HR 6514

Cody Miller Initiative for Safer Prescriptions Act

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 21, 2012
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (Sep 21, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/6514

Sponsor

Name: Rep. Gibson, Christopher P. [R-NY-20]
Party: Republican • **State:** NY • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Frank, Barney [D-MA-4]	D · MA		Nov 13, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Sep 21, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 3212	Related bill	**May 22, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Sep 21, 2012)

Cody Miller Initiative for Safer Prescriptions Act - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to direct the Secretary of Health and Human Services (HHS) to promulgate regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (PMI) for prescription drugs.

Requires such regulations to require the PMI for such a drug: (1) to be scientifically accurate and to be based on the approved professional labeling and authoritative, peer-reviewed literature; and (2) to include plain language that is not promotional in tone or content. Requires that such language include: (1) the established name of the drug; (2) drug uses and clinical benefits; (3) general directions for proper use; (4) contraindications, common side effects, and the most serious risks of the drug; (5) measures patients may take to reduce the side effects and risks; (6) when a patient should contact his or her health care professional; (7) instructions not to share medications; (8) any key storage requirements; (9) recommendations relating to proper disposal of any unused portion of the drug; and (10) known clinically important interactions with other drugs and substances.

Requires such regulations to: (1) include standards related to performing timely updates of drug information, ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications, and developing a process to assess the quality and effectiveness of PMI in promoting patient understanding and safe and effective use; (2) require the sponsor of a new drug or biological product to submit PMI as part of the new drug or abbreviated (generic) new drug application and provide for approval or disapproval of the PMI as part of the application process; (3) require the sponsor of any drug lawfully marketed in the United States to submit PMI for the drug to the Secretary for approval or disapproval of the PMI; (4) require the PMI for a generic drug to be identical to the PMI for the listed drug, except for excluding any portion of such PMI that is protected by patent or an exclusivity period under FFDCA; and (5) provide for the development of a publicly accessible electronic repository for all PMI.

Requires the Secretary to publish on the Food and Drug Administration (FDA) website a link to the Daily Med website.

Actions Timeline

- **Sep 21, 2012:** Introduced in House
- **Sep 21, 2012:** Referred to the House Committee on Energy and Commerce.