



April 2021

COVID-19

Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation

GAO@100 Highlights

Highlights of [GAO-21-443](#), a report to congressional addressees

Why GAO Did This Study

Providing the public with safe and effective vaccines to prevent COVID-19 is crucial to mitigating the public health and economic impacts of the disease. The U.S. had almost 30 million reported cases and over 545,000 reported deaths as of March 27, 2021. The federal government took a critical step in December 2020 in authorizing the first two COVID-19 vaccines and beginning distribution of doses across the nation. The government had distributed about 180.6 million vaccine doses, and about 147.8 million doses had been administered, as of March 27, 2021, according to Centers for Disease Control and Prevention (CDC) data.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report examines, among other issues, actions the federal government has taken to increase the availability of COVID-19 vaccine doses, and challenges with initial vaccine implementation—that is, prioritizing, allocating, distributing, and administering vaccine doses—identified by stakeholders and steps the federal government has taken to improve vaccine implementation.

GAO reviewed documents from the Departments of Defense and Health and Human Services, transcripts of public briefings, data from CDC, and interviewed or received written responses from federal officials, vaccine company representatives, and select public health stakeholders. GAO incorporated technical comments from the Department of Defense, the Department of Health and Human Services, and the Federal Emergency Management Agency as appropriate.

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What GAO Found

The federal government has taken several actions to increase the availability of COVID-19 vaccine doses and indicated it expects to have enough doses available for all adults in the United States by the end of May. As of April 1, 2021, the government had purchased 1.2 billion doses of one- and two-dose regimen vaccines. Also, vaccine companies reported making additional manufacturing sites operational, among other actions to expand capacity and mitigate challenges.

Federal officials said projecting future availability of vaccine doses can be difficult, in part because of uncertainty surrounding complex manufacturing processes. Given this uncertainty, coupled with the significant manufacturing and distribution increases needed to have enough vaccine doses available for all adults, managing public expectations is critical. GAO's prior work has found that timely, clear, and consistent communication about vaccine availability is essential to ensure public confidence and trust, especially as initial vaccine implementation did not match expectations.

COVID-19 Vaccination Site



Source: GAO. | GAO-21-443

Stakeholders GAO interviewed identified challenges with initial COVID-19 vaccine implementation. For example, some stakeholders said states often did not have information critical to distribution at the local level, such as how many doses they would receive and when. The federal government has begun initiatives—outlined in a national response strategy—to improve implementation, such as creating new vaccination sites. In its March 2021 distribution strategy, CDC provided a high-level description of its activities and noted that more details would be included in future reports to Congress. To meet the expectations set by recent announcements, such as the planned expansion of vaccine eligibility to all adults and the introduction of tools to help individuals find vaccines, it will be imperative that the federal government effectively coordinate and communicate its plans, as GAO recommended in September 2020.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
DOD	Department of Defense
EUA	emergency use authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
National Strategy	National Strategy for the COVID-19 Response and Pandemic Preparedness

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April 14, 2021

Congressional Addressees

Providing the public with safe and effective vaccines to prevent Coronavirus Disease 2019 (COVID-19) is crucial to mitigating the public health and economic impacts of the disease and ending the pandemic. There have been almost 30 million reported cases of COVID-19 and over 545,000 reported deaths in the United States as of March 27, 2021.¹ Given this catastrophic loss of life and the pandemic's devastating effects on the U.S. economy, as well as new potentially harmful variants of SARS-CoV-2, the virus that causes COVID-19, vaccines are essential for preventing COVID-19 and related serious outcomes, such as hospitalization or death.

In December 2020, the United States took an important step to protect the public against COVID-19 as the first COVID-19 vaccines—developed in a shorter time than any previous vaccine—were authorized for emergency use and administered.² With three COVID-19 vaccines now authorized for emergency use as of March 27, 2021, more than 91.7 million people had received at least one vaccine dose and more than 50.1

¹Data on COVID-19 cases in the U.S. are based on aggregate case reporting to the Centers for Disease Control and Prevention (CDC) and include probable and confirmed cases as reported by states and jurisdictions. CDC COVID-19 counts are subject to change due to delays or updates in reported data from states and territories. According to CDC, the actual number of COVID-19 cases is unknown for a variety of reasons, including that people who have been infected may have not been tested or may not have sought medical care. CDC's National Center for Health Statistics COVID-19 death counts in the U.S. are based on provisional counts from death certificate data, which do not distinguish between laboratory-confirmed and probable COVID-19 deaths. Provisional counts are incomplete due to an average delay of 2 weeks (a range of 1–8 weeks or longer) for death certificate processing.

²For more information on the accelerated COVID-19 vaccine development process, see GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*. [GAO-21-319](#), (Washington, D.C.: Feb. 11, 2021). GAO has also produced an interactive dashboard that integrates multiple data sources to visualize the status of vaccine development, which may be found at <https://ows.gaoinnovations.gov/>.

million people had been fully vaccinated, according to Centers for Disease Control and Prevention (CDC) data.³

Implementing a nationwide COVID-19 vaccination program is a highly complex undertaking involving many players. It involves multiple federal agencies, the private sector, state, local, and territorial jurisdictions, tribal officials, and health care providers, who must coordinate and work together to make the vaccine available to the public.⁴ At the federal level, efforts to support vaccine development, manufacturing, and distribution to states and other jurisdictions have been led by a partnership between the Department of Defense (DOD) and the Department of Health and Human Services (HHS) announced in May 2020, then known as Operation Warp Speed. As of January 20, 2021, the federal government no longer uses the name Operation Warp Speed, but the DOD and HHS partnership has continued.⁵

Through Operation Warp Speed and the continued DOD and HHS partnership, the federal government has obligated at least \$20 billion as of March 14, 2021, mostly through awards to six vaccine companies for COVID-19 vaccine candidates, with various development and manufacturing activities associated with these awards. Initial awards made from March 2020 through June 2020 were generally to fund vaccine development efforts, including clinical trials, and later awards made from July 2020 through December 2020 were generally for vaccine manufacturing or the purchase of vaccine doses. Since then, the

³Two of the COVID-19 vaccines being administered as of this date were two-dose vaccine regimens and one was a single dose. According to CDC, the count of people receiving at least one dose represents the total number of people who received at least one dose of a COVID-19 vaccine, including those who received the single-dose vaccine. The count of fully vaccinated people represents the number of people who have received the second dose of a two-dose COVID-19 vaccine regimen and those who received the single-dose COVID-19 vaccine.

⁴For COVID-19 vaccination there are 64 jurisdictions including all 50 states, territories, and local health programs in Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio.

⁵DOD and HHS's partnership is to continue through May 1, 2021, per an extension of a memorandum of understanding between the two departments. According to officials working under Operation Warp Speed and the continued partnership, the leadership structure is generally the same, but personnel in some key senior leadership positions have changed. In this report, we use "Operation Warp Speed" to reference the actions the partnership had taken while it was operating under that name and refer to the "DOD and HHS partnership" for actions after January 20, 2021.

government has purchased additional vaccine doses through exercising options on previously awarded contracts.

Since June 2020, we have cited the critical importance of planning for the development, manufacturing, distribution, and administration of COVID-19 vaccines.⁶ We recommended, in September 2020, that the Secretary of Health and Human Services, with support from the Secretary of Defense, establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccines, ensure that such a plan is consistent with best practices for project planning and scheduling, and ensure that the plan outlines an approach for how efforts would be coordinated across federal agencies and nonfederal entities.

We also have noted the importance of timely, clear, and consistent communication to stakeholders like state, territorial, and local health officials and health care providers, as well as to the public about vaccine availability, effectiveness, and safety to help ensure public confidence and trust, which in turn could encourage vaccine use. In January 2021, we reported that initial vaccine implementation did not match expectations, and we reiterated the vital importance of federal planning, leadership, and coordination.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic.⁷ This report is part of our body of work in response to the CARES Act and focuses on the federal government's efforts related to COVID-19 vaccines. Specifically, in this report, we describe

- (1) how the initial awards made under Operation Warp Speed address specific terms and conditions, including government rights to intellectual property;
- (2) actions the federal government has taken to increase the availability of COVID-19 vaccine doses;

⁶We have released a series of products on the federal government's response to COVID-19 since June 2020, including the government's efforts related to COVID-19 vaccines and therapeutics. See the related products section of this report for a list of those products.

⁷Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020). This report also responds, in part, to a bipartisan request from the House Select Subcommittee on the Coronavirus Crisis for GAO to examine Operation Warp Speed.

(3) challenges with initial vaccine implementation—that is, prioritizing, allocating, distributing, and administering vaccine doses—identified by stakeholders and steps the federal government has taken to improve vaccine implementation.

To describe how the awards made under Operation Warp Speed address specific terms and conditions—such as pricing, payment, termination terms and conditions, and government rights to intellectual property and data—we reviewed DOD and HHS acquisition documents related to Operation Warp Speed, including award documents, statements of work, and related amendments for the six vaccine candidates for awards made from March 2020 through November 2020.⁸ We reviewed data reported by Federal Procurement Data System-Next Generation through March 14, 2021 and agreements from DOD, HHS, and Advanced Technology International.⁹ All award amounts are based on Federal Procurement Data System-Next Generation obligations data. We assessed the reliability of data reported to the Federal Procurement Data System-Next Generation by performing electronic testing and by comparing this information to the contract documents we obtained. We determined that the data were sufficiently reliable for the purposes of describing agencies' reported contract obligations for the six vaccine candidates and other vaccine-related obligations. In addition, we interviewed DOD and HHS officials and coordinated with all six vaccine companies to better understand their perspectives on the intellectual property provisions, termination and payment terms and conditions, and the implications of the foregoing.

To describe actions the federal government has taken to increase the availability of COVID-19 vaccines doses, we reviewed information and data from Operation Warp Speed and the continued DOD and HHS partnership on the purchase, manufacture, and release of COVID-19 vaccine doses from July 2020 through March 2021.¹⁰ We also reviewed

⁸The six companies with COVID-19 vaccine candidates are AstraZeneca, Janssen, Moderna, Novavax, Pfizer/BioNTech, and Sanofi/GSK. For the purpose of this report, we refer to the Pfizer/BioNTech collaboration as "Pfizer" and to the Sanofi/GSK collaboration as "Sanofi." Janssen Pharmaceutical Companies are a part of Johnson & Johnson.

