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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R.

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.

Mr. SWALWELL introduced the following bill; which was referred to the Committee on _____

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.

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”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents of this Act is as follows:

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

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

5 The Secretary of Health and Human Services shall—

6 (1) not later than 180 days after the date of
7 enactment of this Act, in coordination with the
8 heads of other relevant Federal departments and
9 agencies including the Director of the National
10 Human Genome Research Institute, and in consulta-
11 tion with the Director of the Eunice Kennedy Shriv-
12 er National Institute of Child Health and Human
13 Development, the Director of the National Center
14 for Biotechnology Information, and the Director of
15 the National Library of Medicine, submit a report to
16 the Congress on—

17 (A) the implementation of the National Ac-
18 tion Plan for Adverse Drug Event Prevention of
19 the Department of Health and Human Services;
20 and

21 (B) the progress in meeting the target ap-
22 proved by the Federal Interagency Steering

1 Committee for Adverse Drug Events for a 10
2 percent reduction for—

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

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

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

12 (iv) the rate of visits to United States
13 hospital emergency departments for ad-
14 verse drug events associated with injury
15 from oral anticoagulants;

16 (v) the rate of visits to United States
17 hospital emergency departments for ad-
18 verse drug events associated with injury
19 from insulin; and

20 (vi) the rate of visits to United States
21 hospital emergency departments for ad-
22 verse drug events associated with thera-
23 peutic use of opioid analgesics;

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

1 National Action Plan for Adverse Drug Event Pre-
2 vention; and

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

6 (A) to consider advances in scientific un-
7 derstanding and technology pertaining to drug-
8 gene-drug interactions, clinical outcomes, health
9 care utilization, and the decreasing cost of ge-
10 netic testing;

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

14 (C) to evaluate operating characteristics
15 for Federal adverse drug event surveillance sys-
16 tems and expand capabilities to identify genetic
17 associations in adverse events.

18 **SEC. 4. ADVERSE DRUG EVENT AND PHARMACOGENOMIC**
19 **TESTING AWARENESS.**

20 Part P of title III of the Public Health Service Act
21 (42 U.S.C. 280g et seq.) is amended by adding at the end
22 the following:

23 **“SEC. 399V-7. ADVERSE DRUG EVENT AND**
24 **PHARMACOGENOMIC TESTING AWARENESS.**

25 **“(a) PUBLIC EDUCATION CAMPAIGN.—**

1 “(1) IN GENERAL.—The Secretary, acting
2 through the Director of the National Human Ge-
3 nome Research Institute, in consultation with the
4 Director of the Eunice Kennedy Shriver National In-
5 stitute of Child Health and Human Development,
6 the Director of the National Center for Bio-
7 technology Information, and the Director of the Na-
8 tional Library of Medicine, shall conduct a national
9 evidence-based education campaign to increase the
10 public’s awareness regarding—

11 “(A) the prevalence of adverse drugs
12 events and adverse drug reactions;

13 “(B) specific risk factors that increase an
14 individual’s likelihood of experiencing an ad-
15 verse drug event or adverse drug reaction;

16 “(C) basic information about
17 pharmacogenomic testing and how its use, in-
18 cluding incorporation in comprehensive medica-
19 tion management, may prevent adverse drug re-
20 actions in certain clinical situations;

21 “(D) the role of health care providers in
22 performing pharmacogenomic testing, inter-
23 preting the results of such testing, and adjust-
24 ing medications based on such results;

1 “(E) the availability of pharmacogenomic
2 testing;

3 “(F) comprehensive medication manage-
4 ment; and

5 “(G) how the benefits of an individual’s
6 pharmacogenomic test results might change or
7 be relevant over time.

8 “(2) CONSIDERATION OF ADVICE OF STAKE-
9 HOLDER EXPERTS.—The education campaign under
10 paragraph (1) shall take into consideration the ad-
11 vice of stakeholder experts, such as those special-
12 izing in medical genetics and pharmacogenetics and
13 collaborative communities focused on
14 pharmacogenomics.

15 “(3) MEDIA CAMPAIGN.—In conducting the
16 education campaign under paragraph (1), the Sec-
17 retary, after considering the advice of stakeholder
18 experts pursuant to paragraph (2), may award
19 grants or contracts to entities to establish national
20 multimedia campaigns that may include advertising
21 through television, radio, print media, billboards,
22 posters, all forms of existing and especially emerging
23 social networking media, other Internet media, and
24 any other medium determined appropriate by the
25 Secretary.

