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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Cody Miller Initiative for Safer Prescriptions Act''.

SEC. 2. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

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

"SEC. 505E. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (referred to in this section as 'PMI') for drugs subject to section 503(b)(1).

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

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

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

''(A) the established name of drug, including the established name of such drug as a listed drug (as described in section 505(j)(2)(A)) and as a drug that is the subject of an ap-

proved abbreviated new drug application under section 505(j) or of an approved license for a biological product submitted under section 351(k) of the Public Health Service Act, if applicable;

"(B) drug uses and clinical benefits;

"(C) general directions for proper use;

"(D) contraindications, common side effects, and most serious risks of the drug, especially with respect to certain groups such as children, pregnant women, and the elderly;

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

"(F) when a patient should contact his or her health care professional;

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

"(H) known clinically important interactions with other drugs and substances.

"(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards related to—

''(1) performing timely updates of drug information as new drugs and new information becomes available;

''(2) ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications in order to avoid patient confusion and harm; and

''(3) developing a process, including consumer testing, to assess the quality and effectiveness of PMI in ensuring that PMI promotes patient understanding and safe and effective medication use.

''(d) SUBMISSION OF PMI.—

''(1) SUBMISSION OF PMI FOR APPROVAL.—The regulations promulgated under subsection (a) shall—

''(A) with respect to any drug for which an application is submitted under subsection (b) or (j) of section 505 of this Act, or under subsection (a) or (k) of section 351 of the Public Health Service Act, on or after the date that is 18 months after the date of the enactment of the Cody Miller initiative for Safer Prescriptions Act—

''(i) require the sponsor of the drug to submit PMI for the drug as part of such application; and

''(ii) provide for approval or disapproval of the PMI as part of the process for approving or disapproving the application; and

''(B) with respect to any other drug lawfully marketed in the United States—

''(i) require the sponsor of the drug to submit PMI for the drug to the Secretary; and

''(ii) provide for approval or disapproval of the PMI.

''(2) IDENTICAL PMI FOR GENERIC DRUGS.—The regulations promulgated under subsection (a) shall require the PMI for a drug subject to an abbreviated new drug application under section 505(j) to be identical to the PMI for the listed drug (as such term is used in section 505(j)), except for excluding any portion of the PMI for the listed drug that is protected by patent or by an exclusivity period under this Act.

''(e) ELECTRONIC REPOSITORY.—

''(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all PMI documents and content to facilitate the availability of PMI.

''(2) EFFECT OF SUBMISSION.—If the sponsor of a drug submits PMI to such electronic registry, the sponsor is deemed, subject to the deadlines specified in subsection (d)(1), to have submitted the PMI for purposes of subsection (d)(1).''.

SEC. 3. PUBLICATION ON INTERNET WEB SITE.

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

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