

116TH CONGRESS
1ST SESSION

H. R. 5198

To amend the Federal Food, Drug, and Cosmetic Act regarding the patient medication information required to be included in the labeling of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 20, 2019

Mr. GOLDEN (for himself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act regarding the patient medication information required to be included in the labeling of prescription drugs, 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 “Patients’ Right to
5 Know Their Medication Act of 2019”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Prescription medications are important to
2 the health and well-being of the American public.

3 (2) According to the Centers for Disease Con-
4 trol and Prevention (CDC), 48.9 percent of Ameri-
5 cans used at least one prescription drug in the past
6 30 days.

7 (3) The utilization of prescription drugs can
8 subject patients to adverse drug events; therefore,
9 patient safety is of the utmost importance.

10 (4) Studies indicate that paper format patient
11 medication information (PMI) can help protect pa-
12 tients and prevent the majority of costly adverse
13 drug events.

14 (5) In addition to bolstering patient safety, the
15 mandatory use of a standardized PMI provided to
16 all patients in nonhospital settings could reduce
17 costs associated with emergency room visits and hos-
18 pital admissions related to adverse drug events by
19 \$14.6 to \$26.2 billion dollars annually.

20 (6) Many patients cannot access electronic
21 versions of PMI, thereby necessitating a paper op-
22 tion.

23 (7) The Government Accountability Office
24 found that relying on electronic labeling as a com-

1 plete substitute for paper labeling could adversely
2 impact public health.

3 (8) A congressionally mandated paper PMI is
4 needed because no standardized PMI in a single
5 page, paper copy, proven patient-friendly format is
6 currently available to patients or required by the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 301 et seq.).

9 **SEC. 3. PATIENT MEDICATION INFORMATION FOR PRE-**
10 **SCRIPTION DRUGS.**

11 (a) IN GENERAL.—Chapter V of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
13 ed by inserting after section 505F (21 U.S.C. 355g) the
14 following:

15 **“SEC. 505G. PATIENT MEDICATION INFORMATION FOR PRE-**
16 **SCRIPTION DRUGS.**

17 “(a) IN GENERAL.—The Secretary shall issue regula-
18 tions on the patient medication information that is re-
19 quired to be in the printed labeling of drugs subject to
20 section 503(b)(1), including regulations regarding the au-
21 thorship, content, format, color, printing, and dissemina-
22 tion requirements for such patient medication information.
23 The Secretary shall issue final regulations pursuant to the
24 preceding sentence not later than 1 year after the date
25 of enactment of this section.

1 “(b) CONTENT.—The regulations promulgated under
2 subsection (a) shall require that the patient medication in-
3 formation with respect to a drug—

4 “(1) be scientifically accurate, include relevant
5 patient safety information, and be approved by the
6 Secretary;

7 “(2) include understandable plain language,
8 and include graphics and pictures when applicable,
9 and be provided in a consistent, standardized format
10 and color for all drug products, and not be pro-
11 motional in tone or content, and contain at least—

12 “(A) the established name of the drug (or,
13 if the drug is a biological product, the proper
14 name of the biological product) and the national
15 drug code for the drug;

16 “(B) indications for use approved by the
17 Food and Drug Administration;

18 “(C) general directions for proper use;

19 “(D) contraindications, warnings, pre-
20 cautions, the most frequently occurring adverse
21 reactions, and adverse reactions that are impor-
22 tant for other reasons (such as because they are
23 serious), especially with respect to certain sub-
24 populations such as children, pregnant women,
25 and the elderly;

1 “(E) measures patients may be able to
2 take, if any, to reduce the side effects and risks
3 of the drug;

4 “(F) information about when a patient
5 should contact his or her health care profes-
6 sional;

7 “(G) instructions not to share medications,
8 and, if applicable, key storage requirements and
9 recommendations relating to proper disposal of
10 any unused portion of the drug;

11 “(H) known clinically important inter-
12 actions with other drugs, food, and other sub-
13 stances;

14 “(I) a statement of whether sufficient data
15 are available concerning the use of the drug in
16 specified subpopulations, such as women, preg-
17 nant women, lactating women, women and men
18 of reproductive age, and pediatric, geriatric, ra-
19 cial, and ethnic minority groups;

20 “(J) the name of the manufacturer and a
21 toll-free telephone number for consumers to
22 contact the manufacturer of the drug; and

23 “(K) a current link to Form FDA 3500B
24 for voluntary reporting for consumers of ad-

1 verse events, product problems, and product use
2 errors (or any successor form); and

3 “(3) be provided to a patient or agent of a pa-
4 tient in a printed format with each prescription dis-
5 pensed, such that a drug labeled for distribution
6 shall be accompanied by printed labeling physically
7 on or within the packaging from which the drug is
8 to be dispensed, in an adequate supply of printed
9 patient medication information to accommodate pre-
10 scriptions dispensed therefrom.

11 “(c) TIMELINESS, CONSISTENCY, ACCURACY, AND
12 EFFECTIVENESS.—The regulations promulgated under
13 subsection (a) shall—

14 “(1) provide for timely reviews, approvals, and
15 updates of patient medication information as new
16 drugs and new information become available;

17 “(2) provide for updates when appropriate to
18 help communicate information that is shared by
19 similar products or drugs within classes of medica-
20 tion to avoid patient confusion and harm;

21 “(3) include specifications for language, graph-
22 ics, format, color, and pictures required by sub-
23 section (b)(2), to be developed based upon docu-
24 mented patient research with one or more actual
25 drug products that demonstrates improved patient

1 learning and understanding of safe and effective
2 medication use; and

3 “(4) be based on a demonstrated causal connec-
4 tion between the enhanced patient medication infor-
5 mation required by the regulations and improved pa-
6 tient medication adherence and compliance for the
7 purpose of reducing the cost of health care and im-
8 proving desired medical outcomes.”.

9 (b) MISBRANDING OFFENSE.—Section 502 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352)
11 is amended by adding at the end the following:

12 “(ee) If it is a drug subject to section 503(b)(1) and
13 patient medication information is not provided in accord-
14 ance with section 505G.”.

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