

116TH CONGRESS  
2D SESSION

# H. R. 9037

To amend the Public Health Service Act to ensure transparency within the health care system through the establishment of a National Healthcare Acquired Infection and Medical Error Reporting Program.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 20, 2020

Ms. GABBARD introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to ensure transparency within the health care system through the establishment of a National Healthcare Acquired Infection and Medical Error Reporting Program.

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 Healthcare  
5       Acquired Infection and Medical Error Transparency Act”.

6       **SEC. 2. FINDINGS.**

7               (1) The Centers for Disease Control and Pre-  
8       vention reported that each day one in thirty-one hos-

1       pital patients has at least one healthcare-associated  
2       infection;

3               (2) 32 percent of all healthcare-acquired infec-  
4       tions are urinary tract;

5               (3) 22 percent of all infections are surgical site  
6       infections;

7               (4) 15 percent are pneumonia (lung infections);

8               (5) 14 percent are bloodstream infections.

9               (6) Patients who acquire infections from sur-  
10      gery spend on average an additional 6.5 days hos-  
11      pitalized;

12              (7) are five times more likely to be readmitted  
13      after discharge;

14              (8) and are twice as likely to die.

15              (9) As recent as 2016, Johns Hopkins Univer-  
16      sity patient safety experts calculated that medical  
17      error is responsible for at least 250,000 deaths per  
18      year (the third leading cause of death in the U.S.).

19   **SEC. 3. ESTABLISHMENT OF OFFICE OF PATIENT SAFETY**  
20                                   **AND HEALTH CARE QUALITY.**

21              Title IX of the Public Health Service Act (42 U.S.C.  
22   299 et seq.) is amended—

23              (1) by redesignating part E as part F;

24              (2) in part F, as redesignated—

1 (A) by redesignating sections 941 through  
2 948 as sections 951 through 958, respectively;  
3 and

4 (B) in section 958(1), as redesignated, by  
5 striking “941” and inserting “951”; and

6 (3) by inserting after part D the following:

7 **“PART E—NATIONAL HEALTHCARE ACQUIRED IN-**  
8 **FECTION AND MEDICAL ERROR REPORTING**  
9 **PROGRAM**

10 **“SEC. 941. DEFINITIONS.**

11 “In this part:

12 “(1) ANTI-RETALIATION.—The term ‘anti-retal-

13 iation’ any patient or legal representative of a pa-

14 tient who engages in Protected Activity will be

15 shielded from retaliation.

16 “(2) DATABASE.—The term ‘Database’ means

17 the National Patient Safety Database established

18 under section 944.

19 “(3) HEALTH CARE PROVIDER.—The term

20 ‘health care provider’ means a person or entity li-

21 censed or otherwise authorized under State law to

22 provide health care services, including—

23 “(A) a hospital, health plan, community

24 clinic, nursing facility, comprehensive rehabili-

25 tation facility, home health agency, hospice pro-

1           gram, renal dialysis facility, ambulatory sur-  
2           gical center, pharmacy, doctor’s or health care  
3           practitioner’s office, long-term care facility, be-  
4           havior health residential treatment facility, clin-  
5           ical laboratory, or health center;

6           “(B) a doctor, nurse, physician assistant,  
7           nurse practitioner, clinical nurse specialist, cer-  
8           tified nurse anesthetist, certified nurse midwife,  
9           psychologist, certified social worker, registered  
10          dietitian or nutrition professional, physical or  
11          occupational therapists, pharmacist, or other in-  
12          dividual healthcare practitioner; and

13          “(C) any other health care professional  
14          specified in regulations promulgated by the Sec-  
15          retary.

16          “(4) HEALTHCARE ACQUIRED INFECTION.—  
17          The term ‘Healthcare Acquired Infection(s) (HAI)’  
18          means an infection that is contracted while in a  
19          healthcare facility, such as an acute care hospital,  
20          skilled nursing care facility, or doctor’s office or clin-  
21          ic.

22          “(6) MEDICAL ERROR.—The term ‘medical  
23          error’ means an unexpected occurrence involving  
24          death or serious physical or psychological injury, or  
25          the risk of such injury, including any process vari-

1       ation of which recurrence may carry significant  
2       chance of a serious adverse outcome.

3               “(7) OFFICE.—The term ‘Office’ means the Of-  
4       fice of Patient Safety and Health Care Quality es-  
5       tablished under section 943, which shall be a cer-  
6       tified patient safety organization as defined under  
7       part C.

