve as  
2                                     the person in charge of the study (in this  
3                                     paragraph referred to as the “Study  
4                                     Lead”); and

5                                     (ii) vest such person with authority to  
6                                     determine the appropriate type of study,  
7                                     assemble a study team of experts, identify  
8                                     the study site or sites, and ask any health  
9                                     care organization that experienced the un-  
10                                    expectedly high or low numbers of patient  
11                                     safety events for permission to conduct the  
12                                     study based on prompts from the Patient  
13                                     Safety Event Monitoring Division.

14                                     (B) STUDY TEAM.—The Study Lead  
15                                     shall—

16                                     (i) assemble a team of multidisci-  
17                                     plinary experts to improve the under-  
18                                     standing of high or low numbers of patient  
19                                     safety events in the context of the study,  
20                                     including by gathering qualitative and  
21                                     quantitative information to understand—

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

- 1                             (II) the causes or probable  
2                             causes of the high or low number pa-  
3                             tient safety events;
- 4                             (ii) include in such team individuals  
5                             with the ability to study and understand  
6                             the interaction of human abilities, expecta-  
7                             tions, and limitations with work environ-  
8                             ments, technologies, and system design and  
9                             other appropriate experts from the public  
10                            and private sectors;
- 11                            (iii) prohibit such team from releasing  
12                            information obtained during the study  
13                            prior to the public release of such informa-  
14                            tion by the National Patient Safety Board;  
15                            and
- 16                            (iv) ensure that such team receives  
17                            permission from each health care organiza-  
18                            tion involved to—
- 19                             (I) enter health care facilities  
20                             participating in the study; and
- 21                             (II) communicate with staff,  
22                             health care providers, patients, ven-  
23                             dors, suppliers, contractors, equip-  
24                             ment manufacturers, and members of  
25                             the Board.

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

3                             (i) create guidelines and criteria to de-  
4                             termine the appropriate type of study to be  
5                             conducted or supported, including whether  
6                             the study should be virtual, in-person, or a  
7                             special board of inquiry; and

8                             (ii) in creating such guidelines and  
9                             criteria, take into account the impact of  
10                             the patient safety events to be studied,  
11                             whether such patient safety events may in-  
12                             dicate a systemic risk, and what may po-  
13                             tentially be learned from the study.

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

19                             (i) to provide independent rec-  
20                             ommendations on a coordinated national  
21                             preparedness and response plan;

22                             (ii) to independently monitor the im-  
23                             plementation of the preparedness and re-  
24                             sponse plan; and

1                   (iii) to recommend technologies to  
 2                  support logistics and autonomous real-time  
 3                  research to inform evidence-based treat-  
 4                  ment options and decisions.

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

7                   (A) provide for the submission to the  
 8                  Board and the Patient Safety Solutions Divi-  
 9                  sion of—

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

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

15                  (B) include in a final report under sub-  
 16                 paragraph (A)(ii) factual information and anal-  
 17                 ysis regarding the probable causes of the high  
 18                 or low numbers of patient safety events being  
 19                 studied and the recommendations of the Patient  
 20                 Safety Solutions Division; and

21                  (C) make such final report publicly avail-  
 22                 able.

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

- 1                             (A) adopt the report;  
2                             (B) work with the Study Division to make  
3                             changes to the report prior to adoption; or  
4                             (C) require the Study Division to conduct  
5                             or support further studies or revisions.

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

- 9                             (A) the study is completed; and  
10                            (B) the final report is made publicly avail-  
11                             able pursuant to paragraph (4)(C).

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

17                             (i) PATIENT SAFETY SOLUTIONS DIVISION.—

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

- 22                             (A) analyze such report; and  
23                             (B) formulate recommendations (including  
24                             solutions) to prevent the patient safety events  
25                             that were studied from occurring.

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

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

9                         (B) include such solutions in the re-  
10 commendations.

11                         (3) RESPONSE BY SECRETARY.—Not later than  
12 90 days after the submission of the final report  
13 under subsection (h)(4)(A)(ii), the Secretary of  
14 Health and Human Services and the Secretary of  
15 Veterans Affairs shall publish a response to the re-  
16 commendations.

17                         (j) ADMINISTRATIVE DIVISION.—

18                         (1) IN GENERAL.—The Director of the Admin-  
19 istrative Division shall support the day-to-day activi-  
20 ties of the Board, including with respect to commu-  
21 nications, facility coordination, shipping and receiv-  
22 ing, supply inventory, labor relations, and human re-  
23 source management.

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

4                         (A) advise on, analyze, and publish proper  
5       safety guidelines to ensure safe working condi-  
6       tions at the Federal, State, and local levels;

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

11                         (C) provide training to enhance employee  
12      safety competence.

13                         (k) PROHIBITION AGAINST ADMISSIBILITY AS EVI-  
14      DENCE.—Any report or other publication of the Board (in-  
15      cluding any division, subdivision, or other component  
16      thereof) shall not be admissible as evidence, or used for  
17      any purpose, in any Federal or State action, suit, or other  
18      judicial, legislative, or administrative proceeding.

19                         (l) PROTECTIONS FOR EMPLOYEES.—

20                         (1) PROHIBITION.—No employer shall dis-  
21      charge or in any manner discriminate against any  
22      employee with respect to compensation, terms, con-  
23      ditions, or other privileges of employment because  
24      the employee (or an individual acting at the request  
25      of the employee)—

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

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

7                             (2) COMPLAINT PROCEDURE.—

8                             (A) IN GENERAL.—An employee who be-  
9                             lieves that he or she has been discharged or  
10                            otherwise discriminated against by any em-  
11                            ployer in violation of this subsection may seek  
12                            relief in accordance with the procedures, notifi-  
13                            cations, burdens of proof, remedies, and stat-  
14                            utes of limitation set forth in section 2087(b) of  
15                            title 15, United States Code.

16                             (B) NO LIMITATION ON RIGHTS.—Nothing  
17                             in this subsection shall be deemed to diminish  
18                             the rights, privileges, or remedies of any em-  
19                             ployee under any Federal or State law or under  
20                             any collective bargaining agreement. The rights  
21                             and remedies in this subsection may not be  
22                             waived by any agreement, policy, form, or con-  
23                             dition of employment.

24                             (3) DEFINITION.—In this subsection, the term  
25                             “employer” has the meaning given to such term in

1 section 3 of the Fair Labor Standards Act of 1938  
2 (29 U.S.C. 203).

3 (m) DEFINITIONS.—In this section:

4 (1) The term “health care setting” means a  
5 hospital, nursing facility, comprehensive outpatient  
6 rehabilitation facility, home health agency, hospice  
7 program, renal dialysis facility, ambulatory surgical  
8 center, pharmacy, physician or other health care  
9 practitioner’s office, long-term care facility, mental  
10 health treatment facility, substance use disorder  
11 treatment facility, clinical laboratory, or health cen-  
12 ter.

13 (2) The term “patient safety event” means an  
14 action or inaction that—

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

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

20 (C) could have caused injury or harm to  
21 the patient but did not cause injury or harm in  
22 a health care setting as a result of chance, pre-  
23 vention, or mitigation.

1       (n) AUTHORIZATION OF APPROPRIATIONS.—To carry  
2 out this section, there is authorized to be appropriated  
3 \$110,000,000 for each of fiscal years 2023 and 2024.

