HR 2186

VALID Compounding Act

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: May 23, 2013
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 24, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/2186

Sponsor

Name: Rep. Markey, Edward J. [D-MA-5]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Clay, Wm. Lacy [D-MO-1]	D · MO		May 23, 2013
Rep. Rangel, Charles B. [D-NY-13]	D · NY		May 23, 2013
Rep. Slaughter, Louise McIntosh [D-NY-25]	D · NY		May 23, 2013
Rep. Eshoo, Anna G. [D-CA-18]	D · CA		Jun 12, 2013

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 24, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 23, 2013)

Verifying Authority and Legality In Drug Compounding Act of 2013 or VALID Compounding Act - Amends the Federal Food, Drug, and Cosmetic Act with respect to the regulation of compounding drugs.

Requires the Secretary of Health and Human Services (HHS) to develop and maintain a list of bulk substances from which drug products may be compounded that specifies any limitation on compounding of the substance and the particular medical need that is met by placing such substance on the list. Requires the Secretary to receive and consider petitions from any person identifying a substance that should be added to or removed from the list. Sets forth requirements for such petitions. Requires the Secretary also to develop and maintain a list of drug products that should not be compounded.

Allows a pharmacy to compound drugs which are not for an identified individual patient based on the receipt of a prescription order if the pharmacy registers with the Secretary and agrees to comply with any condition of operation or limitation of activity the Secretary specifies. Sets forth information that must be included in any such registration.

Authorizes the compounding of a drug that is a copy of a commercially available drug product if: (1) the drug is on the drug shortage list with notice given to the Secretary by the pharmacy, or (2) the drug product is necessary to protect public health and well-being. Requires the pharmacy to demonstrate to the Secretary that controls will be used that are comparable to elements required for safe use for a drug subject to a risk evaluation and mitigation strategy.

Requires the Secretary to establish standards, processes, and procedures for high-risk sterile compounding.

Establishes requirements related to inspections, labeling, and adverse event reporting for compounded drugs.

Requires the Secretary to assess an annual establishment fee from compounding pharmacies and a reinspection fee for any pharmacy subject to a reinspection in a fiscal year. Sets forth a methodology for setting such fees and requires reduced fees for small businesses (pharmacies with $1 million or less in annual sales).

States that the requirements of this Act do not preempt any non-federal requirement that is in addition to, and compatible with, such requirements.

Actions Timeline

- **May 24, 2013:** Referred to the Subcommittee on Health.
- **May 23, 2013:** Introduced in House
- **May 23, 2013:** Referred to the House Committee on Energy and Commerce.