8               “(8) OUTCOMES.—The term ‘outcomes’ means  
9       any result of healthcare acquired infection and/or  
10       medical error on affected patients.

11              “(9) PATIENT SAFETY DATA.—The term ‘pa-  
12       tient safety data’ means information requested by  
13       the Director of the Office to be submitted by the pa-  
14       tient safety officer of a Program participant as de-  
15       scribed in section 945(e).

16              “(6) PATIENT SAFETY EVENT.—The term ‘pa-  
17       tient safety event’ means an occurrence, incident, or  
18       process that either contributes to, or has the poten-  
19       tial to contribute to, a patient injury or degrades the  
20       ability of health care providers to provide the appro-  
21       priate standard of care.

22              “(7) PATIENT SAFETY OFFICER.—The term  
23       ‘patient safety officer’ means the individual des-  
24       ignated by a Program participant as being respon-

1       sible for ensuring that the conditions for participa-  
2       tion in the Program are met.

3               “(8) PATIENT SAFETY ORGANIZATION.—The  
4       term ‘patient safety organization’ has the meaning  
5       given such term in section 921.

6               “(9) PATIENT SAFETY WORK PRODUCT.—The  
7       term ‘patient safety work product’ has the meaning  
8       given such term in section 921.

9               “(10) PROGRAM.—The term ‘Program’ means  
10      the National Healthcare Acquired Infections and  
11      Medical Error Reporting Program established under  
12      section 945.

13              “(11) PROGRAM PARTICIPANT.—The term ‘pro-  
14      gram participant’ means any healthcare provider  
15      who reports healthcare acquired infections and/or  
16      medical errors to the National Healthcare Acquired  
17      Infections and Medical Error Reporting Program.

18              “(12) ROOT CAUSE ANALYSIS.—The term ‘root  
19      cause analysis’ means an examination or investiga-  
20      tion of an occurrence, event, or incident to determine  
21      if a preventable medical error took place or the  
22      standard of care was not followed and to identify the  
23      causal factors that led to such occurrence, event, or  
24      incident.

1           “(14) WHISTLEBLOWER.—The term ‘whistle-  
2           blower’ means any individual or legal representative  
3           of an individual, who provides original information  
4           relating to a Healthcare Acquired Infection or Med-  
5           ical Error outcome.

6   **“SEC. 942. PURPOSE AND GOALS.**

7           “‘It is the purpose of this legislation to promote a cul-  
8           ture of safety and trust within hospitals, health systems,  
9           clinics, and other sites of health care, through the estab-  
10          lishment of a National Healthcare Acquired Infection and  
11          Medical Error Reporting Program. It shall be a goal of  
12          the Program to—

13               “(1) establish standardized procedures for  
14               States to provide reports detailing healthcare ac-  
15               quired infection and medical error disclosure and re-  
16               porting;

17               “(2) require all State departments of health to  
18               use the data provided by hospitals for error report-  
19               ing to analyze trends and identify best practices;

20               “(3) reduce rates of preventable medical errors;  
21               and

22               “(4) ensure patients have access to information  
23               for medical injury or illness due to medical error,  
24               negligence, or malpractice.

1 **“SEC. 943. OFFICE OF PATIENT SAFETY AND HEALTH CARE**  
2 **QUALITY.**

3 “(a) IN GENERAL.—The Secretary shall establish  
4 within the Office of the Secretary, an Office of Patient  
5 Safety and Health Care Quality to collaborate with the  
6 Director of the Agency for Health Care Research and  
7 Quality to improve patient safety and reduce medical error  
8 across the health care system. The Office shall be headed  
9 by a Director to be appointed by the Secretary.

10 “(b) ACTIVITIES.—The activities of the Office shall  
11 be deemed patient safety activities, as defined in section  
12 921.

13 “(c) DUTIES.—The Director of the Office shall—

14 “(1) establish and administer the Program;

15 “(2) determine who is eligible for participation  
16 in the Program in accordance with section 945;

17 “(3) contract with an independent entity for the  
18 purpose of evaluating the Program at least once  
19 every two years, with the results of such evaluations  
20 being disseminated to Program participants, Con-  
21 gress, and the public;

22 “(4) establish and maintain, in consultation  
23 with patient safety organizations, health care quality  
24 organizations, health care providers, and the health  
25 information technology industry, a National Patient  
26 Safety Database as provided for in section 944 to



1 receive nonidentifiable patient safety work product  
2 as described in the reporting requirements for Pro-  
3 gram participants under section 945(c)(10);

