

119TH CONGRESS
1ST SESSION

H. R. 2471

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 27, 2025

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

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.

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 “Right Drug Dose Now
5 Act of 2025”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 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 education for health care professionals.

Sec. 5. Improving EHR systems to improve the use of pharmacogenomic information.

1 **SEC. 3. NATIONAL ACTION PLAN FOR ADVERSE DRUG**
 2 **EVENT PREVENTION.**

3 The Secretary of Health and Human Services (in this
 4 Act referred to as the “Secretary”) shall—

5 (1) not later than 180 days after the date of
 6 enactment of this Act, in coordination with the
 7 heads of other relevant Federal departments and
 8 agencies, submit a report to the Congress on the im-
 9 plementation of the National Action Plan for Ad-
 10 verse Drug Event Prevention of the Department of
 11 Health and Human Services, including on the
 12 progress in meeting the target outcomes approved by
 13 the Federal Interagency Steering Committee for Ad-
 14 verse Drug Events;

15 (2) convene the Federal Interagency Steering
 16 Committee for Adverse Drug Events to update the
 17 National Action Plan for Adverse Drug Event Pre-
 18 vention; and

19 (3) require such Committee, in updating the
 20 National Action Plan for Adverse Drug Event Pre-
 21 vention—

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

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

9 (3) Evidence-based information that would en-
10 courage individuals and their health care profes-
11 sionals to consider pharmacogenomic testing as part
12 of their health care plan to the extent appropriate.

13 (4) The role of medical professionals who spe-
14 cialize in genetics and genomics.

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

17 (6) The importance of reporting information
18 about known and relevant pharmacogenomic infor-
19 mation when reporting adverse drug events to the
20 FDA Adverse Event Reporting System.

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

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

1 care physicians, pharmacists, nurse practitioners, physi-
2 cian assistants, physician medical geneticists, laboratory
3 medical geneticists, genetic counselors, medical educators,
4 and the faculty of schools of medicine and other schools
5 of health professions, on health information technologies,
6 including for electronic prescribing systems and real-time
7 pharmacy benefit checks, regarding how, before a medica-
8 tion order is completed and acted upon during computer-
9 ized provider order entry, interventions might automati-
10 cally indicate to a user—

11 (1) when pharmacogenomic testing is appro-
12 priate based on a drug product's label or peer-re-
13 viewed professional guidelines; and

14 (2) drug-gene and drug-drug-gene associations,
15 established by a drug product's label or peer-re-
16 viewed professional guidelines, based on a patient's
17 medication list, medication allergy list, and results
18 from pharmacogenomic testing.

19 (b) GUIDANCE ON DRUG-GENE INTERACTION
20 ALERTING SYSTEMS.—

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

23 (A) issue routine guidance on drug-gene
24 interaction alerting systems in electronic health
25 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

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

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

5 (2) work with relevant Federal agencies and of-
6 fices, and stakeholders, to create patient-friendly
7 electronic options for reporting adverse drug events
8 such as submission through an optional designated
9 mobile device application or mobile device messaging
10 application; and

11 (3) not later than 1 year after the date of en-
12 actment of this Act, report to the Congress on the
13 progress made in implementing paragraphs (1) and
14 (2).

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

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

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

1 (f) REPORT ON ADDITIONAL IMPROVEMENTS TO
2 ELECTRONIC HEALTH RECORD SYSTEMS.—

3 (1) IN GENERAL.—Not later than 180 days
4 after the date of enactment of this Act, the Sec-
5 retary shall—

6 (A) complete a report on additional im-
7 provements to electronic health record systems
8 that are needed to further the development of
9 real world evidence (as defined in section 505F
10 of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 355g)) in pharmacogenomics; and

12 (B) submit such report to the Congress.

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

○