

114TH CONGRESS
1ST SESSION

S. 2214

To amend the Federal Food, Drug, and Cosmetic Act to require patient medication information to be provided with certain prescription drugs.

IN THE SENATE OF THE UNITED STATES

OCTOBER 28, 2015

Mrs. GILLIBRAND (for herself, Ms. WARREN, Ms. STABENOW, Mr. BROWN, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require patient medication information to be provided with certain prescription drugs.

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 “Cody Miller Patient
5 Medication Information Act”.

1 **SEC. 2. PATIENT MEDICATION INFORMATION FOR PRE-**
 2 **SCRIPTION DRUGS.**

3 Chapter V of the Federal Food, Drug, and Cosmetic
 4 Act (21 U.S.C. 351 et seq.) is amended by inserting after
 5 section 505E the following:

6 **“SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRE-**
 7 **SCRIPTION DRUGS.**

8 “(a) IN GENERAL.—Not later than 2 years after the
 9 date of enactment of this section, the Secretary shall issue
 10 final regulations regarding the authorship, content, for-
 11 mat, and dissemination requirements for patient medica-
 12 tion information for drugs subject to section 503(b)(1).

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

16 “(1) be scientifically accurate, include relevant
 17 patient safety information, and be based on the pro-
 18 fessional labeling approved by the Secretary; and

19 “(2) include standard, nontechnical, under-
 20 standable, plain language that is not promotional in
 21 tone or content, and contain at least—

22 “(A) the established name of the drug or
 23 the proper name of the biological product, as
 24 applicable;

25 “(B) drug uses;

26 “(C) general directions for proper use;

1 “(D) contraindications, the most fre-
2 quently occurring adverse reactions, and ad-
3 verse reactions that are important for other
4 reasons (such as because they are serious), es-
5 pecially with respect to certain groups such as
6 children, pregnant women, and the elderly;

7 “(E) measures patients may be able to
8 take, if any, to reduce the side effects and risks
9 of the drug;

10 “(F) when a patient should contact his or
11 her health care professional;

12 “(G) instructions not to share medications,
13 and, if any exist, key storage requirements, and
14 recommendations relating to proper disposal of
15 any unused portion of the drug;

16 “(H) known clinically important inter-
17 actions with other drugs and substances; and

18 “(I) a statement of whether sufficient data
19 are available concerning the use of the drug in
20 specified subpopulations, such as women, preg-
21 nant women, lactating women, women and men
22 of reproductive age, pediatric, geriatric, racial
23 and ethnic minority groups, and other sub-
24 populations.

1 “(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—

2 The regulations promulgated under subsection (a) shall in-
3 clude standards relating to how the Secretary—

4 “(1) shall perform timely reviews and updates
5 of patient medication information as new drugs and
6 new information become available;

7 “(2) may perform, when appropriate, updates
8 to help communicate information that is shared by
9 similar drug products or drugs within classes of
10 medications in order to avoid patient confusion and
11 harm; and

12 “(3) shall develop a process, including consumer
13 testing, to assess the quality and effectiveness of pa-
14 tient medication information in ensuring that patient
15 medication information developed in accordance with
16 this section promotes patient understanding and safe
17 and effective medication use.

18 “(d) ELECTRONIC REPOSITORY.—The regulations
19 promulgated under subsection (a) shall provide for the de-
20 velopment of a publicly accessible electronic repository for
21 all patient medication information documents and content
22 to facilitate the availability of patient medication informa-
23 tion.”.

1 **SEC. 3. ENFORCEMENT AND DISSEMINATION.**

2 (a) **ENFORCEMENT.**—Section 502 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
4 ed by adding at the end the following:

5 “(dd) If it is a drug subject to section 503(b)(1) and
6 patient medical information described in section 505F is
7 not provided, as required under section 503(b)(1).”.

8 (b) **DISSEMINATION.**—Section 503(b) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amend-
10 ed by inserting “Under the circumstances determined by
11 the Secretary through regulation or guidance, a drug dis-
12 pensed in accordance with this paragraph shall be accom-
13 panied by the patient medication information for such
14 drug developed in accordance with section 505F” after
15 “by the pharmacist.”.

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