4 “(5) determine and adopt a standardized pa-  
5 tient safety taxonomy, necessary elements, common  
6 and consistent definitions, and standardized formats  
7 for the electronic reporting of patient safety data to  
8 the Database as described in section 944(e);

9 “(6) survey Federal, State, and local require-  
10 ments for the reporting of patient safety data and  
11 work to streamline and reduce duplication of such  
12 requirements;

13 “(7) grant patient safety organizations, re-  
14 searchers, and other qualified individuals and insti-  
15 tutions access to the Database as determined appro-  
16 priate through the evaluation of completed applica-  
17 tions submitted to the Office for such purpose;

18 “(8) analyze, directly or through a contract  
19 with a patient safety organization, all data entered  
20 into the Database and provide Program participants,  
21 Congress, and the public with healthcare acquired  
22 infection and medical error trend reports and other  
23 analyses as determined appropriate by the Director  
24 on a quarterly basis;

1           “(9) develop, directly or through a contract  
2           with a patient safety organization, safety and train-  
3           ing recommendations for health care providers that  
4           focus on the reduction of medical errors, improved  
5           patient safety, and increased quality of care on at  
6           least a yearly basis;

7           “(10) maintain a publicly accessible internet  
8           website to provide patients and health care providers  
9           with information concerning the Program and the  
10          Database; and

11          “(11) perform any other duties for the adminis-  
12          tration of the Program as determined necessary by  
13          the Secretary.

14          “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
15          are authorized to be appropriated such sums as may be  
16          necessary for each fiscal year to carry out the activities  
17          of the Office.

18          **“SEC. 944. NATIONAL PATIENT SAFETY DATABASE.**

19          “(a) IN GENERAL.—The Director of the Office shall,  
20          in accordance with section 943(c)(6), establish a National  
21          Patient Safety Database that shall—

22                 “(1) adopt standardized patient safety tax-  
23                 onomy in consultation with the Joint Commission on  
24                 Accreditation of the Healthcare Organizations and  
25                 other entities with relevant expertise;

1           “(2) include necessary elements, common and  
2           consistent definitions, and a standardized electronic  
3           interface for the entry and processing of the data by  
4           Program participants, as developed by the Director  
5           in consultation with patient safety organizations,  
6           health care providers, and the health information  
7           technology industry;

8           “(3) allow for the comprehensive collection and  
9           analysis of the patient safety data required to be  
10          submitted by all Program participants under section  
11          945; and

12          “(4) include patient safety data required to be  
13          submitted by Program participants under section  
14          945 as nonidentifiable patient safety work product  
15          and privileged and confidential in accordance with  
16          section 922.

17          “(b) LIMITATION.—Information submitted to the  
18          Database shall be confidential and protected from dislo-  
19          sure in accordance with the regulations promulgated  
20          under section 264(e) of the Health Insurance Portability  
21          and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

22          “(c) ACCESS.—Access to the patient safety data con-  
23          tained within the Database shall only be provided through  
24          application to and approval by the Director.

1 **“SEC. 945. NATIONAL HEALTHCARE ACQUIRED INFECTION**  
2 **AND MEDICAL ERROR REPORTING PROGRAM.**

3 “(a) ESTABLISHMENT.—The Secretary, acting  
4 through the Director of the Office, shall establish a Na-  
5 tional Healthcare Acquired Infection and Medical Error  
6 Reporting Program to provide for the confidential disclo-  
7 sure of medical errors and patient safety events in order  
8 to improve patient safety and health care quality, reduce  
9 preventable medical errors, ensure patient access to data  
10 and reports for medical injury due to medical error, neg-  
11 ligence, or malpractice.

12 “(b) ELIGIBLE PARTICIPANTS.—To be eligible to  
13 participate in the Program an entity shall—

14 “(1)(A) be a healthcare provider; or

15 “(B) be any other entity determined to be eligi-  
16 ble by the Director;

17 “(2) designate a patient safety officer to ensure  
18 that the conditions of participation described in sub-  
19 section (c) are met;

20 “(3) submit a completed application to the Of-  
21 fice at such time, in such manner, and containing  
22 such information as the Director may require; and

23 “(4) agree to comply with the conditions of par-  
24 ticipation under subsection (c).

