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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.

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.

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 Healthcare Acquired Infection and Medical Error Transparency Act''.

SEC. 2. FINDINGS.

(1) The Centers for Disease Control and Prevention reported that each day one in thirty-one hos-

pital patients has at least one healthcare-associated infection;

(2) 32 percent of all healthcare-acquired infections are urinary tract;

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

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

(5) 14 percent are bloodstream infections.

(6) Patients who acquire infections from surgery spend on average an additional 6.5 days hospitalized;

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

(8) and are twice as likely to die.

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

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

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

(1) by redesignating part E as part F;

(2) in part F, as redesignated—

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

(B) in section 958(1), as redesignated, by striking ''941'' and inserting ''951''; and

(3) by inserting after part D the following:

"PART E—NATIONAL HEALTHCARE ACQUIRED INFECTION AND MEDICAL ERROR REPORTING PROGRAM

"SEC. 941. DEFINITIONS.

''In this part:

''(1) ANTI-RETALIATION.—The term 'anti-retaliation' any patient or legal representative of a patient who engages in Protected Activity will be shielded from retaliation.

''(2) DATABASE.—The term 'Database' means the National Patient Safety Database established under section 944.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' means a person or entity licensed or otherwise authorized under State law to provide health care services, including—

''(A) a hospital, health plan, community clinic, nursing facility, comprehensive rehabilitation facility, home health agency, hospice pro-

gram, renal dialysis facility, ambulatory surgical center, pharmacy, doctor's or health care practitioner's office, long-term care facility, behavior health residential treatment facility, clinical laboratory, or health center;

"(B) a doctor, nurse, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapists, pharmacist, or other individual healthcare practitioner; and

"(C) any other health care professional specified in regulations promulgated by the Secretary.

"(4) HEALTHCARE ACQUIRED INFECTION.—The term 'Healthcare Acquired Infection(s) (HAI)' means an infection that is contracted while in a healthcare facility, such as an acute care hospital, skilled nursing care facility, or doctor's office or clinic.

"(6) MEDICAL ERROR.—The term 'medical error' means an unexpected occurrence involving death or serious physical or psychological injury, or the risk of such injury, including any process vari-

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

"(7) OFFICE.—The term 'Office' means the Office of Patient Safety and Health Care Quality established under section 943, which shall be a certified patient safety organization as defined under part C.

"(8) OUTCOMES.—The term 'outcomes' means any result of healthcare acquired infection and/or medical error on affected patients.

"(9) PATIENT SAFETY DATA.—The term 'patient safety data' means information requested by the Director of the Office to be submitted by the patient safety officer of a Program participant as described in section 945(e).

"(6) PATIENT SAFETY EVENT.—The term 'patient safety event' means an occurrence, incident, or process that either contributes to, or has the potential to contribute to, a patient injury or degrades the ability of health care providers to provide the appropriate standard of care.

"(7) PATIENT SAFETY OFFICER.—The term 'patient safety officer' means the individual designated by a Program participant as being respon-

sible for ensuring that the conditions for participation in the Program are met.

"(8) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' has the meaning given such term in section 921.

"(9) PATIENT SAFETY WORK PRODUCT.—The term 'patient safety work product' has the meaning given such term in section 921.

"(10) PROGRAM.—The term 'Program' means the National Healthcare Acquired Infections and Medical Error Reporting Program established under section 945.

"(11) PROGRAM PARTICIPANT.—The term 'program participant' means any healthcare provider who reports healthcare acquired infections and/or medical errors to the National Healthcare Acquired Infections and Medical Error Reporting Program.

"(12) ROOT CAUSE ANALYSIS.—The term 'root cause analysis' means an examination or investigation of an occurrence, event, or incident to determine if a preventable medical error took place or the standard of care was not followed and to identify the causal factors that led to such occurrence, event, or incident.

"(14) WHISTLEBLOWER.—The term 'whistleblower' means any individual or legal representative of an individual, who provides original information relating to a Healthcare Acquired Infection or Medical Error outcome.

"SEC. 942. PURPOSE AND GOALS.

"It is the purpose of this legislation to promote a culture of safety and trust within hospitals, health systems, clinics, and other sites of health care, through the establishment of a National Healthcare Acquired Infection and Medical Error Reporting Program. It shall be a goal of the Program to—

"(1) establish standardized procedures for States to provide reports detailing healthcare acquired infection and medical error disclosure and reporting;

"(2) require all State departments of health to use the data provided by hospitals for error reporting to analyze trends and identify best practices;

"(3) reduce rates of preventable medical errors; and

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

"SEC. 943. OFFICE OF PATIENT SAFETY AND HEALTH CARE QUALITY.

