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INSIGHT

Funding for COVID-19 Vaccines: An Overview

December 15, 2020

On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer/BioNTech's Coronavirus Disease 2019 (COVID-19) vaccine. Several other COVID-19 vaccines are currently in clinical trials or under review; additional vaccines may become available by the end of 2020. Moderna has announced preliminary Phase 3 results and is under EUA consideration. As a part of Operation Warp Speed (OWS)—the Trump Administration's COVID-19 medical countermeasure initiative led by the Department of Health and Human Services (HHS) and the Department of Defense (DOD)—the U.S. government has entered into several contracts with vaccine manufacturers to purchase hundreds of millions of doses (including Pfizer/BioNTech and Moderna's vaccine) and has also supported manufacturing and procurement of related supplies. Other OWS vaccine efforts include planning and implementation of a nationwide immunization program, public awareness, and vaccine data tracking, among others.

OWS has thus far been financed largely by emergency funding provided in the coronavirus supplemental appropriations acts. To date, not much supplemental funding has been appropriated *specifically* for COVID-19 vaccine-related efforts. Instead, funding has been provided to several accounts that *may* be used toward relevant 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 such 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. As Congress considers regular FY2021 discretionary appropriations and potential additional emergency appropriations, it may consider whether to provide additional vaccine-related 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, which represents a collaboration among several federal agencies, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), DOD, and others. As of October 29, 2020, OWS was supporting eight investigational vaccines, with six contractual partnerships announced. The terms of the contracts vary by vaccine, but

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IN11556

generally they support the development (including clinical testing), manufacturing, and/or purchase of vaccine doses. Some vaccine R&D is supported by NIH, BARDA, and DOD separately from the OWS efforts.

Appropriations

In two of the four 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 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 *may* be used for vaccine development, manufacturing, and purchase. 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.

Allocations and Obligations

According to a Government Accountability Office (GAO) report published on November 30, as of October 31, 2020, HHS had allocated about $13.9 billion in coronavirus supplemental funding for "vaccines." Of this allocated amount, about $13.3 billion had been obligated and $1.28 billion had been expended.

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.

BARDA is supporting COVID-19 vaccine-related efforts both within and separately from OWS. Detailed funding data provided by HHS to CRS shows that, as of October 31, 2020,

- $9.6 billion of BARDA funding has been allocated for COVID-19 vaccine-related efforts as a part of OWS, and
- $5.7 billion of BARDA funding has been allocated for COVID-19 vaccine-related efforts separately from OWS.

BARDA contracts have been used to support the development, manufacturing, and purchase of COVID-19 vaccines.

For NIH, HHS funding data show that about $150 million of supplemental budget authority available to the National Institute of Allergy and Infectious Diseases (NIAID) has been allocated for vaccine-related research. NIH funding data are often not categorized by research area; therefore, a total for NIH-supported COVID-19 vaccine-related research is not currently available.

The November 30 GAO 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.

Vaccine Deployment and Distribution

A vaccine distribution program, led by OWS with the Centers for Disease Control and Prevention (CDC), has begun for the Pfizer/BioNTech vaccine. CDC has been working with state and other jurisdictions to plan and implement the immunization program. Activities include, among other things, vaccine transportation and delivery; provider enrollment and training; education and awareness; preparing for

vaccine storage and handling (including procuring dry ice for storage); and readying data collection systems to track vaccine inventory, doses administered (through Immunization Information Systems), and safety/adverse event monitoring.

Appropriations

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 was designated global response funding). Much of this funding is available broadly "to prevent, prepare for, and respond to the coronavirus, domestically and internationally." Some of this funding is being used for domestic vaccine-related activities, as well as for support to jurisdictions' public health agencies, including for testing, contact tracing, and surveillance. Funding in DOD and PHSSEF accounts may also be relevant.

Allocations and Obligations

CRS could not identify an exact amount of allocations and obligations provided for vaccine distribution-related activities. As of October 31, 2020, about $3.5 billion of the total $5.7 billion available to CDC had been obligated, according to HHS funding data. CDC has funded several activities to prepare for and implement the vaccine distribution campaign. It has awarded a contract to a company, McKesson, to manage the nationwide vaccine distribution effort and announced a partnership with commercial pharmacies for providing vaccines to long-term care facility residents. It has also awarded grants to state and other jurisdictions under an existing immunization cooperative agreement and for other demonstration programs to support preparation for a vaccine campaign. DOD has assisted with logistics planning. Other agencies are to manage vaccine distribution efforts among their employees and covered populations (e.g., the Indian Health Service [IHS] and the Department of Veterans Affairs [VA]), in collaboration with the nationwide effort.

In terms of expected spending, the HHS CARES Act spend plan does not identify planned vaccine distribution-related spending. An HHS response to questions from the National Governors Association indicates that states and other jurisdictions would receive an additional $140 million by December 15, 2020. It also indicates further spending for "expanding vaccine safety systems, connecting vaccine information systems, centralized distribution costs and support to state and local communication programs to encourage vaccination."

Author Information

Kavya Sekar
Analyst in Health Policy

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