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117TH CONGRESS
2D SESSION

H. R. 6875

To update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 2022

Mr. SWALWELL (for himself and Mr. EMMER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

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 ''Right Drug Dose Now Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. National Action Plan for Adverse Drug Event Prevention.
Sec. 4. Adverse drug event and pharmacogenomic testing awareness.
Sec. 5. Improving EHR systems to improve the use of pharmacogenomic information.
Sec. 6. Increased authorization for pharmacogenomics implementation research.
Sec. 7. Definition.

SEC. 3. NATIONAL ACTION PLAN FOR ADVERSE DRUG EVENT PREVENTION.

The Secretary of Health and Human Services shall—

(1) not later than 180 days after the date of enactment of this Act, in coordination with the heads of other relevant Federal departments and agencies including the Director of the National Human Genome Research Institute, and in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Director of the National Center for Biotechnology Information, and the Director of the National Library of Medicine, submit a report to the Congress on—

(A) the implementation of the National Action Plan for Adverse Drug Event Prevention of the Department of Health and Human Services; and

(B) the progress in meeting the target approved by the Federal Interagency Steering

Committee for Adverse Drug Events for a 10-percent reduction for—

(i) the rate of adverse drug events from anticoagulants among United States inpatient stays;

(ii) the rate of adverse drug events from hypoglycemic agents among United States inpatient stays;

(iii) the rate of adverse drug events from opioid analgesics among United States inpatient stays;

(iv) the rate of visits to United States hospital emergency departments for adverse drug events associated with injury from oral anticoagulants;

(v) the rate of visits to United States hospital emergency departments for adverse drug events associated with injury from insulin; and

(vi) the rate of visits to United States hospital emergency departments for adverse drug events associated with therapeutic use of opioid analgesics;

(2) convene the Federal Interagency Steering Committee for Adverse Drug Events to update the

National Action Plan for Adverse Drug Event Prevention; and

(3) require such Committee, in updating the National Action Plan for Adverse Drug Event Prevention—

(A) to consider advances in scientific understanding and technology pertaining to drug-gene-drug interactions, clinical outcomes, health care utilization, and the decreasing cost of genetic testing;

(B) to assess the role of pharmacogenetics testing combined with clinical decision support as an evidence-based prevention tool; and

(C) to evaluate operating characteristics for Federal adverse drug event surveillance systems and expand capabilities to identify genetic associations in adverse events.

SEC. 4. ADVERSE DRUG EVENT AND PHARMACOGENOMIC TESTING AWARENESS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–7. ADVERSE DRUG EVENT AND PHARMACOGENOMIC TESTING AWARENESS.

''(a) PUBLIC EDUCATION CAMPAIGN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the National Human Genome Research Institute, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Director of the National Center for Biotechnology Information, and the Director of the National Library of Medicine, shall conduct a national evidence-based education campaign to increase the public's awareness regarding—

''(A) the prevalence of adverse drug events and adverse drug reactions;

''(B) specific risk factors that increase an individual's likelihood of experiencing an adverse drug event or adverse drug reaction;

''(C) basic information about pharmacogenomic testing and how its use, including incorporation in comprehensive medication management, may prevent adverse drug reactions in certain clinical situations;

''(D) the role of health care providers in performing pharmacogenomic testing, interpreting the results of such testing, and adjusting medications based on such results;

"(E) the availability of pharmacogenomic testing;

"(F) comprehensive medication management; and

"(G) how the benefits of an individual's pharmacogenomic test results might change or be relevant over time.

"(2) CONSIDERATION OF ADVICE OF STAKEHOLDER EXPERTS.—The education campaign under paragraph (1) shall take into consideration the advice of stakeholder expects, such as those specializing in medical genetics and pharmacogenetics and collaborative communities focused on pharmacogenomics.

"(3) MEDIA CAMPAIGN.—In conducting the education campaign under paragraph (1), the Secretary, after considering the advice of stakeholder experts pursuant to paragraph (2), may award grants or contracts to entities to establish national multimedia campaigns that may include advertising through television, radio, print media, billboards, posters, all forms of existing and especially emerging social networking media, other Internet media, and any other medium determined appropriate by the Secretary.