25 “(c) CONDITIONS OF PARTICIPATION.—A Program  
26 participant shall, directly or indirectly—

1           “(1) submit a comprehensive plan, as part of  
2           the application for participation in the Program, to  
3           reduce the incidence of medical errors and improve  
4           patient safety in the case of a Program participant  
5           that is a health care provider, activities that result  
6           in the reduction of medical errors or that otherwise  
7           improve patient safety;

8           “(2) require health care providers included in  
9           the Program by the Program participant and as out-  
10          lined in the Program participant application, to sub-  
11          mit to the patient safety officer a report of any inci-  
12          dent or occurrence involving a patient that is  
13          thought to either be a medical error or patient safe-  
14          ty event;

15          “(3) ensure that the reports filed under para-  
16          graph (2) are submitted to the Database in a stand-  
17          ardized format as designated by the Director;

18          “(4) where appropriate, ensure that a root  
19          cause analysis of any report submitted to the patient  
20          safety officer under paragraph (2) is performed  
21          within 90 days of the filing of a report under such  
22          paragraph;

23          “(5) ensure that if a patient was harmed or in-  
24          jured as the result of a healthcare acquired infection  
25          or medical error, or as a result of the relevant stand-

1       ard of care not being followed, an account of the in-  
2       cident or occurrence, as described in paragraph (2)  
3       shall be disclosed to the patient not later than 5  
4       business days after the completion of root cause  
5       analysis;

6               “(6) disclose information contained in any re-  
7       port submitted to the patient safety officer under  
8       paragraph (2) upon the request of the patient with  
9       respect to whom the report has been filed;

10              “(7) offer, at the time of disclosure of an inci-  
11       dent or occurrence in which it was determined that  
12       a patient was harmed or injured as a result of med-  
13       ical error or as a result of the relevant standard of  
14       care not being followed, to share, where practicable,  
15       any efforts the health care provider will undertake to  
16       prevent reoccurrence; and

17              “(8) prepare and submit entries to the Data-  
18       base as required by the Director of the Office and  
19       in accordance with subsection (d).

20       “(d) SUBMISSION OF PATIENT SAFETY DATA.—

21              “(1) IN GENERAL.—All entries into the Data-  
22       base shall—

23                      “(A) contain only non-identifiable patient  
24       safety work product;

1           “(B) be in a standardized electronic format  
2           to be determined by the Director; and

3           “(C) if related to a single occurrence or in-  
4           cident, be given a common identifier to link en-  
5           tries of related data.

6           “(2) REPORTING REQUIREMENTS.—The patient  
7           safety officer of a Program participant shall be re-  
8           quired to prepare and enter into the Database—

9           “(A) reports, containing only nonidentifi-  
10          able patient safety work product, filed by a  
11          health care provider under subsection (c)(4)  
12          and a summary of the findings of the root  
13          cause analysis with respect to such report with-  
14          in 5 business days of the completion of the root  
15          cause analysis;

16          “(B) any disciplinary actions taken against  
17          a health care provider as a result of involve-  
18          ment in any incident or occurrence involving a  
19          patient that is thought to be a medical error or  
20          patient safety event, or legal action for which a  
21          report under subsection (c)(4) was filed; or

22          “(C) other data as determined appropriate  
23          by the Director.

1           “(3) PRIVILEGE AND CONFIDENTIALITY.—The  
2           provisions of section 922 shall apply to patient safe-  
3           ty data submitted under this subsection.

4   **“SEC. 946. THE NATIONAL HEALTHCARE ACQUIRED INFEC-**  
5                   **TION AND MEDICAL ERROR REPORTING AC-**  
6                   **COUNTABILITY STUDY.**

7           “(a) IN GENERAL.—The Director of the Office shall  
8           conduct, directly or through a contract with patient safety  
9           organizations or qualified individuals or institutions, an  
10          analysis of the patient safety data in the Database and  
11          other available data to determine performance and sys-  
12          tems standards, tools, and best practices (including peer  
13          review) for doctors and other health care providers nec-  
14          essary to prevent medical errors, improve patient safety,  
15          and increase accountability within the health care system.  
16          Such analysis shall also consider the value of increasing  
17          the transparency of the patient safety data to include the  
18          identity of health care providers and provide recommenda-  
19          tions for improvements to the peer review process.

20          “(b) REPORT AND RECOMMENDATIONS.—Not later  
21          than 2 years after the date of enactment of this section,  
22          the Director of the Office shall submit to Congress and  
23          make available to States, State medical boards, and the  
24          public a report that describes the results of the study car-



1 ried out under subsection (a) and contains recommenda-  
2 tions for Congress based on the findings of the report.”.

○