⁹Advanced Technology International manages the Medical Chemical, Biological, Radiological and Nuclear Defense Consortium, a partnership with industry, academic, and not-for-profit partners to support the DOD's medical, pharmaceutical, and diagnostic requirements.

¹⁰According to DOD and HHS partnership officials, once through manufacturing and quality assurance, the vaccine doses are released for distribution.

CDC data on vaccine doses distributed to jurisdictions and federal entities as of March 27, 2021. We also interviewed or received written responses from the six companies with COVID-19 vaccine candidates and DOD, HHS, and CDC officials about the data and the actions they had taken to increase the availability of vaccines. We assessed the reliability of the data from CDC and the DOD and HHS partnership by reviewing relevant CDC documentation, such as documentation that defines data points, including any caveats, and interviewing DOD and HHS partnership officials about these data. We determined that these data were sufficiently reliable for the purposes of our reporting objective.

To describe challenges with initial vaccine implementation—that is, prioritizing, allocating, distributing, and administering vaccine doses—identified by stakeholders and steps the federal government has taken to improve vaccine implementation, we interviewed representatives of state, territorial, and local health officials and health care providers who are involved in vaccine distribution and administration efforts.¹¹ We also reviewed documentation, such as recommendations published by CDC’s Advisory Committee on Immunization Practices (ACIP), the White House’s National Strategy for the COVID-19 Response and Pandemic Preparedness (National Strategy) released in January 2021, White House fact sheets issued in January and February 2021 related to vaccine distribution, CDC’s COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex, CDC vaccine allocation data, and vaccine administration data from CDC’s COVID Data Tracker website,

¹¹For perspectives of state, territorial, and local health officials, we reviewed documents from and interviewed representatives from the Association of State and Territorial Health Officials, Association of Immunization Managers, American Immunization Registry Association, and the National Association of County and City Health Officials. We also interviewed one public health infectious disease specialist who also serves as the Health Officer for Public Health for a county that includes a major metropolitan area. We also interviewed officials from the National Governors Association.

For perspectives of health care providers, we interviewed representatives from the American Hospital Association, American Medical Association, American Nurses Association, American College of Emergency Physicians, America’s Essential Hospitals, Association for Health Care Resource & Materials Management, American Public Health Association, and the National Association of Community Health Centers.

among others.¹² In addition, we interviewed and reviewed written responses from HHS and DOD officials, including officials from their partnership and CDC, and reviewed documentation such as transcripts from briefings during which the Secretary of Health and Human Services or other federal officials provided information to the public about vaccine distribution and administration efforts.

We conducted this performance audit from October 2020 to April 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

DOD and HHS Partnership and COVID-19 Vaccines

To accelerate the availability of a vaccine to prevent COVID-19, DOD, on behalf of HHS, awarded contracts and other transaction agreements (referred to in this report as “agreements”) in 2020 to six vaccine companies for different types of activities.¹³ Operation Warp Speed officials indicated in August 2020 that they selected the six vaccine candidates from three vaccine-platform technologies that they considered to be the most likely to quickly yield a safe and effective vaccine.¹⁴

As of March 14, 2021, DOD and HHS had obligated at least \$20 billion to develop, manufacture, track, and distribute vaccines for COVID-19 under

¹²See White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021), accessed on January 21, 2021 at <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf> and Department of Health and Human Services, Centers for Disease Control and Prevention, COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex (Atlanta, Ga.: Jan. 11, 2021), accessed on February 4, 2021, <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vaccination-program-playbook-annex.pdf>. For the CDC data tracker see <https://covid.cdc.gov/covid-data-tracker/#vaccinations> (accessed Mar. 1, 2021).

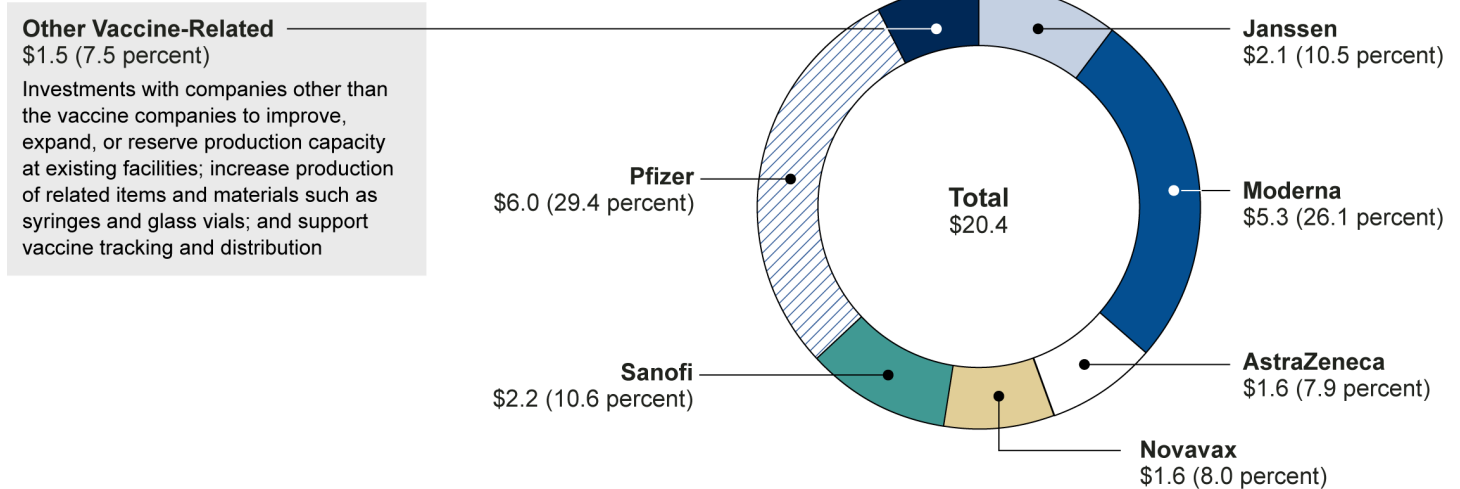
¹³For example, for some vaccine candidates, Operation Warp Speed and the continued DOD and HHS partnership publicly announced support for both clinical development and manufacturing activities; while for some candidates, it only announced support for the manufacturing or purchase of vaccine doses.

¹⁴For more information on the characteristics and development status of the individual Operation Warp Speed vaccine candidates, see [GAO-21-319](#).

Operation Warp Speed and the continued DOD and HHS partnership, as shown in figure 1 below.

Figure 1: Department of Defense (DOD) and Department of Health and Human Services (HHS) Obligations for COVID-19 Vaccine Candidates under the DOD and HHS Partnership, as of March 14, 2021

Dollars in billions



Source: GAO analysis of Federal Procurement Data System – Next Generation data. | GAO-21-443

Note: The DOD and HHS partnership was formerly known as Operation Warp Speed. We used the HHS Operation Warp Speed website and HHS press releases to determine which contract obligations to include in our analysis. For some vaccine candidates, Operation Warp Speed and the continued DOD and HHS partnership publicly announced support for both clinical development and manufacturing activities; while for some candidates, it only announced support for the manufacturing or purchase of vaccine doses. HHS announced two awards related to distribution for which we could not identify obligations in the Federal Procurement Data System-Next Generation, which are not included in the chart above.

Typically, before a vaccine can be marketed in the United States, it must be licensed by the Food and Drug Administration (FDA).¹⁵ An emergency

¹⁵FDA—an agency within HHS—licenses biological products, including vaccines, through review of a biologics license application.

use authorization (EUA) allows for the temporary use of vaccines without FDA licensure, provided certain statutory criteria are met.¹⁶

As of March 27, 2021, FDA had issued EUAs for three COVID-19 vaccines: (1) Pfizer’s COVID-19 vaccine on December 11, 2020; (2) Moderna’s COVID-19 vaccine on December 18, 2020, and (3) Janssen’s COVID-19 vaccine on February 27, 2021.¹⁷ There were no FDA-licensed COVID-19 vaccines, as of March 27, 2021.¹⁸ See table 1 for the status of each of the six vaccine candidates under the DOD and HHS partnership, as of March 27, 2021.

Table 1: Status of Six COVID-19 Vaccine Candidates under the DOD and HHS Partnership, as of March 27, 2021

Vaccine company	Started phase 3 clinical trials ^a	Announced initial findings from phase 3 clinical trials	Submitted emergency use authorization (EUA) request to FDA ^b	FDA issued EUA
Pfizer	•	•	•	•
Moderna	•	•	•	•
Janssen ^c	•	•	•	•
AstraZeneca	•	•		

¹⁶The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products, such as vaccines. Once a declaration of an emergency has been made, FDA may temporarily allow use of unlicensed vaccines through an EUA. For FDA to issue an EUA for a vaccine, it must be reasonable to believe that the vaccine may be effective and that the known and potential benefits of the vaccine outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3.

¹⁷On February 4, 2021, FDA announced that it was assessing the impact of new SARS-CoV-2 strains on authorized vaccines, and was working with companies and international partners to evaluate the impact that each variant may have on the effectiveness of authorized vaccines. FDA also stated that at the time, available information suggested that the authorized vaccines remained effective in protecting the American public against currently circulating strains of COVID-19. On February 22, 2021, FDA released an updated version of its October 2020 guidance, *Emergency Use Authorization for Vaccines to Prevent COVID-19*, to provide recommendations to companies seeking to amend their EUAs for COVID-19 vaccines to address new variants.

On Tuesday, April 13, 2021, CDC and FDA released a joint statement recommending a pause in the use of Janssen vaccine while CDC and FDA review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving this vaccine. CDC and FDA’s announcement occurred after we finalized our analyses for this report, but we will continue to monitor this in our future work.

¹⁸Any COVID-19 vaccine that initially receives an EUA from FDA is expected to ultimately be reviewed and receive licensure through a biologics license application, according to FDA guidance.

Vaccine company	Started phase 3 clinical trials ^a	Announced initial findings from phase 3 clinical trials	Submitted emergency use authorization (EUA) request to FDA ^b	FDA issued EUA
Novavax	•	• ^d		
Sanofi	e			

Source: GAO analysis of vaccine company, Operation Warp Speed, and Food and Drug Administration (FDA) information. | GAO-21-443

Note: The partnership between the Department of Defense (DOD) and the Department of Health and Human Services (HHS) was formerly known as Operation Warp Speed.