''(4) RURAL REGIONS, HEALTH PROFESSIONAL SHORTAGE AREAS, AND UNDERSERVED COMMUNITIES.—The Secretary shall ensure that the education campaign under paragraph (1)—

''(A) reaches rural and medically underserved communities (as defined in section 799); and

''(B) includes the involvement of community health centers, community pharmacies, and other local health clinics.

''(b) HEALTH CARE PROFESSIONAL EDUCATION CAMPAIGN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the National Human Genome Research Institute, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Director of the National Center for Biotechnology Information, the Director of the National Library of Medicine, and the Administrator of the Health Resources and Services Administration, shall establish a national health education program for health care providers and health care leaders, including administrators, pharmacists, nurse practitioners, physicians' assistants, physician medical geneticists,

laboratory medical geneticists, genetic counselors, medical educators, and the faculty of schools of medicine and other schools of health professions, on the following:

"(A) Pharmacogenomic testing and the extent of its ability to prevent adverse drug reactions.

"(B) Pharmacogenomic testing, drug interaction alerting systems, when to refer to or consult with a genetics provider, and the standards of care for patients who are suspected or known to have a genetic variant that is known to impact drug metabolism.

"(C) Evidence-based information that would encourage individuals and their health care professionals to consider pharmacogenomic testing as part of their health care plan to the extent appropriate.

"(D) The role of medical professionals who specialize in genetics and genomics.

"(E) How to incorporate pharmacogenomics into comprehensive medication management.

"(2) GRANTS.—

"(A) AWARD.—In carrying out the national health education program under this subsection, the Secretary, acting through the Director of the National Human Genome Research Institute, may award grants to nonprofit organizations to carry out educational activities with respect to the topics listed in subparagraphs (A) through (D) of paragraph (1).

"(B) USE OF FUNDS.—A grant under subparagraph (A) may be used to support one or more of the following activities:

"(i) Increasing the knowledge and awareness of health care providers and health care leaders about pharmacogenomic testing and drug interactions.

"(ii) Increasing the number of health professional schools that incorporate pharmacogenomic curricula in classroom instruction.

"(iii) Increasing the ability of health care providers to note and respond to the impact of gender, ethnicity, age, and other relevant characteristics on drug metabolism.

"(iv) Developing principles, practices, and curriculum instruction that prepare medical, nursing, pharmacy, and other health professions students to effectively apply knowledge and skills needed to recognize—

"(I) when a patient is eligible for pharmacogenomic testing, including as part of comprehensive medication management when appropriate, and in accordance with the patient's health care team, a drug product's label, and professional clinical guidelines; and

"(II) how to appropriately use the test results to adjust a prescription or otherwise change a patient's health care plan.

"(v) Providing opportunities for practicing health care professionals to receive pharmacogenomics training and education through a variety of modalities including in-person, electronic media, professional meetings and conferences, and social media.

''(c) REPORTING.—At least every three years, the Secretary, acting through the Director of the National Human Genome Research Institute, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Director of the National Center for Biotechnology Information, the Director of the National Library of Medicine, the Administrator of the Centers for Medicare & Medicaid Services, and relevant stakeholders with expertise in developing quality measures of label and peer-reviewed professional guidelines on drug-gene interactions, shall publish data on—

''(1) the public's awareness regarding adverse drug events and pharmacogenomic testing;

''(2) the number or percentage of individuals utilizing information to inform their health care decisions regarding prescription medications and pharmacogenomic testing;

''(3) the change in the number or percentage of individuals enrolled in a prescription drug plan under part D of the title XVIII of the Social Security Act receiving a pharmacogenetic test, as recommended in alignment with a drug product's label or peer-reviewed professional guidelines; and

''(4) the number or percentage of changes, beginning one year after the date of enactment of this section, in medication management as a result of incorporating information from pharmacogenomic testing.