1 “(4) RURAL REGIONS, HEALTH PROFESSIONAL
2 SHORTAGE AREAS, AND UNDERSERVED COMMU-
3 NITIES.—The Secretary shall ensure that the edu-
4 cation campaign under paragraph (1)—

5 “(A) reaches rural and medically under-
6 served communities (as defined in section 799);
7 and

8 “(B) includes the involvement of commu-
9 nity health centers, community pharmacies, and
10 other local health clinics.

11 “(b) HEALTH CARE PROFESSIONAL EDUCATION
12 CAMPAIGN.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through the Director of the National Human Ge-
15 nome Research Institute, in consultation with the
16 Director of the Eunice Kennedy Shriver National In-
17 stitute of Child Health and Human Development,
18 the Director of the National Center for Bio-
19 technology Information, the Director of the National
20 Library of Medicine, and the Administrator of the
21 Health Resources and Services Administration, shall
22 establish a national health education program for
23 health care providers and health care leaders, includ-
24 ing administrators, pharmacists, nurse practitioners,
25 physicians’ assistants, physician medical geneticists,

1 laboratory medical geneticists, genetic counselors,
2 medical educators, and the faculty of schools of med-
3 icine and other schools of health professions, on the
4 following:

5 “(A) Pharmacogenomic testing and the ex-
6 tent of its ability to prevent adverse drug reac-
7 tions.

8 “(B) Pharmacogenomic testing, drug inter-
9 action alerting systems, when to refer to or con-
10 sult with a genetics provider, and the standards
11 of care for patients who are suspected or known
12 to have a genetic variant that is known to im-
13 pact drug metabolism.

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

19 “(D) The role of medical professionals who
20 specialize in genetics and genomics.

21 “(E) How to incorporate
22 pharmacogenomics into comprehensive medica-
23 tion management.

24 “(2) GRANTS.—

1 “(A) AWARD.—In carrying out the na-
2 tional health education program under this sub-
3 section, the Secretary, acting through the Di-
4 rector of the National Human Genome Re-
5 search Institute, may award grants to nonprofit
6 organizations to carry out educational activities
7 with respect to the topics listed in subpara-
8 graphs (A) through (D) of paragraph (1).

9 “(B) USE OF FUNDS.—A grant under sub-
10 paragraph (A) may be used to support one or
11 more of the following activities:

12 “(i) Increasing the knowledge and
13 awareness of health care providers and
14 health care leaders about
15 pharmacogenomic testing and drug inter-
16 actions.

17 “(ii) Increasing the number of health
18 professional schools that incorporate
19 pharmacogenomic curricula in classroom
20 instruction.

21 “(iii) Increasing the ability of health
22 care providers to note and respond to the
23 impact of gender, ethnicity, age, and other
24 relevant characteristics on drug metabo-
25 lism.

1 “(iv) Developing principles, practices,
2 and curriculum instruction that prepare
3 medical, nursing, pharmacy, and other
4 health professions students to effectively
5 apply knowledge and skills needed to recognize—
6

7 “(I) when a patient is eligible for
8 pharmacogenomic testing, including
9 as part of comprehensive medication
10 management when appropriate, and in
11 accordance with the patient’s health
12 care team, a drug product’s label, and
13 professional clinical guidelines; and

14 “(II) how to appropriately use
15 the test results to adjust a prescription
16 or otherwise change a patient’s
17 health care plan.

18 “(v) Providing opportunities for practicing health care professionals to receive
19 pharmacogenomics training and education
20 through a variety of modalities including
21 in-person, electronic media, professional
22 meetings and conferences, and social
23 media.
24

1 “(c) REPORTING.—At least every three years, the
2 Secretary, acting through the Director of the National
3 Human Genome Research Institute, in consultation with
4 the Director of the Eunice Kennedy Shriver National In-
5 stitute of Child Health and Human Development, the Di-
6 rector of the National Center for Biotechnology Informa-
7 tion, the Director of the National Library of Medicine, the
8 Administrator of the Centers for Medicare & Medicaid
9 Services, and relevant stakeholders with expertise in devel-
10 oping quality measures of label and peer-reviewed profes-
11 sional guidelines on drug-gene interactions, shall publish
12 data on—

13 “(1) the public’s awareness regarding adverse
14 drug events and pharmacogenomic testing;

15 “(2) the number or percentage of individuals
16 utilizing information to inform their health care de-
17 cisions regarding prescription medications and
18 pharmacogenomic testing;

19 “(3) the change in the number or percentage of
20 individuals enrolled in a prescription drug plan
21 under part D of the title XVIII of the Social Secu-
22 rity Act receiving a pharmacogenetic test, as rec-
23 ommended in alignment with a drug product’s label
24 or peer-reviewed professional guidelines; and

1 “(4) the number or percentage of changes, be-
2 ginning one year after the date of enactment of this
3 section, in medication management as a result of in-
4 corporating information from pharmacogenomic test-
5 ing.