^aPhase 3 clinical trials are performed after preliminary evidence suggesting effectiveness of a product has been obtained, and are intended to gather additional information about safety and effectiveness. These trials involve several hundred to thousands of volunteers, usually including participants who are at increased risk for infection. Earlier phases generally involve fewer volunteers and test issues such as safety of the product (phase 1) and the effectiveness of the product for a particular use and additional safety information (phase 2).

^bDuring an emergency, as declared by the Secretary of Health and Human Services under 21 U.S.C. § 360bbb-3(b), FDA may temporarily authorize unlicensed vaccines through an EUA, provided certain statutory criteria are met. FDA has indicated that issuance of an EUA for a COVID-19 vaccine for which there is adequate manufacturing information would require a determination by FDA that the vaccines benefits outweigh its risks based on data from at least one well-designed phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner. Any COVID-19 vaccine that initially receives an EUA from FDA is expected to ultimately be reviewed and receive licensure through a biologics license application, according to FDA guidance.

^cJanssen Pharmaceutical Companies are a part of Johnson & Johnson.

^dNovavax has announced findings from its final analysis of phase 3 clinical trial data from the United Kingdom. As of March 27, 2021, it had not yet announced findings based on its phase 3 clinical trial in the United States.

^eSanofi announced in December 2020 that global phase 3 clinical trials could start during the second quarter of 2021; pending positive data from a phase 2 study expected to start in February 2021. On February 22, 2021, Sanofi announced the start of its phase 2 study.

COVID-19 Vaccine Manufacturing and Related Challenges

The six vaccine companies with candidates under the DOD and HHS partnership are working with different manufacturing partners, as of March 2021, to make use of available manufacturing capacity, as shown in table 2. These U.S. manufacturing partners are located at sites across the country.

Table 2: Manufacturing Partners for the Six COVID-19 Vaccine Candidates under the DOD and HHS Partnership, as of March 2021

Vaccine company	Drug substance manufacturing partners for U.S. market ^a	Fill-Finish manufacturing partners for U.S. market ^b
Pfizer	All manufacturing is currently being conducted by Pfizer	All manufacturing is currently being conducted by Pfizer
Moderna	Lonza	Baxter BioPharma Solutions and Catalent

Vaccine company	Drug substance manufacturing partners for U.S. market ^a	Fill-Finish manufacturing partners for U.S. market ^b
Janssen	Emergent BioSolutions and Merck ^c	Catalent, Grand River Aseptic Manufacturing, Merck ^c , and PCI Pharma Services
AstraZeneca	Emergent BioSolutions	AMRI and PCI Pharma Services
Novavax	AGC Biologics and Fuji Diosynth Biotechnologies	Jubilant HollisterStier and Par Sterile Products
Sanofi	Fuji Diosynth Biotechnologies	Sanofi has not yet begun fill-finish manufacturing for its vaccine candidate

Source: GAO analysis of information from vaccine companies. | GAO-21-443.

Note: The Department of Defense (DOD) and Department of Health and Human Services (HHS) partnership was formerly known as Operation Warp Speed.

^aDrug substance manufacturing is the production of bulk amounts of the vaccine drug substance.

^bFill-finish manufacturing is the transfer of vaccine into sterile containers.

^cAs of March 2021, the Merck drug substance and fill-finish facilities had not yet been activated and will not be used to produce any of the initial 100 million COVID-19 vaccine doses that Janssen provides to the U.S. government, according to a Janssen representative.

As we reported in November 2020 and February 2021, the federal government is working with vaccine companies to help mitigate challenges that could hinder vaccine manufacturing, including:

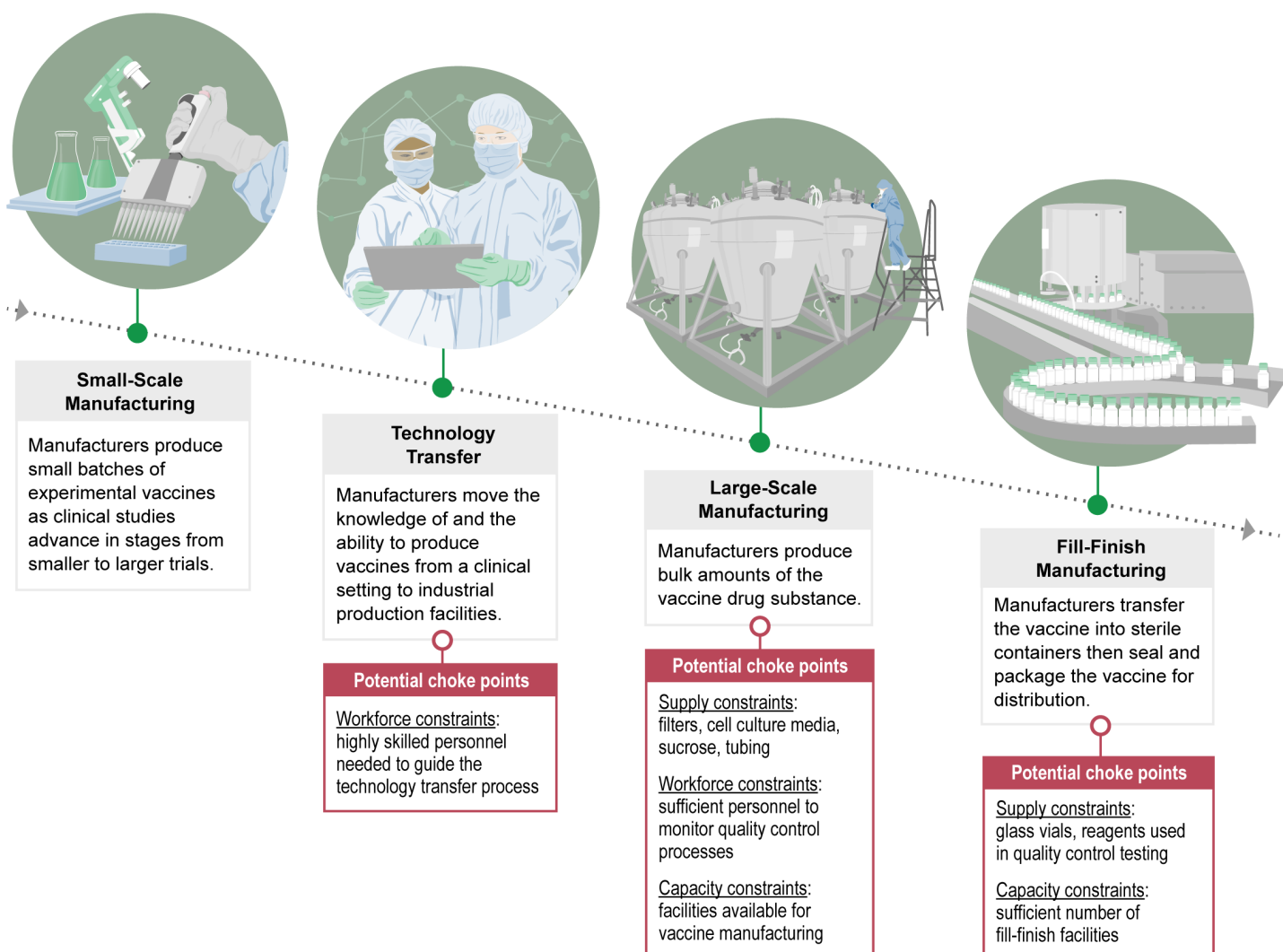
- (1) limited manufacturing capacity,
- (2) disruption to supply chains,
- (3) difficult technology transfer processes, and
- (4) gaps in workforce availability.¹⁹

There are a number of potential manufacturing choke points that could result from those manufacturing challenges, as shown in figure 2 below. For example, the ability to hire and train personnel with the specialized skills needed to run vaccine manufacturing processes can be a challenge for even experienced manufacturers. We heard from representatives at a facility manufacturing COVID-19 vaccines that filling open positions for mid- to upper management had been a challenge. These positions are

¹⁹GAO-21-319; GAO, *COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations*, GAO-21-207 (Washington, D.C.: Nov. 17, 2020).

significant because manufacturing managers function as the technical points of contact for production questions and are responsible for managing safety, quality, and compliance with current good manufacturing practices.

Figure 2: Potential Choke Points in Scaling Up Vaccine Production Related to Key Manufacturing Challenges



Source: GAO analysis of information from literature reviews and interviews with industry representatives and federal officials. | GAO-21-443

Implementation of COVID-19 Vaccines

Vaccine implementation, following authorization or licensure, involves several key steps (which may happen concurrently) and various stakeholders. The stakeholders include several federal agencies and multiple state and local stakeholders, including the DOD and HHS partnership, CDC, private industry, jurisdictions, local health departments, tribal officials, and health care providers.

- **Prioritization.** ACIP issues recommendations to the CDC Director for target groups to receive initial vaccine doses based on its review of data, including vaccine safety and efficacy data.²⁰ These recommendations as adopted are not binding on jurisdictions, and jurisdictions can adopt different approaches. In addition, the Secretary of Health and Human Services may issue directives regarding prioritization and eligibility for COVID-19 vaccinations, according to HHS.
- **Allocation.** The DOD and HHS partnership determines the amount of COVID-19 vaccine allocated for 64 jurisdictions, which include all U.S. states, territories, the District of Columbia and local health programs in Chicago, Houston, New York City, Philadelphia, and San Antonio.²¹ According to DOD and HHS partnership officials, allocations are based on each jurisdiction's adult population. The partnership also allocates additional doses to jurisdictions for American Indian/Alaskan Native populations that elected to receive vaccines through the state

²⁰Within priority groups are separate target groups that are added as vaccine supply increases. For example, ACIP recommended that when vaccine supplies are not sufficient to meet demand, vaccine should be offered in phases. In December 2020, ACIP recommended that phase 1 include the target groups of 1a (residents of long-term care facilities and health care workers), 1b (persons 75 years and older and frontline essential workers), and 1c (persons aged 65-74 years and persons aged 16-64 years with medical conditions that increase the risk for severe COVID-19). ACIP is comprised of medical and public health experts who make recommendations on the use of vaccines in the civilian population of the United States. Its recommendations serve as public health guidance for safe use of vaccines and other related products. If adopted by the CDC Director, ACIP's recommendations are published as official HHS/CDC recommendations in the *Morbidity and Mortality Weekly Report*. See *COVID-19 ACIP Vaccine Recommendations*, accessed March 9, 2021, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>.