''(d) DEFINITIONS.—In this section:

''(1) ADVERSE DRUG EVENT.—The term 'adverse drug event' means an injury resulting from any medical intervention with a drug.

''(2) ADVERSE DRUG REACTION.—The term 'adverse drug reaction' means a response to a drug that—

''(A) is noxious and unintended; and

''(B) occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $50,000,000 for each of fiscal years 2022 through 2027.''.

SEC. 5. IMPROVING EHR SYSTEMS TO IMPROVE THE USE OF PHARMACOGENOMIC INFORMATION.

(a) CERTIFICATION CRITERIA.—The Secretary of Health and Human Services (in this section referred to

as the ''Secretary'') shall adopt pursuant to subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) certification criteria for health information technology, including for electronic prescribing systems and real-time pharmacy benefit checks, such that before a medication order is completed and acted upon during computerized provider order entry, interventions must automatically indicate to a user—

(1) when pharmacogenomic testing is appropriate based on a drug product's label or peer-reviewed professional guidelines; and

(2) drug-gene and drug-drug-gene associations, established by a drug product's label or peer-reviewed professional guidelines, based on a patient's medication list, medication allergy list, and results from pharmacogenomic testing.

(b) REPORTING AND ASSOCIATION OF ADVERSE DRUG EVENTS.—The Secretary, in consultation with the Commissioner of Food and Drugs, shall carry out a program to improve the reporting of adverse drug events and the association, if any, of such events to a patient's genetic status. As part of the program, the Secretary shall issue regulations pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other applicable statutory authorities to—

(1) ensure that drug-gene interaction alerting systems are continuously updated to incorporate information from new or updated drug labels with pharmacogenomic information and newly established peer-reviewed professional guidelines on drug-gene associations;

(2) facilitate the reporting of adverse drug events to the FDA Adverse Event Reporting System directly through the use of the health care provider's electronic health record system; and

(3) allow for the reporting of whether an adverse drug event is caused by pharmacogenetic interactions to the FDA Adverse Event Reporting System directly through the use of the health care provider's electronic health record system.

(c) UPDATING FAERS; PATIENT-FRIENDLY REPORTING.—The Secretary, acting through the Commissioner of Food and Drugs, shall—

(1) update the FDA Adverse Event Reporting System, including to—

(A) accept information directly from health care providers' electronic health record systems;

(B) improve the collection of real world evidence (as defined in section 505F of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g)); and

(C) create a selection tool that allows individuals to report whether an adverse drug event is associated with a drug-gene interaction;

(2) work with relevant Federal agencies and offices, and stakeholders, to create patient-friendly electronic options for reporting adverse drug events such as submission through a designated mobile device application or mobile device messaging application; and

(3) not later than 1 year after the date of enactment of this Act, report to the Congress on the progress made in implementing paragraphs (1) and (2).

(d) ASSESSMENT ON ADDITIONAL IMPROVEMENTS TO ELECTRONIC HEALTH RECORD SYSTEMS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary shall—

(A) complete an assessment on additional improvements to electronic health record systems that are needed to further the development of real world evidence (as defined in section 505F of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 355g)) in pharmacogenomics; and

(B) submit a report to the Congress on the findings on the assessment.

(2) CONSIDERATION OF NEEDED ADVANCEMENTS.—As part of the assessment under paragraph (1), the Secretary shall consider what advancements are needed to capture information about the laboratory and the test used as part of pharmacogenomic testing.

SEC. 6. INCREASED AUTHORIZATION FOR PHARMACOGENOMICS IMPLEMENTATION RESEARCH.

There is authorized to be appropriated to the National Institutes of Health $7,000,000 for each of fiscal years 2022 through 2025 for the conduct, support, and maintenance of pharmacogenomics implementation research through the Genomic Community Resources program.

SEC. 7. DEFINITIONS.

In this Act:

(1) The term ''adverse drug event'' means an injury resulting from any medical intervention with a drug.

(2) The term ''comprehensive medication management'' means medication management pursuant to a standard of care that ensures each patient's medications are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, and safe given the comorbidities and other medications being taken and able to be taken by the patient as intended.

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