HR 3019

S.A.F.E. Compounded Drugs Act of 2013

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: Aug 2, 2013
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Aug 2, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/3019

Sponsor

Name: Rep. DeLauro, Rosa L. [D-CT-3]
Party: Democratic • **State:** CT • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Conyers, John, Jr. [D-MI-13]	D · MI		Aug 2, 2013
Rep. Ellison, Keith [D-MN-5]	D · MN		Aug 2, 2013
Rep. Honda, Michael M. [D-CA-17]	D · CA		Aug 2, 2013
Rep. Lowey, Nita M. [D-NY-17]	D · NY		Aug 2, 2013

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 2, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 2, 2013)

Supporting Access to Formulated and Effective Compounded Drugs Act of 2013 or S.A.F.E. Compounded Drugs Act of 2013 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to the regulation of compounded drugs.

Eliminates authority for compounding pharmacies to compound any drug product that is a copy of a commercially available drug. Prohibits such pharmacies from compounding: (1) any drug product appearing on a list of active ingredients and dosage forms that the Secretary of Health and Human Services (HHS) determines should not be compounded, or (2) in violation of promulgated minimum standards for the safe production of compounded drug products.

Establishes notification requirements before a patient is prescribed, dispensed, or administered a compounded drug, which must include providing the patient a document concerning the availability, safety, and production of such drugs.

Requires a drug product compounded under the FFDCA to be clearly labeled as a “non-FDA approved compounded drug product.” Authorizes the Secretary of Health and Human Services (HHS) to establish different labeling requirements for compounded drugs.

Requires the Secretary to establish a process for pharmacies to register as compounding pharmacies. Exempts pharmacies that employ fewer than 20 full-time employees and perform traditional compounding of drug products for use in a single state.

Requires the Secretary to: (1) establish a database of information on compounding pharmacies licensed in more than one state for oversight purposes, (2) establish minimum standards for the safe production of compounded drugs as well as for which drugs must meet those standards, and (3) conduct regional training for state agencies that regulate compounding pharmacies.

Directs the Secretary to establish advisory committees on labeling of compounded drugs and on the database under this Act. Requires the Secretary to convene an Advisory Committee on Pharmacy Compounding as appropriate to consider issues related to the safety and availability of compounded drugs.

Directs the Comptroller General (GAO) to review: (1) the extent to which federal health care programs ensure that compounded drug products they pay for are compounded in FFDCA-compliant facilities, (2) whether the reimbursement rates for such products under these federal programs are appropriate, and (3) whether these programs encourage the use of compounded drug products in place of otherwise available lawfully marketed drug products.

Prescribes criminal penalties for violations of prohibitions concerning compounded drug products that are committed: (1) knowingly and intentionally to defraud or mislead, or (2) with conscious or reckless disregard of a risk of death or serious bodily injury.

Actions Timeline

- **Aug 2, 2013:** Introduced in House
- **Aug 2, 2013:** Sponsor introductory remarks on measure. (CR E1223)
- **Aug 2, 2013:** Referred to the House Committee on Energy and Commerce.
- **Aug 2, 2013:** Referred to the Subcommittee on Health.