²¹Included in the vaccines allocated to the jurisdictions were vaccine doses for the federal government's Pharmacy Partnership for Long-Term Care Program, which has facilitated on-site vaccination of residents and staff at long-term care facilities. In addition to the vaccine doses allocated to the 64 jurisdictions, the DOD and HHS partnership directly allocates vaccine doses to five federal entities (the Bureau of Prisons, DOD, Department of State, Indian Health Service, and Veterans Health Administration).

instead of through the Indian Health Service.²² According to HHS data, 10 jurisdictions are receiving these additional doses—called “Sovereign Nation Supplements” by the DOD and HHS partnership—in their allocations.

In addition, vaccine doses are also being made available through other federal efforts. For example, in February 2021, the administration announced that vaccine doses would go to specific mass vaccination clinics, pharmacy partnerships, and federally qualified health centers. These allocations are in addition to the jurisdiction and federal entity allocations.

- **Distribution.** Health care providers receiving COVID-19 vaccine doses from their jurisdictions’ allocations place orders for vaccines that the jurisdictions review and approve.²³ Vaccine doses and ancillary supplies (such as syringes) are distributed to jurisdictions and health care providers from a central distributor, except for Pfizer’s vaccine doses, which are shipped to jurisdictions and health care providers directly from the manufacturer. According to CDC, vaccine doses are considered “delivered” when the jurisdictions and other sites receive them.²⁴
- **Administration.** Health care providers administer vaccines at administration sites, including pharmacies, hospitals, long-term care facilities, federally qualified health centers, rural health centers, physician offices, colleges and universities, and mass-vaccination

²²Tribal health programs and Urban Indian Organizations can decide to receive vaccines either through the Indian Health Service or through the jurisdiction in which they are located.

²³The maximum number of doses a jurisdiction can approve for order is an order cap set for each jurisdiction based on the allocated amount. When the number of doses ordered by health care providers exceeds the jurisdiction’s order cap, not all orders will be approved.

²⁴Where vaccines are delivered within a jurisdiction can vary and depends on what jurisdictions have specified in their vaccine implementation planning. Moderna’s vaccine is delivered in lot sizes of 100 doses, while the Pfizer vaccine is delivered in lot sizes of 1,170 doses as of February 16, 2021. In some cases, vaccines are delivered to a centralized site within a jurisdiction and then further subdivided into smaller lot sizes for delivery to additional sites, such as facilities in rural areas, for administration; in other cases, vaccines are directly delivered to sites for administration, such as to large health care systems that have the needed storage and handling capability, according to CDC.

clinics.²⁵ After administration, health care providers must record the vaccination data for each individual vaccinated in the appropriate data systems for their jurisdiction within 72 hours, according to CDC.²⁶

As of March 27, 2021, CDC data showed the federal government had distributed about 180.6 million doses of COVID-19 vaccine, and health care providers reported administering about 147.8 million COVID-19 vaccine doses, which includes both first and second doses administered.²⁷ See figure 3 below for the number of doses reported to CDC as administered, for each day from mid-December 2020, when vaccine doses were first administered, through March 27, 2021.

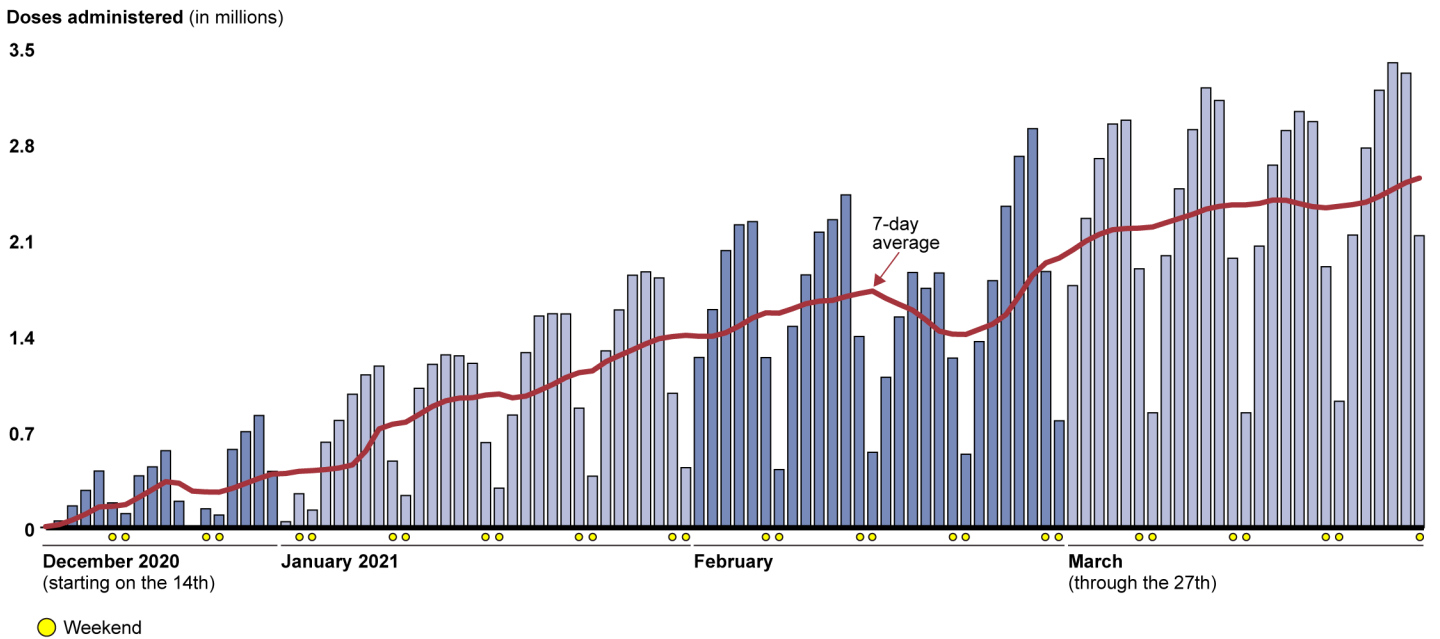
²⁵Only those providers participating in the CDC COVID-19 Vaccination Program may administer COVID-19 vaccines. These providers must sign a CDC COVID-19 Vaccination Program Provider Agreement and adhere to all requirements outlined in the agreement.

Federally qualified health centers operate as part of the Health Center Program administered by the Bureau of Primary Health Care within the Health Resources and Services Administration. The Health Center Program provides grants to federally qualified health centers under section 330 of the Public Health Service Act. See 42 U.S.C. § 254b.

²⁶For patients administered a vaccine requiring two doses, health care providers should use redundant methods and systems, such as phone calls, emails, or text messages to remind patients to obtain their second dose, according to CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.

²⁷Vaccine doses distributed is the total number that have been delivered to jurisdictions, retail pharmacies, long-term care facilities, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entities. However, for Palau, Micronesia, Marshall Islands, Guam, American Samoa, and Northern Marianas Islands, total counts of COVID-19 vaccine doses distributed include doses marked as shipped in CDC's Vaccine Tracking System since December 13, 2020.

Figure 3: Daily Count of Doses of COVID-19 Vaccine Administered and Reported to CDC as of March 27, 2021



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO 21-443

Note: Data show the number of COVID-19 vaccine doses administered in the U.S. as reported to CDC by state, territorial, and local public health agencies, and federal entities, since the national vaccine program began on December 14, 2020, and include doses administered through all vaccine partners including jurisdictional partner clinics, retail pharmacies, long-term care facilities, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entity facilities. The data were accessed April 1, 2021. As of March 27, 2021, three COVID-19 vaccines were authorized for emergency use; two of these vaccines are two-dose regimens and the third vaccine requires one dose. The number of doses administered on a given day may be affected by several factors, such as weekend days, holidays, weather, and vaccine availability. On February 19, 2021, officials from the White House COVID-19 Response Team said severe weather across the country impacted vaccine distribution and administration in all 50 states. Further, officials said the shipment of 3 days' worth of vaccine doses—about 6 million doses—was delayed due to weather.

National Strategy for COVID-19 Response and Pandemic Preparedness

On January 21, 2021, the White House issued its National Strategy for COVID-19 Response and Pandemic Preparedness.²⁸ The National Strategy identifies seven goals for a coordinated response to address the COVID-19 pandemic and outlines several ongoing and new actions to

²⁸White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021), accessed on January 21, 2021 at <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>.

help achieve the administration’s goals.²⁹ The National Strategy states that, among other things, the federal government will ensure the availability of safe, effective vaccines for the American public through actions to purchase and manufacture doses sufficient to vaccinate the U.S. population.

The Federal Government’s Contracting Approach Aimed to Accelerate Vaccine Development and Manufacturing While Mitigating Cost Risk to the Government

From March to November 2020, the federal government awarded contracts and agreements to six vaccine companies to accelerate the development of safe and effective COVID-19 vaccines while balancing the risk to the government in doing so. Specifically, during this time, the federal government made awards for vaccine development, manufacture, or purchase of an initial 600 million doses with an estimated value of \$12.8 billion.³⁰ These awards were made, according to DOD and HHS partnership officials, in anticipation that some of the vaccine candidates would subsequently receive authorization or licensure. By providing significant funding up front, these officials told us, the government took on some financial risk, which enabled the companies to accelerate vaccine development and production. However, the government also incorporated safeguards in the contracts and agreements to mitigate its financial risk, by including, for example, payment and termination language intended to limit the government’s liability if a vaccine candidate is not authorized or licensed.³¹ In effect, according to DOD officials, the government aimed to balance financial risks and help ensure that the government would

²⁹The seven goals are: (1) restore trust with the American people; (2) mount a safe, effective, and comprehensive vaccination campaign; (3) mitigate spread through expanding masking, testing, data, treatments, health care workforce, and clear public health standards; (4) immediately expand emergency relief and exercise the Defense Production Act; (5) safely reopen schools, businesses, and travel while protecting workers; (6) protect those most at risk and advance equity, including across racial, ethnic, and rural/urban lines; and (7) restore U.S. leadership globally and build better preparedness for future threats.

