

H.R. 4369, National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing Act of 2021

As passed by the House of Representatives on October 19, 2021

By Fiscal Year, Millions of Dollars	2022	2022-2026	2022-2031
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	0	0
Spending Subject to Appropriation (Outlays)	1	72	not estimated
Statutory pay-as-you-go procedures apply?	No	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2032?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

H.R. 4369 would direct the Food and Drug Administration (FDA) to award grants to the National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (NCEs) to improve the manufacturing of pharmaceuticals and would authorize the appropriation of \$100 million for the 2022-2026 period for those purposes.

H.R. 4369 would require NCEs to submit data and annual reports to FDA in collaboration with industry partners and direct FDA to submit annual reports to the Congress that include information describing the program's activities. Finally, the act would require FDA to report to the Congress on its vision and role in supporting continuous manufacturing within two years of designating an NCE.

Based on historical spending for similar activities, CBO estimates that the grant payments to NCEs and related administrative and reporting costs would cost \$72 million over the 2022-2026 period, assuming appropriation of the authorized amounts. The remaining funds would be spent after 2026.

The CBO staff contact for this estimate is Ryan Greenfield. The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.