

HR 3089

Compounding Clarity Act of 2013

**Congress:** 113 (2013–2015, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Sep 12, 2013

**Current Status:** Referred to the House Committee on Energy and Commerce.

**Latest Action:** Referred to the House Committee on Energy and Commerce. (Sep 12, 2013)

**Official Text:** <https://www.congress.gov/bill/113th-congress/house-bill/3089>

Sponsor

**Name:** Rep. Griffith, H. Morgan [R-VA-9]

**Party:** Republican • **State:** VA • **Chamber:** House

Cosponsors (6 total)

| Cosponsor                        | Party / State | Role | Date Joined  |
|----------------------------------|---------------|------|--------------|
| Rep. DeGette, Diana [D-CO-1]     | D · CO        |      | Sep 12, 2013 |
| Rep. Green, Gene [D-TX-29]       | D · TX        |      | Sep 12, 2013 |
| Rep. Forbes, J. Randy [R-VA-4]   | R · VA        |      | Sep 16, 2013 |
| Rep. Harper, Gregg [R-MS-3]      | R · MS        |      | Sep 16, 2013 |
| Rep. Wittman, Robert J. [R-VA-1] | R · VA        |      | Sep 18, 2013 |
| Rep. Hinojosa, Ruben [D-TX-15]   | D · TX        |      | Sep 20, 2013 |

Committee Activity

| Committee                     | Chamber | Activity    | Date         |
|-------------------------------|---------|-------------|--------------|
| Energy and Commerce Committee | House   | Referred To | Sep 12, 2013 |

Subjects & Policy Tags

**Policy Area:**

Health

Related Bills

No related bills are listed.

Compounding Clarity Act of 2013 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise requirements for the regulation of compounding drugs.

Revises the exemption of compounded drugs from certain new drug, labeling, and biological product requirements. Adds an exemption for drug products compounded by a licensed pharmacist or a licensed physician, pursuant to a non-patient-specific purchase order, which: (1) will be administered by a health care practitioner within a physician's office, a hospital, or another health care setting; and (2) meet other specified criteria.

Revises requirements for exempted bulk drug substances.

Prohibits the sale of a drug product by an entity other than the pharmacy or physician that compounded it.

Directs the Secretary of Health and Human Services (HHS) to develop a system for receiving and reviewing submissions from state boards of pharmacy: (1) describing actions taken against compounding pharmacies, or (2) expressing concerns that a compounding pharmacy may be acting in violation of one or more requirements of this section. Requires the Secretary to review such submissions and determine whether the pharmacy involved may be in violation of one or more compounding requirements.

Authorizes the Secretary to inspect a pharmacy's records to determine whether the pharmacy is in violation of one or more FFDCA requirements.

Exempts from certain new drug, labeling, and biological product requirements a drug product compounded for human use by a licensed pharmacist in a registered outsourcing facility if specified conditions, including labeling requirements, are met.

Establishes annual registration requirements for any outsourcing facility. Requires a facility to report to the Secretary biannually on what drugs are compounded in it and to submit adverse event reports. Subjects such facilities to a risk-based inspection schedule.

Requires the Secretary to: (1) publish a list of drugs presenting demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug, taking into account the risk and benefits to patients; and (2) convene an advisory committee on compounding before creating the list.

Requires the Secretary to assess an annual establishment fee on each outsourcing facility and a reinspection fee, as necessary.

Prohibits the intentional falsification of a required prescription, a purchase order, or patient name for a compounded drug.

Prohibits the intentional failure of an outsourcing facility to register.

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## **Actions Timeline**

- **Sep 12, 2013:** Introduced in House
- **Sep 12, 2013:** Referred to the House Committee on Energy and Commerce.

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