³⁰From March to April 2020 before Operation Warp Speed was formally established, HHS made awards to three companies—Janssen, Moderna and Sanofi—for development and/or clinical studies. After Operation Warp Speed was established in May 2020, DOD awarded additional contracts and agreements for vaccine manufacturing. We refer to all these awards as part of the Operation Warp Speed effort. The production awards allow the government to purchase additional doses through options or follow-on awards. In October, DOD made an additional award to AstraZeneca for 200 million doses. The Pfizer and Moderna vaccines received EUAs on December 11, 2020 and December 18, 2020 respectively, and the federal government awarded an additional contract and exercised a contract option for an additional 200 million doses from Pfizer, and exercised options for an additional 200 million doses from Moderna.

³¹According to DOD officials, another risk mitigation strategy included negotiating a requirement for domestic, large-scale vaccine manufacturing, which was intended to avoid manufacturing-related risks and better ensure timely delivery.

receive a sufficient number of vaccine doses, even if one or more companies' efforts failed to produce a viable vaccine.

DOD and HHS officials told us that they took a different contracting approach with each of the six vaccine companies as each came to the negotiating table with differing levels of product maturity and manufacturing capability. For example, with the exception of Pfizer, the federal government provided funding to five companies for some level of vaccine development including for activities such as preclinical and clinical trials. According to DOD and HHS partnership officials, this funding gave the government insight into vaccine development or manufacturing that it did not have with Pfizer. For example, according to these officials, the five other vaccine companies agreed to allow DOD and HHS partnership officials in their manufacturing facilities to provide in-depth visibility into production capabilities and any challenges that may arise.

Our review of awards made to the six Operation Warp Speed vaccine candidates through November 2020 found that the specific terms and conditions the federal government negotiated with the companies varied. For example:

- Pursuant to Pfizer's July 2020 agreement with the U.S. government, which awarded Pfizer \$1.95 billion, the government agreed to pay a firm-fixed-price of \$19.50 per dose for the first 100 million doses of the Pfizer COVID-19 vaccine. To minimize financial risk to the government, the parties agreed that the government would pay Pfizer only after its vaccine received authorization or licensure from FDA and as the doses were delivered. Further, Pfizer and the government agreed that if Pfizer should cease to develop the vaccine due to emerging safety or efficacy data, the government would be able to terminate the July 2020 agreement and put into effect a no-cost settlement to end the performance under the agreement within 30 days of notifying the company.
- In April 2020, HHS awarded an agreement with Moderna for \$430 million for clinical trials and other aspects of vaccine development, which included providing the government insight into the vaccine candidate's progress toward viability.³² Subsequently, in August 2020,

³²The agreement also included manufacturing scale up and validation of manufacturing capacities.

DOD awarded Moderna a production contract and obligated \$1.2 billion to manufacture 100 million doses at a price of \$12.25 per dose with options to buy 400 million more.³³ DOD agreed to pay Moderna incrementally for meeting certain milestones without requiring Moderna to first obtain an EUA or licensure.³⁴ In the event that Moderna failed to obtain an EUA or licensure, DOD would be able to terminate the contract in whole or in part. According to Operation Warp Speed officials, this approach assisted the company with cash flow by providing interim payments. Further, the government could unilaterally decide that it would not exercise any of the four options included in the award, which provided for 100 million doses each at a cost of \$16.50 per dose.

For the other four vaccine companies, the federal government provided different levels of support for vaccine development, but DOD negotiated similar payment and termination terms and conditions in their production agreements. These payment and termination terms and conditions enabled the government to adjust its reliance on the various companies as time progressed and more was known about their vaccine candidates, according to DOD officials we interviewed.

DOD's approach to event-based terminations and termination in the federal government's best interests is similar to the approach used in most federal contracts. For example, DOD could terminate its agreements with AstraZeneca or Janssen for an event-based reason such as if FDA placed clinical trials on hold for a certain amount of time (AstraZeneca) or revoked an existing EUA (both companies).³⁵ DOD could also terminate its agreements with several companies if it determined that doing so was in the government's interests. The government would then pay the relevant company for work performed in accordance with the agreement terms. Table 3 summarizes the selected payment and termination terms

³³While the contract has a firm-fixed price of \$12.25 per dose for the first 100 million doses, it also included an incentive of \$3.00 per dose for meeting an EUA deadline of January 31, 2021. As Moderna's vaccine received an EUA on December 18, 2020, the company is eligible to receive the additional incentive payment.

³⁴See Federal Acquisition Regulation § 52.232-32 (Performance-Based Payments).

³⁵FDA may revise or revoke an EUA if the circumstances giving rise to the emergency declaration no longer exist, the statutory criteria for issuance are no longer met, or revocation is appropriate to protect public health or safety. For example, an EUA may be revoked if new data become available indicating that the vaccine is not safe or effective. In general, unless it is revoked, an EUA will remain in effect for the duration of the emergency declaration. See 21 U.S.C. § 360bbb-3(f) and (g).

and conditions that were included in the vaccine agreements we reviewed in the stated timeframe.

Table 3: Summary of Selected Payment and Termination Terms and Conditions Contained in the Production Awards for the Six Operation Warp Speed Vaccine Candidates, July 2020-November 2020

Company/initial award date/value/quantity	Payment	Termination
Pfizer July 2020 \$1.95 billion 100 million doses	No payment until biologics license application (BLA) or emergency use authorization (EUA) obtained and as doses are delivered pursuant to the agreement. ^a	If Pfizer ceases to develop the vaccine for reasons enumerated in the agreement, or if the EUA is revoked and the federal government determines after a reasonable time that it is not likely to be restored, the government can terminate the agreement. A no-cost settlement to end Pfizer's performance is expected within 30 days of the government providing notice.
Moderna August 2020 \$1.2 billion 100 million doses	Payment for meeting incremental milestones without EUA required. ^b	If Moderna fails to obtain an EUA, the federal government can terminate the contract. The government can also terminate the contract for convenience otherwise, in accordance with FAR § 52.249-2. The government reduced the stop-work period to no more than 30 days, less than the usual 90-day period under Federal Acquisition Regulation (FAR) § 52.242-15, in consideration of the expedited award and performance under the contract. In the event that the government issues a stop-work order and Moderna continues to work, Moderna shall not be entitled to an equitable adjustment by the government.
Janssen August 2020 \$1 billion 100 million doses	Payment for meeting incremental milestones without EUA required.	<p>If Janssen ceases to develop the vaccine for reasons enumerated in the agreement, or if the EUA is revoked and the federal government determines after a reasonable time that it is not likely to be restored, the government can terminate the agreement. Janssen would be entitled to full payment for regimens for which manufacturing had been completed, but which had not yet been delivered. With respect to regimens for which manufacturing had been initiated but not completed, Janssen would be entitled to payment of a proportion of the price based on percentage of the work performed, among other things.</p> <p>If Janssen fails to comply with current good manufacturing practices and that failure results in a material adverse effect, Janssen will have 30 days to cure the failure. If Janssen fails to take appropriate action the government can terminate the contract.</p>

Company/initial award date/value/quantity	Payment	Termination
AstraZeneca October 2020 \$1.2 billion 100 million doses	Payment for meeting incremental milestones without EUA required. ^c	The federal government can terminate its agreement with AstraZeneca for certain event-based reasons, including the Food and Drug Administration (FDA) placing clinical trials on hold by FDA for a certain period of time, FDA revoking an existing EUA, or AstraZeneca discontinuing development for safety or efficacy reasons. The government can also terminate its agreement if DOD decides termination is in its best interests. In the event the government terminates the contract for event-based reasons, AstraZeneca is entitled to payment based on a percentage of work completed and reasonable charges that AstraZeneca can demonstrate resulted from the termination. In addition to the foregoing, in the event of a termination in the government's best interest, AstraZeneca will be paid in full for certain milestones regardless of percentage of work completed.
Novavax July 2020 \$1.6 billion 100 million doses	Payment for meeting incremental milestones without EUA required.	The government may terminate work under the agreement if the government determines that a termination is in its interest. The government and Novavax will negotiate equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects.
Sanofi July 2020 \$1.8 billion 100 million doses	Payment for meeting incremental milestones without EUA required.	The government may terminate work under the agreement if the government determines that a termination is in its interest. The government and Sanofi will negotiate equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects.

Source: GAO analysis of Federal Procurement Data System – Next Generation data, award and other acquisition related documents and information provided by Operation Warp Speed officials. | GAO-21-443

^aThe federal government did not provide funding for development of the Pfizer vaccine; instead, it purchased doses. Subsequent to this Department of Defense (DOD) other transaction agreement, DOD awarded Pfizer a separate contract for 100 million doses in December 2020. DOD exercised a contract option for 100 million additional doses in February 2021.

^bDOD exercised options under Moderna's contract in December 2020 for 100 million doses and in February 2021 for an additional 100 million doses.

^cSubsequent to this DOD other transaction agreement, in October 2020, DOD awarded AstraZeneca a contract for 200 million additional doses.

Federal Government Rights to Intellectual Property Generally Limited to Technical Data

According to DOD and HHS officials, the intellectual property underlying the vaccine technology for the six vaccine candidates—including intellectual property necessary for the formula and know-how to produce it—was developed by the vaccine companies, or, in part, by the government, before any funding was provided under Operation Warp Speed and the continued DOD and HHS partnership. As a result, the government does not have rights to the majority of intellectual property developed prior to Operation Warp Speed-related efforts, according to these officials.

DOD and HHS contracting officials stated that they evaluated the preexisting intellectual property to ensure that the companies had the legal rights either through ownership or license to the patents that were needed to enter into an agreement with the government to develop or produce vaccines. According to DOD officials, this evaluation was also done to determine whether any previous federal government investment existed, and if so, to determine the scope of any previous investment and rights and to inform each party's negotiating position. For example, these officials said that during the contract award process a DOD legal team worked with HHS and Defense Advanced Research Projects Agency attorneys to discuss related prior work to form a basis for the negotiations.³⁶ Officials said DOD concluded that the government did not own, in whole or in substantial part, the underlying intellectual property or associated patents that the six companies identified as essential to developing or manufacturing their specific vaccine candidates. For example, DOD's contract with Moderna includes an attachment identifying Moderna's background intellectual property. Moderna has also publicly identified seven issued U.S. patents relevant to its vaccine, none of which listed government inventors. At the same time, government officials and company representatives noted that government scientists had contributed to Moderna's vaccine development and that some government co-owned intellectual property could result from those contributions.

