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118TH CONGRESS
2D SESSION

H. R. 7848

To update the National Action Plan for Adverse Drug Event Prevention to consider advances in pharmacogenomic research and testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 2024

Mr. SWALWELL (for himself and Mr. CRENSHAW) 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 consider advances in pharmacogenomic research and 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 of 2024''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

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

The Secretary of Health and Human Services (in this Act referred to as the ''Secretary'') 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, submit a report to the Congress on the implementation of the National Action Plan for Adverse Drug Event Prevention of the Department of Health and Human Services, including on the progress in meeting the target outcomes approved by the Federal Interagency Steering Committee for Adverse Drug Events;

(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 interactions (including interactions among multiple drugs and genes), 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 monitoring systems and expand capabilities to identify genetic associations in adverse events.

SEC. 4. ADVERSE DRUG EVENT AND PHARMACOGENOMIC TESTING EDUCATION FOR HEALTH CARE PROFESSIONALS.

The Secretary shall issue guidance for health care providers and health care leaders, including administrators, primary and specialty care physicians, pharmacists, nurse practitioners, physician 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:

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

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

(3) 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.

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

(5) How to incorporate pharmacogenomics into comprehensive medication management.

(6) The importance of reporting information about known and relevant pharmacogenomic information when reporting adverse drug events to the FDA Adverse Event Reporting System.

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

(a) CERTIFICATION CRITERIA.—The Secretary shall provide guidance for health care providers and health care leaders, including administrators, primary and specialty

care physicians, pharmacists, nurse practitioners, physician 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 health information technologies, including for electronic prescribing systems and real-time pharmacy benefit checks, regarding how, before a medication order is completed and acted upon during computerized provider order entry, interventions might 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) GUIDANCE ON DRUG-GENE INTERACTION ALERTING SYSTEMS.—

(1) ISSUANCE AND UPDATES.—The Secretary shall—

(A) issue routine guidance on drug-gene interaction alerting systems in electronic health records; and

(B) not less than biannually, update such guidance to incorporate pharmacogenomic information from—

(i) new or updated drug labels; and

(ii) newly established peer-reviewed professional guidelines on drug-gene associations.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed as prohibiting an entity from updating the results of pharmacogenomic testing, or alerting the provider, if a medication is contraindicated by the results of pharmacogenomic testing.

(c) REDUCING ADVERSE DRUG EVENTS REPORTING BURDENS.—The Secretary shall encourage the development of electronic health record systems that allow for adverse drug event information to be directly reported to the FDA Adverse Event Reporting System.

(d) UPDATING FAERS; PATIENT-FRIENDLY REPORTING.—The Secretary shall—

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

(A) create an optional selection tool that allows individuals to report whether an adverse

drug event is associated with a drug-gene or drug-drug-gene interaction; and

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

(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 an optional 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).

(e) GAO STUDY AND RECOMMENDATIONS ON INCLUSION OF INFORMATION ON DRUG-GENE INTERACTIONS ON DRUG LABELS.—Not later than 180 days after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) study, and formulate recommendations on, how the Food and Drug Administration can include and update information on drug-gene interactions on drug labels; and

(2) submit recommendations to the relevant committees of jurisdiction.

(f) REPORT 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 a report 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 Cosmetic Act (21 U.S.C. 355g)) in pharmacogenomics; and

(B) submit such report to the Congress.

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

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