

113TH CONGRESS  
1ST SESSION

# H. R. 1608

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.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2013

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

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## 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) ELECTRONIC REPOSITORY.—The regulations  
14          promulgated under subsection (a) shall provide for the de-  
15          velopment of a publicly accessible electronic repository for  
16          all PMI documents and content to facilitate the avail-  
17          ability of PMI.”.

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

19          The Secretary of Health and Human Services shall  
20          publish on the Internet Web site of the Food and Drug  
21          Administration a link to the Daily Med Web site ([http://](http://dailymed.nlm.nih.gov/dailymed)  
22          dailymed.nlm.nih.gov/dailymed) (or any successor Web  
23          site).

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