DOD officials said in the absence of full rights to the underlying intellectual property, and as part of DOD's strategy to ensure the availability of vaccines, they developed a unique contract clause to address a potential scenario in which a vaccine company cannot ensure

³⁶Generally, the government only has rights in a company's preexisting or "background" intellectual property if there has been some previous agreement with the company. We have found past instances in which the government and vaccine companies entered into agreements to develop vaccine technology, but we do not have enough information about the technology that was developed under those agreements or the nature of the rights that were negotiated. For example, DOD's price and cost analysis for the Moderna vaccine noted that the Defense Advanced Research Project Agency awarded Moderna an up-to-5-year, \$24.6 million grant in October 2013 to research and develop its mRNA platform. However, DOD's price analysis did not provide additional information on this grant or resulting patent information. DOD officials said DOD conducted a separate assessment of the government's underlying interest or co-ownership of background intellectual property used in producing the new COVID-19 vaccine. We did not independently assess or validate DOD's process to review the company's background intellectual property assertions nor did we review the specific terms of the company's previous government-funded efforts.

sufficient supply of doses subject to the terms of the contract or agreement, and makes a business decision to stop production or sale of the vaccine, or files for bankruptcy, among other things. For these situations, DOD worked with companies to negotiate additional government rights requiring the company to license the intellectual property necessary to pursue FDA authorization or licensure, if required, and manufacturing of the vaccine so that a third party may produce the vaccine for exclusive sale to the government.

DOD officials said the intellectual property licensed would include the vaccine formula and the technical know-how to produce it.³⁷ DOD officials indicated, however, that implementing this approach would have some practical limitations and considerations, such as whether the costs and time associated with transferring technology to a third party might outweigh the benefits. For example, the government or third party would need to have the expertise and facilities necessary to use the licensed intellectual property. These officials said they would need to determine whether it would instead be more prudent to buy additional vaccine doses from another company.

The additional rights DOD negotiated to allow for third-party manufacturing of a vaccine do not apply in other potential scenarios, which include:

- if a vaccine company experiences quality control or manufacturing problems under its existing contract but does not make a business decision to stop production or sale of the vaccine,
- if the government wants to increase the availability of a particular vaccine by authorizing a different vaccine company to manufacture it, or
- if a company significantly increases its proposed vaccine price on subsequent contracts (i.e., an attempt to “price gouge”).

³⁷This language was included in five of the six companies’ contracts or agreements, excluding Pfizer. According to DOD officials, DOD was unable to negotiate with Pfizer to include third party manufacture as a remedy in its agreement due to the government’s lack of involvement in the Pfizer vaccine’s development. Pfizer officials noted that Pfizer’s agreement does not allow the government to “march-in,” as that term is defined in 35 U.S.C. § 203, and according to their agreement, government funding was limited to payment for doses.

While these other potential scenarios could create similar risks and challenges, DOD officials identified mitigating circumstances or strategies that minimized the risk. For example, DOD officials told us that the expected availability of multiple vaccines would promote competition between multiple vaccine companies and would make any price gouging unlikely. Further, DOD officials stated that should the government need to increase domestic manufacturing capacity to make certain vaccines, it could invoke the Defense Production Act.³⁸ For example, the government could modify existing priority ratings for specific companies to allow them to obtain materials more quickly or they could expand manufacturing capacity for supplies such as syringes.³⁹

DOD and HHS contracting officials noted that they are not aware of any new intellectual property that will be created in the form of a “subject invention” as a result of U.S. government funding for the Operation Warp Speed-related contracts and agreements.⁴⁰ However, DOD generally negotiated rights to the technical data—typically the scientific or engineering data—generated under the production contract or agreements, as applicable.

According to DOD contracting officials, the data the government may obtain under the contracts and other agreements is generally limited to technical data derived from the manufacturing scale-up process, such as batch records and quality-related data. Generally, officials said, this technical data gives the government insights into the vaccine production process. In addition, having government representatives on site at manufacturing plants allows them to observe the production process and

³⁸The Defense Production Act, as delegated, generally provides federal agencies authority to, among other things, place priority ratings on contracts so that they receive priority treatment over any other unrated contracts or orders if necessary to meet the delivery or performance dates specified in the order; and provide financial incentives to help maintain, restore, or expand the domestic industrial base. See Pub. L. No. 81-774, 64 Stat. 798 (1950) (codified, as amended, at 50 U.S.C. § 4501, et seq.); Exec. Order No. 13,603, 77 Fed. Reg. 16,651 (Mar. 22, 2012); 15 C.F.R. Part 700, Sch. 1 (2020).

³⁹DOD and HHS partnership officials stated that all six vaccine candidates have priority ratings under the Defense Production Act.

⁴⁰The term “subject invention” means “any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. § 201(e).

any challenges that arise.⁴¹ The related technical data the companies provide allows for government oversight of production activities and regulatory compliance according to DOD officials, but not access to the vaccine formulas or know-how required to produce them.

The Federal Government Has Purchased Additional Vaccine Doses and Helped Mitigate Manufacturing Challenges to Increase Vaccine Availability

The DOD and HHS partnership has taken several actions to increase the availability of COVID-19 vaccine doses. As of March 25, 2021, partnership officials stated that their aim is to have enough vaccine doses distributed for all adults in the U.S.—about 265 million people—by the end of May 2021.⁴² They told us they expect to meet this time frame given their additional purchase of vaccine doses and manufacturing expansion efforts, which will lead to increased distribution of vaccines to jurisdictions and federal partners, as described below.

Purchasing vaccine doses. As of April 1, 2021, DOD and HHS have announced the purchase of at least 1.2 billion COVID-19 vaccine doses, including 200 million doses each from Pfizer and Moderna, to be manufactured and released by May 31, 2021 (see table 4). This is a significant increase from the total of 600 million vaccine doses the federal government had contracted to purchase as of November 2020.

Table 4: Contracted Amount of COVID-19 Vaccine Doses under the Department of Defense (DOD) and Department of Health and Human Services (HHS) Partnership, by Vaccine Company, as of April 1, 2021

Vaccine company	Contracted amount (millions of doses)	Contracted amount expected by the end of May 2021 (millions of doses)	Emergency use authorization (EUA)
Pfizer	300 ^a	200 ^b	✓
Moderna	300 ^c	200	✓
Janssen	100	87	✓
AstraZeneca	300 ^d	TBD ^e	
Novavax	100 ^f	TBD ^g	
Sanofi	100	TBD ^h	
Total	1,200	487	

Source: GAO analysis of award and other acquisition related documents and information from HHS, DOD, Advanced Technology International, and vaccine companies. | GAO-21-443

⁴¹According to Pfizer representatives, since Pfizer did not accept U.S. government funding under its agreement, the agreement did not include a “person in plant” provision to allow a federal government official to observe its vaccine production process.

⁴²FDA authorized Pfizer’s vaccine for individuals 16 years of age and older, and authorized Moderna’s vaccine for individuals 18 years of age and older. DOD and HHS partnership officials told us that some vaccine companies have begun clinical trials for adolescent and pediatric populations. On March 2, 2020, the White House announced there would be sufficient doses for all adults in the U.S. by the end of May 2021.

Note: The contracted amount includes base and exercised options.

^aThe federal government first awarded Pfizer an other transaction agreement for 100 million vaccine doses. On December 22, 2020, the federal government awarded Pfizer a contract for an additional 100 million doses. On February 11, 2021, the government exercised another option in the Pfizer contract for an additional 100 million doses, for a total of 300 million doses to be delivered by the end of July 2021.

^bAccording to a company representative, Pfizer remains on track to fulfill its commitment to the federal government to reach the 200 million doses mark by the end of May, and 300 million total doses by the end of July.

^cThe federal government first contracted with Moderna for 100 million vaccine doses. On December 11, 2020, the federal government announced that it had exercised an option with Moderna for an additional 100 million doses. This was followed by an announcement on February 11, 2021, that the government had exercised another option with Moderna for an additional 100 million doses, for a total of 300 million doses.

^dThe federal government awarded AstraZeneca an other transaction agreement for 100 million doses, and later awarded AstraZeneca a contract for an additional 200 million doses, for a total of 300 million doses, which will be provided to the government on a rolling basis, according to the company.

^eAccording to an AstraZeneca representative, the federal government and AstraZeneca are working closely on a delivery schedule for the doses.

^fAccording to a Novavax representative, the company was also awarded a DOD contract in June 2020 that includes the delivery of 10 million doses. We do not include that amount in this table.

^gAccording to a Novavax representative, delivery of doses is dependent upon an EUA being granted by the Food and Drug Administration.

