

## HR 5388

PREPARE ACT of 2021

**Congress:** 117 (2021–2023, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Sep 27, 2021

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Sep 28, 2021)

**Official Text:** <https://www.congress.gov/bill/117th-congress/house-bill/5388>

### Sponsor

**Name:** Rep. Spanberger, Abigail Davis [D-VA-7]

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

### Cosponsors (15 total)

Cosponsor	Party / State	Role	Date Joined
Rep. McKinley, David B. [R-WV-1]	R · WV		Sep 27, 2021
Rep. Ryan, Tim [D-OH-13]	D · OH		Nov 17, 2021
Rep. Wild, Susan [D-PA-7]	D · PA		Nov 17, 2021
Rep. Allred, Colin Z. [D-TX-32]	D · TX		Nov 30, 2021
Rep. Dean, Madeleine [D-PA-4]	D · PA		Dec 1, 2021
Rep. Bacon, Don [R-NE-2]	R · NE		Dec 2, 2021
Rep. Houlahan, Chrissy [D-PA-6]	D · PA		Dec 8, 2021
Rep. Fitzpatrick, Brian K. [R-PA-1]	R · PA		Jan 6, 2022
Rep. Costa, Jim [D-CA-16]	D · CA		Jan 14, 2022
Rep. Gottheimer, Josh [D-NJ-5]	D · NJ		Jan 18, 2022
Rep. Schrader, Kurt [D-OR-5]	D · OR		Jan 19, 2022
Rep. Bourdeaux, Carolyn [D-GA-7]	D · GA		Jan 20, 2022
Rep. Case, Ed [D-HI-1]	D · HI		Jan 25, 2022
Rep. Higgins, Brian [D-NY-26]	D · NY		Feb 11, 2022
Rep. Carson, Andre [D-IN-7]	D · IN		Aug 5, 2022

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Sep 28, 2021

### Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

Bill	Relationship	Last Action
117 S 2740	Related bill	<b>Sep 14, 2021:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## Summary (as of Sep 27, 2021)

### Promoting Readiness and Ensuring Proper Active pharmaceutical ingredient Reserves of Essential medicines Act of 2021 or the PREPARE Act of 2021

This bill establishes the Strategic Active Pharmaceutical Ingredient Reserve.

The Department of Health and Human Services (HHS) must annually publish a public list of essential generic medicines that are medically necessary to have available at all times.

HHS must report and implement a plan to establish the reserve, which must be designed to minimize the impact of an interruption or reduction in imports of (1) key starting materials (including active pharmaceutical ingredients) for essential generic medicines, and (2) finished dosage forms of essential generic medicines for which key starting materials are not imported. The plan must also contain provisions to strengthen domestic capacity for active pharmaceutical ingredient production, storage, and conversion.

Within one year of this bill's enactment, the plan must include at least 25 of the essential generic medicines on the required list. The plan must add at least 25 medicines each year until the full list is covered.

HHS must prioritize domestically manufactured key starting materials for the reserve to the maximum extent possible.

A manufacturer of an essential generic medicine that switches to an active pharmaceutical ingredient sourced through the reserve shall not have to update the approved application for that medicine.

The Government Accountability Office must report to Congress on active pharmaceutical ingredient manufacturing, including the time and costs needed to develop domestic manufacturing capabilities.

## Actions Timeline

- **Sep 28, 2021:** Referred to the Subcommittee on Health.
- **Sep 27, 2021:** Introduced in House
- **Sep 27, 2021:** Referred to the House Committee on Energy and Commerce.