

HR 167

Patient Access to Urgent-Use Pharmacy Compounding Act of 2023

Congress: 118 (2023–2025, Ended)

Chamber: House

Policy Area: Health

Introduced: Jan 9, 2023

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jan 20, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/house-bill/167>

Sponsor

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

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

Cosponsors (12 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Cuellar, Henry [D-TX-28]	D · TX		Jan 9, 2023
Rep. Duncan, Jeff [R-SC-3]	R · SC		Mar 28, 2023
Rep. Harshbarger, Diana [R-TN-1]	R · TN		May 15, 2023
Rep. Palmer, Gary J. [R-AL-6]	R · AL		Jun 5, 2023
Rep. Carter, Earl L. "Buddy" [R-GA-1]	R · GA		Jun 30, 2023
Rep. Dunn, Neal P. [R-FL-2]	R · FL		Jul 25, 2023
Rep. Lesko, Debbie [R-AZ-8]	R · AZ		Aug 25, 2023
Rep. Miller-Meeks, Mariannette [R-IA-1]	R · IA		Aug 29, 2023
Rep. Moolenaar, John R. [R-MI-2]	R · MI		Sep 21, 2023
Rep. Pocan, Mark [D-WI-2]	D · WI		Dec 11, 2023
Rep. Nickel, Wiley [D-NC-13]	D · NC		Jan 25, 2024
Rep. Cline, Ben [R-VA-6]	R · VA		Mar 20, 2024

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jan 20, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Patient Access to Urgent-Use Pharmacy Compounding Act of 2023

This bill relaxes certain requirements for compounding drugs that are facing shortages.

Drug compounding is the process of mixing or otherwise altering drugs to create a medication. Currently, the Food and Drug Administration (FDA) allows for drug compounding subject to certain requirements. Generally, a licensed pharmacist or physician not registered with the FDA may only compound drugs in limited quantities for prescriptions for a specific individual patient. On the other hand, an FDA-registered outsourcing facility may compound drugs in bulk for use in medical facilities but is subject to additional requirements.

This bill allows a compounder not registered with the FDA to compound drugs in limited quantities for an urgent medical need not involving a specific patient if, among other requirements (1) the prescriber certifies that the prescriber is unable, despite reasonable attempts, to obtain certain related drugs with the same active ingredient and route of administration; (2) the compounded drug meets certain labeling requirements, including an indication that the compounded drug is provided only for urgent administration to a patient; and (3) the compounder requests and maintains certain records about patients receiving the compounded drug.

Furthermore, a restriction against an unregistered compounder regularly compounding (or compounding inordinate amounts of) what is essentially a copy of a commercially available drug shall not apply if the drug is on a shortage list maintained by the FDA or the American Society of Hospital Pharmacists.

Actions Timeline

- **Jan 20, 2023:** Referred to the Subcommittee on Health.
- **Jan 9, 2023:** Introduced in House
- **Jan 9, 2023:** Referred to the House Committee on Energy and Commerce.