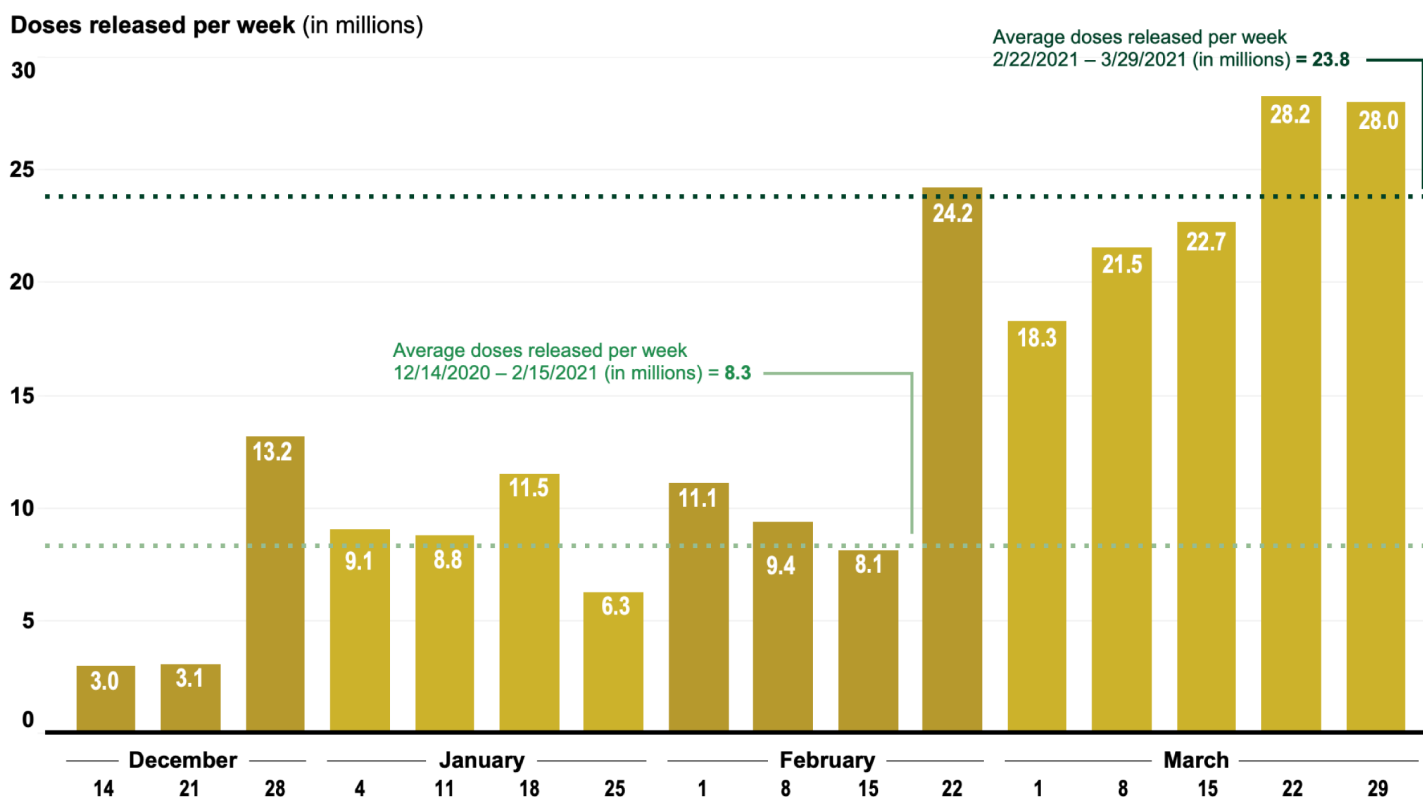
^hAccording to a Sanofi representative, the release of the company's vaccine doses is dependent upon results of the phase 3 clinical study evaluating safety and efficacy, which is expected to begin in the second quarter of 2021.

The 400 million purchased doses of the Pfizer and Moderna vaccines expected by May 31, 2021 would be enough to fully vaccinate—that is to provide 2 doses for each person being vaccinated, as necessary for each of these vaccines—about 200 million people. In addition, Janssen is expected to provide 87 million doses of its 1-dose vaccine by the end of May 2021, which would be enough to vaccinate an additional 87 million people. Combined with the expected 400 million doses from Moderna and Pfizer (enough for 200 million people), the government would have enough doses to vaccinate 287 million people which would exceed the DOD and HHS partnership's aim to have enough vaccine doses available for all adults in the U.S. by the end of May 2021. Federal officials also said that expected manufacturing of the AstraZeneca and Novavax vaccine candidates would add to this total if those vaccine companies request and receive EUAs to allow those vaccines to be marketed in the United States.

Manufacturing and releasing vaccine doses. As of March 29, 2021, 226 million vaccine doses of the Pfizer, Moderna, and Janssen vaccines had been manufactured and released, according to officials from the DOD

and HHS partnership.⁴³ The number of vaccine doses released increased notably at the end of February (see figure 4). According to information from partnership officials, between December and mid-February of 2021, an average of 8 million doses of the Pfizer and Moderna vaccines were released per week. Between February 22, 2021, and March 29, 2021, this increased to an average of 24 million doses per week. Representatives from Pfizer and Moderna publicly stated that their vaccine manufacturing rates would increase to 13 million doses per week for Pfizer by mid-March and over 40 million doses per month—over 9 million doses per week—for Moderna by April.

Figure 4: Number of Doses of COVID-19 Vaccine Released in the U.S. per Week (in millions), as of March 29, 2021



Source: GAO analysis of information from the partnership between the Department of Defense (DOD) and Department of Health and Human Services (HHS), formerly known as Operation Warp Speed. | GAO-21-443

⁴³According to the DOD and HHS partnership, once through manufacturing and quality assurance, the vaccine doses are released for distribution.

Note: Numbers presented here are doses that have been released—that is, they have passed the quality assurance process after manufacturing and been released for distribution, according to officials from partnership between the Department of Defense (DOD) and Department of Health and Human Services (HHS), formerly known as Operation Warp Speed.

DOD and HHS partnership officials said that they expect the rate of vaccine doses manufactured and released to continue to increase. DOD and HHS partnership officials and vaccine company representatives described ways in which they continue to work together to mitigate manufacturing challenges in order to increase manufacturing rates. Specifically:

- **Manufacturing capacity.** Some vaccine companies have sought to expand their capacity through making additional manufacturing sites operational or modifying existing production facilities to manufacture enough doses to fulfill their contracts with the federal government. DOD and HHS partnership officials told us that they were working to ensure that bottlenecks do not occur by helping companies obtain additional fill-finish capacity for vaccines, with priority going to vaccines with EUAs. For example, officials stated that they were working with Catalent to add an additional production line at Catalent’s fill-finish facility, which handles fill-finish manufacturing for the Moderna and Janssen vaccines. Pfizer is also adding two production lines at one of its fill-finish facilities. According to DOD officials, the U.S. Army Corps of Engineers supported the fill-finish facility upgrades by working with contractors to provide an additional layer of quality control on behalf of the U.S. government. Officials further stated that the U.S. Army Corps of Engineers leverages its relationships with state and local governments in support of manufacturers obtaining their permits and working with the manufacturer’s suppliers in expediting the shipment of equipment and supplies. Table 5 summarizes the status of the manufacturing capacity expansion efforts for the six vaccine candidates under the DOD and HHS partnership.
- **Supply chains.** Most vaccine company representatives indicated that supply constraints were not impeding their manufacturing process as of March 2021, and the companies have continued to utilize prioritized contracts under the Defense Production Act to expedite the receipt of supply constrained materials. These companies generally reported that the priority rating process had been beneficial in providing uninterrupted supply of materials. However, Janssen representatives stated that providing priority ratings for multiple companies producing COVID-19 vaccines may have unintended negative consequences, such as creating constrained supplies for other life-saving medicines

and unnecessary stockpiling of supplies that may be at risk of being prioritized under the Defense Production Act. DOD and HHS partnership officials also provided information that priority ratings for COVID-19 vaccine materials are beginning to crowd out producers of non-COVID-related life-saving therapies and medicines, including the seasonal flu vaccine.

According to HHS, the administration is aware and working through wider supply-chain disruptions resulting from the U.S. government use of the Defense Production Act. HHS officials stated that it is important to note that the supply-chain constraints are a result of unprecedented global demand as global manufacturing races to produce vaccine for more than 7 billion people using existing manufacturing infrastructure. They further stated that the U.S. government's use of the Defense Production Act allows for prioritization of U.S. government contracts for U.S.-based manufacturing, but it is not the primary cause of shortages.

Additionally, partnership officials provided information on efforts to mitigate risks from supply constrained materials. For example, officials identified the potential risk of limited production capability for at least one raw material for which supply has been hindered by (1) a fire at a domestic facility which is delaying delivery of the material from this facility by 4 to 10 weeks, and (2) an explosion at a foreign facility that has required production to be shifted to a facility in a different country. According to information provided by partnership officials, they are closely monitoring shipments of this material from remaining foreign sources and believe that this supply issue is unlikely to impact near-term production due to supplies vaccine companies already have. However, these supply disruptions highlight the overall fragility of the global supply chain and the risks of relying on raw materials from a small number of primarily foreign sources.

- **Available workforce.** The six vaccine companies indicated that workforce gaps were not impeding their manufacturing process as of March 2021. However, there continues to be a need to recruit and train the highly skilled workforce needed to run vaccine production processes.⁴⁴ As of March 2021, DOD personnel were continuing to serve as quality control staff at the Emergent BioSolutions manufacturing partner site until the company could hire the required

⁴⁴For example, Janssen representatives noted that each of the company's manufacturing partner sites continues to have vacancies, with sites that are still ramping up production having a greater numbers of vacancies. Pfizer representatives stated that hiring staff with specialized skills is always a challenge, but in general the company has been successful in hiring qualified people.

personnel, according to partnership officials. Although the DOD personnel were originally scheduled to depart in mid-February 2021, partnership officials told us that DOD personnel were extended to stay until mid-April as Emergent BioSolutions continued to recruit, hire, and train additional staff.

Table 5: Status of Manufacturing Capacity Expansion Efforts for Six COVID-19 Vaccine Candidates under the DOD and HHS Partnership, as of March 2021

Vaccine company	U.S. manufacturing capacity expansion efforts
Pfizer	Has made and continues to make improvements and expansion at its current facilities
Moderna	Completed work on near-term planned capacity; contracted with an additional fill-finish manufacturing partner; making new capital investments to increase capacity at its owned and partnered manufacturing facilities
Janssen	Continuing to add additional manufacturing capacity, including contracting with an additional manufacturing partner
AstraZeneca	Operating at full capacity in the United States
Novavax	Continuing to explore options for additional manufacturing capacity
Sanofi	Large-scale manufacturing has been delayed due to the results of the combined phase 1 and 2 clinical trial

Source: GAO analysis of information from vaccine companies. | GAO-21-443.

