HR 6584

Verifying Authority and Legality In Drug Compounding Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Nov 2, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Nov 2, 2012)
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Sponsor

Name: Rep. Markey, Edward J. [D-MA-7]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Cohen, Steve [D-TN-9]	D · TN		Nov 2, 2012
Rep. Lynch, Stephen F. [D-MA-9]	D · MA		Nov 2, 2012
Rep. Olver, John W. [D-MA-1]	D · MA		Nov 2, 2012
Rep. Slaughter, Louise McIntosh [D-NY-28]	D · NY		Nov 2, 2012
Rep. Clay, Wm. Lacy [D-MO-1]	D · MO		Nov 27, 2012
Rep. Frank, Barney [D-MA-4]	D · MA		Nov 27, 2012
Rep. McGovern, James P. [D-MA-3]	D · MA		Nov 27, 2012
Rep. Rangel, Charles B. [D-NY-15]	D · NY		Nov 27, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Nov 2, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Nov 2, 2012)

Verifying Authority and Legality In Drug Compounding Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to the regulation of compounding drugs.

Eliminates authority for compounding pharmacies to: (1) compound drugs before the receipt of a valid prescription order, or (2) compound any drug product that is a copy of a commercially available drug.

Requires the Secretary of Health and Human Services (HHS) to develop, maintain and transmit to the appropriate state agencies a list of drug products that should not be compounded, including: (1) drug products whose compounding is reasonably likely to cause an adverse effect on their safety or effectiveness; and (2) drug products that have been withdrawn or removed from the market because they have been found to be unsafe or not effective.

Authorizes the Secretary to waive the requirement that a drug product must be compounded for an individually identified patient based on a valid prescription order or similar notation if compounding the drug product is necessary to address a drug shortage, or to protect public health or well-being. Prohibits the Secretary from authorizing a state to grant such waivers.

Authorizes the Secretary to waive the requirement that a drug product must be compounded for an individually identified patient based on a valid prescription order or similar notation if the pharmacy or pharmacist: (1) submits a satisfactory application to the Secretary; and (2) agrees to comply with any condition or limitation specified by the Secretary. Makes a pharmacy or pharmacist required to be registered under the FFDCA as a drug producer ineligible for a waiver. Permits the Secretary to authorize a state to grant such waivers applicable to compounded drug products sold or dispensed within the state pursuant to a memorandum of understanding between the Secretary and the state.

Authorizes the Secretary to waive the prohibition against compounding any drug product that is a copy of a commercially available drug if it is necessary to protect public health or well-being. Prohibits the Secretary from authorizing a state to waive such prohibition.

Subjects the facilities of any pharmacy receiving a waiver under this Act to inspection to determine compliance with this Act.

Requires the Secretary to publish notice at least 30 days before cancelling a waiver, unless it is necessary to prevent an adverse impact on public health or safety.

Sets forth a required label statement for any drug compounded pursuant to this Act.

Requires a pharmacist or physician compounding a drug product to report any adverse event associated with the use of the product within a specified time frame.

Actions Timeline

- **Nov 2, 2012:** Introduced in House
- **Nov 2, 2012:** Referred to the House Committee on Energy and Commerce.
- **Nov 2, 2012:** Referred to the Subcommittee on Health.