6 “(d) DEFINITIONS.—In this section:

7 “(1) ADVERSE DRUG EVENT.—The term ‘ad-
8 verse drug event’ means an injury resulting from
9 any medical intervention with a drug.

10 “(2) ADVERSE DRUG REACTION.—The term
11 ‘adverse drug reaction’ means a response to a drug
12 that—

13 “(A) is noxious and unintended; and

14 “(B) occurs at doses normally used in hu-
15 mans for prophylaxis, diagnosis, or therapy of
16 disease or for the modification of physiologic
17 function.

18 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
19 carry out this section, there is authorized to be appro-
20 priated \$50,000,000 for each of fiscal years 2022 through
21 2027.”.

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

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

1 as the “Secretary”) shall adopt pursuant to subtitle A of
2 title XXX of the Public Health Service Act (42 U.S.C.
3 300jj–11 et seq.) certification criteria for health informa-
4 tion technology, including for electronic prescribing sys-
5 tems and real-time pharmacy benefit checks, such that be-
6 fore a medication order is completed and acted upon dur-
7 ing computerized provider order entry, interventions must
8 automatically indicate to a user—

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

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

17 (b) REPORTING AND ASSOCIATION OF ADVERSE
18 DRUG EVENTS.—The Secretary, in consultation with the
19 Commissioner of Food and Drugs, shall carry out a pro-
20 gram to improve the reporting of adverse drug events and
21 the association, if any, of such events to a patient’s genetic
22 status. As part of the program, the Secretary shall issue
23 regulations pursuant to the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 301 et seq.) and other applicable
25 statutory authorities to—

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

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

11 (3) allow for the reporting of whether an ad-
12 verse drug event is caused by pharmacogenetic inter-
13 actions to the FDA Adverse Event Reporting Sys-
14 tem directly through the use of the health care pro-
15 vider's electronic health record system.

16 (c) UPDATING FAERS; PATIENT-FRIENDLY RE-
17 PORTING.—The Secretary, acting through the Commis-
18 sioner of Food and Drugs, shall—

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

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

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

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

3 (C) create a selection tool that allows indi-
4 viduals to report whether an adverse drug event
5 is associated with a drug-gene interaction;

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

12 (3) not later than 1 year after the date of en-
13 actment of this Act, report to the Congress on the
14 progress made in implementing paragraphs (1) and
15 (2).

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

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

21 (A) complete an assessment on additional
22 improvements to electronic health record sys-
23 tems that are needed to further the develop-
24 ment of real world evidence (as defined in sec-
25 tion 505F of the Federal Food, Drug, and Cos-

1 metac Act (21 U.S.C. 355g)) in
2 pharmacogenomics; and

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

5 (2) CONSIDERATION OF NEEDED ADVANCE-
6 MENTS.—As part of the assessment under para-
7 graph (1), the Secretary shall consider what ad-
8 vancements are needed to capture information about
9 the laboratory and the test used as part of
10 pharmacogenomic testing.

11 **SEC. 6. INCREASED AUTHORIZATION FOR**
12 **PHARMACOGENOMICS IMPLEMENTATION RE-**
13 **SEARCH.**

14 There is authorized to be appropriated to the Na-
15 tional Institutes of Health \$7,000,000 for each of fiscal
16 years 2022 through 2025 for the conduct, support, and
17 maintenance of pharmacogenomics implementation re-
18 search through the Genomic Community Resources pro-
19 gram.

20 **SEC. 7. DEFINITIONS.**

21 In this Act:

22 (1) The term “adverse drug event” means an
23 injury resulting from any medical intervention with
24 a drug.

1 (2) The term “comprehensive medication man-
2 agement” means medication management pursuant
3 to a standard of care that ensures each patient’s
4 medications are individually assessed to determine
5 that each medication is appropriate for the patient,
6 effective for the medical condition, and safe given
7 the comorbidities and other medications being taken
8 and able to be taken by the patient as intended.