

112TH CONGRESS
2D SESSION

H. R. 6514

To require the Secretary of Health and Human Services to promulgate regulations regarding the authorship, content, format, and dissemination of Patient Medication Information to ensure patients receive consistent and high-quality information about their prescription medications and are aware of the potential risks and benefits of prescription medications.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2012

Mr. GIBSON introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Secretary of Health and Human Services to promulgate regulations regarding the authorship, content, format, and dissemination of Patient Medication Information to ensure patients receive consistent and high-quality information about their prescription medications and are aware of the potential risks and benefits of prescription medications.

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 Initiative
5 for Safer Prescriptions 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 505D the following:

6 **“SEC. 505E. 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 regulations regarding the authorship, content, format, and
11 dissemination requirements for patient medication infor-
12 mation (referred to in this section as ‘PMI’) for drugs sub-
13 ject to section 503(b)(1).

14 “(b) CONTENT.—The regulations promulgated under
15 subsection (a) shall require that the PMI with respect to
16 a drug—

17 “(1) be scientifically accurate and based on the
18 professional labeling approved by the Secretary and
19 authoritative, peer-reviewed literature; and

20 “(2) includes nontechnical, understandable,
21 plain language that is not promotional in tone or
22 content, and contains at least—

23 “(A) the established name of drug, includ-
24 ing the established name of such drug as a list-
25 ed drug (as described in section 505(j)(2)(A))
26 and as a drug that is the subject of an ap-

1 proved abbreviated new drug application under
2 section 505(j) or of an approved license for a
3 biological product submitted under section
4 351(k) of the Public Health Service Act, if ap-
5 plicable;

6 “(B) drug uses and clinical benefits;

7 “(C) general directions for proper use;

8 “(D) contraindications, common side ef-
9 fects, and most serious risks of the drug, espe-
10 cially with respect to certain groups such as
11 children, pregnant women, and the elderly;

12 “(E) measures patients may be able to
13 take, if any, to reduce the side effects and risks
14 of the drug;

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

17 “(G) instructions not to share medications,
18 and, if any exist, key storage requirements, and
19 recommendations relating to proper disposal of
20 any unused portion of the drug; and

21 “(H) known clinically important inter-
22 actions with other drugs and substances.

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

24 The regulations promulgated under subsection (a) shall in-
25 clude standards related to—

1 “(1) performing timely updates of drug infor-
2 mation as new drugs and new information becomes
3 available;

4 “(2) ensuring that common information is ap-
5 plied consistently and simultaneously across similar
6 drug products and for drugs within classes of medi-
7 cations in order to avoid patient confusion and
8 harm; and

9 “(3) developing a process, including consumer
10 testing, to assess the quality and effectiveness of
11 PMI in ensuring that PMI promotes patient under-
12 standing and safe and effective medication use.

13 “(d) SUBMISSION OF PMI.—

14 “(1) SUBMISSION OF PMI FOR APPROVAL.—The
15 regulations promulgated under subsection (a)
16 shall—

17 “(A) with respect to any drug for which an
18 application is submitted under subsection (b) or
19 (j) of section 505 of this Act, or under sub-
20 section (a) or (k) of section 351 of the Public
21 Health Service Act, on or after the date that is
22 18 months after the date of the enactment of
23 the Cody Miller initiative for Safer Prescrip-
24 tions Act—

1 “(i) require the sponsor of the drug to
2 submit PMI for the drug as part of such
3 application; and

4 “(ii) provide for approval or dis-
5 approval of the PMI as part of the process
6 for approving or disapproving the applica-
7 tion; and

8 “(B) with respect to any other drug law-
9 fully marketed in the United States—

10 “(i) require the sponsor of the drug to
11 submit PMI for the drug to the Secretary;
12 and

13 “(ii) provide for approval or dis-
14 approval of the PMI.

15 “(2) IDENTICAL PMI FOR GENERIC DRUGS.—

16 The regulations promulgated under subsection (a)
17 shall require the PMI for a drug subject to an ab-
18 breviated new drug application under section 505(j)
19 to be identical to the PMI for the listed drug (as
20 such term is used in section 505(j)), except for ex-
21 cluding any portion of the PMI for the listed drug
22 that is protected by patent or by an exclusivity pe-
23 riod under this Act.

24 “(e) ELECTRONIC REPOSITORY.—

1 “(1) IN GENERAL.—The regulations promul-
2 gated under subsection (a) shall provide for the de-
3 velopment of a publicly accessible electronic reposi-
4 tory for all PMI documents and content to facilitate
5 the availability of PMI.

6 “(2) EFFECT OF SUBMISSION.—If the sponsor
7 of a drug submits PMI to such electronic registry,
8 the sponsor is deemed, subject to the deadlines spec-
9 ified in subsection (d)(1), to have submitted the
10 PMI for purposes of subsection (d)(1).”.

11 **SEC. 3. PUBLICATION ON INTERNET WEB SITE.**

12 The Secretary of Health and Human Services shall
13 publish on the Internet Web site of the Food and Drug
14 Administration a link to the Daily Med Web site ([http://](http://dailymed.nlm.nih.gov/dailymed)
15 dailymed.nlm.nih.gov/dailymed) (or any successor Web
16 site).

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