

HR 3662

Patient Access to Urgent-Use Pharmacy Compounding Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: House

Policy Area: Health

Introduced: Jun 1, 2021

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jun 2, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/house-bill/3662>

Sponsor

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

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

Cosponsors (13 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Cuellar, Henry [D-TX-28]	D · TX		Jun 1, 2021
Rep. Harshbarger, Diana [R-TN-1]	R · TN		Jun 11, 2021
Rep. Duncan, Jeff [R-SC-3]	R · SC		Jun 22, 2021
Rep. Gosar, Paul A. [R-AZ-4]	R · AZ		Jun 28, 2021
Rep. Palmer, Gary J. [R-AL-6]	R · AL		Jul 26, 2021
Rep. Dunn, Neal P. [R-FL-2]	R · FL		Jul 29, 2021
Rep. Carter, Earl L. "Buddy" [R-GA-1]	R · GA		Oct 8, 2021
Rep. Schrader, Kurt [D-OR-5]	D · OR		Oct 19, 2021
Rep. Wittman, Robert J. [R-VA-1]	R · VA		Nov 3, 2021
Rep. Smith, Adrian [R-NE-3]	R · NE		Nov 17, 2021
Rep. Lesko, Debbie [R-AZ-8]	R · AZ		Mar 16, 2022
Rep. Joyce, John [R-PA-13]	R · PA		Jun 7, 2022
Rep. Carl, Jerry L. [R-AL-1]	R · AL		Nov 3, 2022

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 2, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Patient Access to Urgent-Use Pharmacy Compounding Act of 2021

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 urgent medical need not involving a specific patient if, among other things, (1) the prescriber certifies that they are unable to obtain, despite reasonable attempts, 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

- **Jun 2, 2021:** Referred to the Subcommittee on Health.
- **Jun 1, 2021:** Introduced in House
- **Jun 1, 2021:** Referred to the House Committee on Energy and Commerce.