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INSIGHT

Funding for COVID-19 Vaccines: An Overview

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The U.S. Food and Drug Administration (FDA) has authorized for emergency use Coronavirus Disease 2019 (COVID-19) vaccines sponsored by Pfizer/BioNTech and Moderna. Several other COVID-19 vaccines are currently in clinical trials; additional vaccines may become available within months. Operation Warp Speed (OWS)—the COVID-19 medical countermeasure initiative led by the Department of Health and Human Services (HHS) and the Department of Defense (DOD)—has contracted with manufacturers to purchase hundreds of millions of doses (including Pfizer/BioNTech and Moderna's vaccines) and related supplies. OWS is also planning and implementing a nationwide vaccine program.

OWS has thus far been financed largely by emergency funding provided in the coronavirus supplemental appropriations acts. In the FY2020 laws, not much was appropriated *specifically* for COVID-19 vaccine-related efforts; instead, several accounts have funding *available* for relevant activities. In FY2021, Division M of (P.L. 116-260) includes emergency appropriations directed for vaccine-specific activities. Much of the HHS supplemental funding is available for multiple years or until expended. In addition, HHS transfer authorities in the laws allow for transfers between funds in certain HHS accounts. This Insight provides overviews of supplemental appropriations for selected vaccine-related activities and available information on allocations and obligations. It does not address health care financing issues related to vaccine administration or regular appropriations.

Vaccine Research and Development, Manufacturing, and Purchase

COVID-19 vaccine research and development (R&D), manufacturing, and purchasing efforts are largely supported by OWS, a collaboration among several federal agencies, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), DOD, and others. Some vaccine R&D is supported by NIH, BARDA, and DOD separately from the OWS efforts.

Appropriations

FY2020. In two of the four FY2020 coronavirus supplemental appropriations acts (P.L. 116-123 and P.L. 116-136), funding was made available for vaccine-related efforts to accounts at NIH, DOD, and the Public Health and Social Services Emergency Fund (PHSSEF). (PHSSEF, the parent account for BARDA, is an account for the HHS Secretary that funds additional emergency preparedness and response

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activities and is regularly used for one-time and pass-through funding to address public health emergencies.) In particular, up to roughly $30 billion (accounting for set-asides and transfers) in the PHSSEF account is *available* for vaccine development, manufacturing, and purchase until September 30, 2024. These funds are also designated for other emergency response activities, such as medical supply procurement for the Strategic National Stockpile, supporting health care surge response, and the development, purchase, and manufacturing of therapeutics and diagnostics.

FY2021. Division M of P.L. 116-260 appropriates $22.945 billion to the PHSSEF account to be available for similar purposes as described above until September 30, 2024. Of the total, $19.695 billion is available to BARDA for "necessary expenses of manufacturing, production, and purchase ... of vaccines, therapeutics, and ancillary supplies." The law directs the HHS Secretary to "purchase vaccines developed using funds made available ... to respond to an outbreak or pandemic related to coronavirus in quantities determined by the Secretary to be adequate to address the public health need." Funds may reimburse obligations for vaccines and therapeutics "planning, development, preparation, and purchase" incurred prior to enactment.

Supplemental appropriations to NIH Office of the Director account could also be used, in part, for vaccine-related R&D.

Allocations, Obligations, and Reporting

According to a Government Accountability Office (GAO) report published on November 30, as of October 31, 2020, HHS had allocated about $13.8 billion in coronavirus supplemental funding for "vaccines"—including $150 million in NIH allocations and the rest in BARDA allocations. Of this allocated amount, about $13.3 billion had been obligated and $1.28 billion had been expended.

The report also states that DOD has allocated about $1.64 billion in funding from the CARES Act (P.L. 116-136) toward a medical countermeasures development portfolio. DOD has five COVID-19 vaccine development projects underway.

According to a separate November GAO report, as of October 15, OWS had announced contract awards to support six vaccines, with obligations totaling at least $10 billion and a total estimated value of at least $18 billion, with awards made by both DOD and BARDA.

P.L. 116-260 adds a reporting requirement on OWS funding that includes total obligations and funding awards exceeding $20 million by department/agency and appropriations act, to be provided not later than 30 days after enactment, and regularly updated thereafter, to the House and Senate Appropriations committees.

Vaccine Deployment and Distribution

As a part of OWS, CDC has been working with state, local, tribal, and territorial (SLTT) jurisdictions to plan and implement a nationwide vaccination program.

Appropriations

FY2020. In two COVID-19 supplemental appropriations acts (P.L. 116-123 and P.L. 116-136), CDC received a total of $6.5 billion (of which $800 million is designated global funding). Much of this funding is available broadly "to prevent, prepare for, and respond to coronavirus, domestically and internationally."

FY2021. Division M of P.L. 116-260 appropriates $8.75 billion to CDC, for "activities to plan, prepare for, promote, distribute, administer, monitor, and track coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage," to be available until September 30, 2024. Of this total, $4.5

billion is for SLTT grants (or cooperative agreements), of which $210 million is to be transferred to the Indian Health Service (IHS) for tribes and tribal organizations and a separate amount of not less than $300 million is for "high-risk and underserved populations, including racial and ethnic minority populations and rural communities." At least $1 billion in SLTT grants must be made available within 21 days, and funds can reimburse obligations incurred prior to enactment. PHSSEF appropriations described above may also be relevant.

Allocations, Obligations, and Reporting

To date, CRS could not identify an exact amount of related allocations and obligations. Funding announcements include the following:

- a contract to a company, McKesson, to manage the nationwide distribution;
- a partnership with commercial pharmacies for providing vaccines to long-term care facilities;
- SLTT grants under an existing immunization cooperative agreement—announced in September and December—and other smaller demonstration grants; and
- the first $3 billion in SLTT grants from P.L. 116-260 is to be provided by January 19, 2021.

DOD has assisted with logistics planning. Other agencies manage vaccine distribution efforts among their employees and covered populations (e.g., IHS and the Department of Veterans Affairs [VA]), in collaboration with the nationwide effort.

P.L. 116-260 adds a requirement that CDC "provide an updated and comprehensive coronavirus vaccine distribution strategy and a spend plan, to include funds already allocated for distribution" to specified congressional committees within 30 days.

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