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

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

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

"(1) establish and administer the Program;

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

"(3) contract with an independent entity for the purpose of evaluating the Program at least once every two years, with the results of such evaluations being disseminated to Program participants, Congress, and the public;

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

receive nonidentifiable patient safety work product as described in the reporting requirements for Program participants under section 945(c)(10);

''(5) determine and adopt a standardized patient safety taxonomy, necessary elements, common and consistent definitions, and standardized formats for the electronic reporting of patient safety data to the Database as described in section 944(e);

''(6) survey Federal, State, and local requirements for the reporting of patient safety data and work to streamline and reduce duplication of such requirements;

''(7) grant patient safety organizations, researchers, and other qualified individuals and institutions access to the Database as determined appropriate through the evaluation of completed applications submitted to the Office for such purpose;

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

"(9) develop, directly or through a contract with a patient safety organization, safety and training recommendations for health care providers that focus on the reduction of medical errors, improved patient safety, and increased quality of care on at least a yearly basis;

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

"(11) perform any other duties for the administration of the Program as determined necessary by the Secretary.

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

"SEC. 944. NATIONAL PATIENT SAFETY DATABASE.

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

"(1) adopt standardized patient safety taxonomy in consultation with the Joint Commission on Accreditation of the Healthcare Organizations and other entities with relevant expertise;

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

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

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

"(b) LIMITATION.—Information submitted to the Database shall be confidential and protected from disclosure in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(c) ACCESS.—Access to the patient safety data contained within the Database shall only be provided through application to and approval by the Director.

"SEC. 945. NATIONAL HEALTHCARE ACQUIRED INFECTION AND MEDICAL ERROR REPORTING PROGRAM.

"(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Office, shall establish a National Healthcare Acquired Infection and Medical Error Reporting Program to provide for the confidential disclosure of medical errors and patient safety events in order to improve patient safety and health care quality, reduce preventable medical errors, ensure patient access to data and reports for medical injury due to medical error, negligence, or malpractice.

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

"(1)(A) be a healthcare provider; or

"(B) be any other entity determined to be eligible by the Director;

"(2) designate a patient safety officer to ensure that the conditions of participation described in subsection (c) are met;

"(3) submit a completed application to the Office at such time, in such manner, and containing such information as the Director may require; and

"(4) agree to comply with the conditions of participation under subsection (c).

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

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

"(2) require health care providers included in the Program by the Program participant and as outlined in the Program participant application, to submit to the patient safety officer a report of any incident or occurrence involving a patient that is thought to either be a medical error or patient safety event;

"(3) ensure that the reports filed under paragraph (2) are submitted to the Database in a standardized format as designated by the Director;

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

"(5) ensure that if a patient was harmed or injured as the result of a healthcare acquired infection or medical error, or as a result of the relevant stand-

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

"(6) disclose information contained in any report submitted to the patient safety officer under paragraph (2) upon the request of the patient with respect to whom the report has been filed;

"(7) offer, at the time of disclosure of an incident or occurrence in which it was determined that a patient was harmed or injured as a result of medical error or as a result of the relevant standard of care not being followed, to share, where practicable, any efforts the health care provider will undertake to prevent reoccurrence; and

"(8) prepare and submit entries to the Database as required by the Director of the Office and in accordance with subsection (d).

"(d) SUBMISSION OF PATIENT SAFETY DATA.—

"(1) IN GENERAL.—All entries into the Database shall—

"(A) contain only non-identifiable patient safety work product;

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

"(C) if related to a single occurrence or incident, be given a common identifier to link entries of related data.

"(2) REPORTING REQUIREMENTS.—The patient safety officer of a Program participant shall be required to prepare and enter into the Database—

"(A) reports, containing only nonidentifiable patient safety work product, filed by a health care provider under subsection (c)(4) and a summary of the findings of the root cause analysis with respect to such report within 5 business days of the completion of the root cause analysis;

"(B) any disciplinary actions taken against a health care provider as a result of involvement in any incident or occurrence involving a patient that is thought to be a medical error or patient safety event, or legal action for which a report under subsection (c)(4) was filed; or

"(C) other data as determined appropriate by the Director.

"(3) PRIVILEGE AND CONFIDENTIALITY.—The provisions of section 922 shall apply to patient safety data submitted under this subsection.

"SEC. 946. THE NATIONAL HEALTHCARE ACQUIRED INFECTION AND MEDICAL ERROR REPORTING ACCOUNTABILITY STUDY.

"(a) IN GENERAL.—The Director of the Office shall conduct, directly or through a contract with patient safety organizations or qualified individuals or institutions, an analysis of the patient safety data in the Database and other available data to determine performance and systems standards, tools, and best practices (including peer review) for doctors and other health care providers necessary to prevent medical errors, improve patient safety, and increase accountability within the health care system. Such analysis shall also consider the value of increasing the transparency of the patient safety data to include the identity of health care providers and provide recommendations for improvements to the peer review process.

"(b) REPORT AND RECOMMENDATIONS.—Not later than 2 years after the date of enactment of this section, the Director of the Office shall submit to Congress and make available to States, State medical boards, and the 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.''.

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