

H.R. 4866, National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2020

As passed by the House of Representatives on September 21, 2020

By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	0	0
Spending Subject to Appropriation (Outlays)	2	70	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 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

H.R. 4866 would direct the Food and Drug Administration (FDA) to award grants to the National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs) to improve the manufacturing of pharmaceuticals, and it would authorize the appropriation of \$80 million for the 2021-2025 period for those purposes.

Based on historical spending for similar activities, CBO estimates that the grant payments to NCEs would cost \$59 million over the 2021-2025 period, assuming appropriation of the authorized amounts. The remaining funds would be spent after 2025.

H.R. 4866 would also 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 information provided by FDA, CBO projects that about seven full-time equivalent positions (mostly subject matter experts and other professionals with technical expertise) would be required each year to administer the grants and fulfill the reporting requirements, at an average cost of \$350,000 each per year. CBO estimates that those personnel and administration costs would total \$11 million over the 2021-2025 period. Such spending would be subject to the availability of appropriated funds.

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