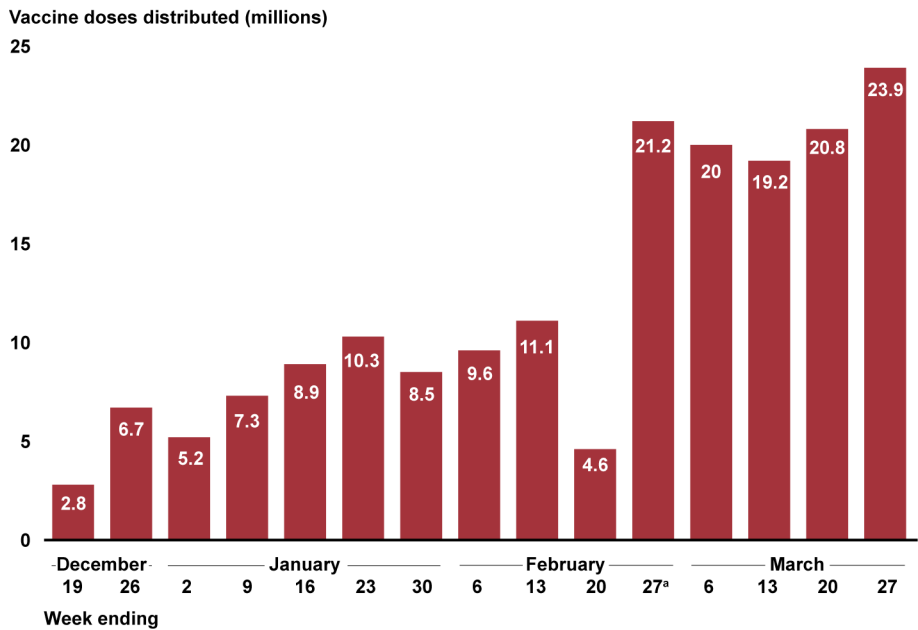
Note: The Department of Defense (DOD) and Department of Health and Human Services (HHS) partnership was formerly known as Operation Warp Speed.

Distributing vaccine doses. As of March 27, 2021, the partnership had distributed 180.6 million total doses, according to data from CDC. The number of vaccine doses distributed to jurisdictions and federal partners has varied each week since the process began in December 2020. From February 28, 2021 to March 27, 2021, the partnership distributed an average of about 21.1 million doses of the Pfizer, Moderna, and Janssen vaccines per week (see figure 5).⁴⁵ Because the Pfizer and Moderna vaccines are 2-dose vaccines and the Janssen vaccine is a 1-dose vaccine, this average weekly number of doses from each manufacturer

⁴⁵We chose this 4-week period to include the initial release of the Janssen vaccine during the week of February 28, 2021, plus 3 additional weeks to reflect week-to-week variation. The 21.1 million average number of doses per week included about 11.0 million doses of Pfizer, 8.9 million doses of Moderna, and 1.2 million doses of Janssen vaccines (when rounding).

corresponds to enough doses each week for about 11.2 million people to eventually be fully vaccinated.

Figure 5: Number of Vaccine Doses Distributed in the U.S. per Week, as of March 27, 2021



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO-21-443

Note: Vaccine doses distributed is the total number that have been delivered to jurisdictions, retail pharmacies, long-term care facilities, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entities. However, for Palau, Micronesia, Marshall Islands, Guam, American Samoa, and Northern Marianas Islands, total counts of COVID-19 vaccine doses include doses marked as shipped in CDC’s Vaccine Tracking System since December 13, 2020. For COVID-19 vaccination there are 64 jurisdictions including all 50 states, territories, and local health programs in Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio.

^aFor the week ending on February 27, 2021, the national doses distributed totals show larger than typical daily increases. This is an accurate reflection of the data and is the result of weather events causing a backlog of vaccine distributed to many parts of the United States.

DOD and HHS partnership officials noted that projecting future vaccine dose availability beyond approximately 3 weeks is inherently uncertain, in part because of the complex manufacturing processes for biologics like

vaccines, as well as the manufacturing challenges discussed earlier.⁴⁶ Further, while they indicated that they expect the number of vaccine doses distributed to increase each week in line with the expected increases in vaccine manufacturing, there may be slight differences due to the time it takes to package and ship the doses.

With the expected increases in vaccine manufacturing and distribution, HHS announced on March 17, 2021 that the Acting Secretary of Health and Human Services was directing all states, Tribes, and territories to make all adults in the U.S. eligible for the vaccine by May 1, 2021.⁴⁷ Effective communication on vaccine availability will be critical to manage public expectations, particularly given the uncertainty with future projections and the significant effort required to manufacture and distribute sufficient vaccine doses available for all adults in the U.S. In particular, having sufficient vaccine doses available by the end of May 2021 will generally require an increase of more than half of weekly distribution amounts compared to the average weekly rate for February 28 through March 27, 2021.⁴⁸

In our prior work on the H1N1 influenza pandemic, we found that although the federal government was able to purchase and distribute millions of doses of H1N1 vaccine, the vaccine was not widely available when the public expected it, and the failure to effectively manage public expectations undermined government credibility.⁴⁹ As we reported in January 2021, initial vaccine rollout did not match public expectations, with initial numbers of distributed and administered COVID-19 vaccines

⁴⁶The manufacturing of vaccines can be more uncertain than drug-related manufacturing, in part because vaccines often need to grow living material that can take time and be imprecise. DOD and HHS partnership officials told us that projecting future vaccine doses availability was also difficult because of the inherent challenge with scale-up and production in a short timeframe.

⁴⁷On April 6, 2021, the President revised this, announcing that all states, Tribes, and territories would be directed to make all adults in the U.S. eligible by April 19, 2021.

⁴⁸The average weekly rate from February 28 through March 27 corresponds to enough doses each week for about 11.2 million people to eventually be fully vaccinated, based on the number of 2-dose and 1-dose vaccines distributed during this time. We calculated that this weekly rate would need to increase by about 59 percent, on average, to have enough doses available by May 31 to eventually allow for all adults in the U.S. to be fully vaccinated. Our calculation assumes that the proportion of 2-dose and 1-dose vaccines would remain the same.

⁴⁹See GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, [GAO-11-632](#) (Washington, D.C., Jun. 27, 2011).

falling short of implementation expectations set by officials.⁵⁰ Further, as we have reported since June 2020, timely, clear, and consistent communication is essential to ensure public confidence and trust.

Stakeholders Identified Challenges with Initial COVID-19 Vaccination; the Federal Government Has Taken Some Steps to Help Improve Vaccine Implementation

Stakeholders Identified Multiple Challenges with Initial COVID-19 Vaccination Implementation, Which Were Exacerbated by Changing Federal Procedures

Stakeholders—including representatives of state, territorial, and local health officials and health care providers—identified multiple challenges with initial implementation of COVID-19 vaccination, which includes prioritizing, allocating, distributing, and administering available vaccine doses to individuals. Through our interviews with stakeholders conducted from January 6 through February 1, 2021, when vaccine doses were initially available, we found that state, territorial, and local health officials and health care providers faced challenges such as competing priorities with limited resources and lack of information needed for on-the-ground planning for vaccine administration. Table 6 provides examples of challenges in the initial COVID-19 vaccine implementation identified by some of these stakeholders.

⁵⁰See GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, [GAO-21-265](#) (Washington, D.C.: Jan. 28, 2021).

Table 6: Examples of Challenges with Initial COVID-19 Vaccine Implementation Reported by Stakeholders, as of February 1, 2021

Challenge	Description
Health officials and health care providers faced competing priorities with limited resources	Some stakeholders, including representatives of state, territorial, and local health officials and health care providers, said that they faced challenges in trying to plan for and conduct vaccine distribution and administration activities while also managing their other COVID-19 response efforts, such as contact tracing. Prior to December 14, 2020, when vaccination began, some stakeholders indicated limited resources were available for planning these efforts. For example, some stakeholders said they needed to hire and train new staff to enhance existing data systems to handle the anticipated increase in data collection or to run vaccination clinics, while also treating patients. ^a
Health officials and health care providers lacked information on vaccine shipments needed for on-the-ground planning	Stakeholders said some state, territorial, and local health officials and health care providers lacked information on vaccine shipments, such as on the number of doses they would receive and when they would arrive, which is critical to planning for and administering vaccinations. For example, one stakeholder noted not having this information makes it difficult for states to plan further distribution to the local level. Another stakeholder noted that this information is critical for planning vaccinations, particularly for health care providers in rural communities that may not have hospitals. These communities might use mobile vans or recreational centers that require advance planning so that people can be at a particular location on a specific day.
Health officials identified challenges with reporting administration data to the Centers for Disease Control and Prevention (CDC)	Stakeholders said some state, territorial, and local health officials have experienced challenges affecting their ability to report vaccine administration data to CDC. For example, health officials in one state had to update their data reporting systems with new functionality for the pandemic, and there have been some interoperability challenges with getting access to administration data. One stakeholder also noted there can be as much as a 4-5 day delay in reporting data from the health care provider to CDC because health care providers have up to 72 hours to report administration data to the jurisdictions and jurisdictions have 24 hours to review these data before reporting them to CDC.
Local health departments and health care providers could not plan for their vaccination efforts because they were not included in federal planning efforts, which focused on coordination at the jurisdictional (e.g., state) level	Some local health departments and some health care providers did not participate in planning exercises organized by the federal government because federal planning efforts focused on coordination at the jurisdictional (e.g., state) level, according to stakeholders. Thus, stakeholders said some local health departments and some health care providers did not have key information needed for planning, such as when and how many vaccine doses would be arriving. This lack of information affected some local health departments' and some health care providers' ability to coordinate and plan, including their ability to develop their own community education and messaging around vaccination.
Local health departments and health care providers were uncertain on who to vaccinate or where to provide vaccinations	Some local health departments were not initially informed when jurisdictions deviated from federally recommended groups targeted for vaccination, resulting in uncertainty about who they should vaccinate, according to one stakeholder representing local health officials. For example, when the Secretary of Health and Human Services recommended expanding the initial vaccination target group from persons aged 75 and older to those 65 and older, this stakeholder said there was little or no planning done by local communities, including by local health departments and health care providers, for such an expansion.
	Additionally, some hospital officials did not initially know whether they were responsible for vaccinating health care providers in their community who were eligible to be vaccinated but were not affiliated with a particular hospital, according to one stakeholder. Similarly, unaffiliated providers did not know where or when they could get vaccinated when they were in the initial priority group for vaccination, according to another stakeholder.

Challenge	Description
Health care providers did not have information from an authoritative source to combat misinformation and vaccine hesitancy ^b	Some stakeholders said health care providers needed science-based information to combat misinformation and vaccine hesitancy during the initial vaccine implementation. For example, one stakeholder noted that certain spokespeople made inaccurate statements about who could be vaccinated. Further, some health care providers were hesitant to be vaccinated because of misinformation about the vaccines, resulting in a lower proportion of health care staff in long-term care facilities willing to be vaccinated than initially expected, according to some stakeholders. Additionally, another stakeholder noted that health care providers of color were more likely to refuse a COVID-19 vaccine when offered than their white counterparts, and a second stakeholder said that some members of the public remain hesitant to be vaccinated, in part, due to misinformation about the vaccines.

Source: GAO analysis of interviews with representatives of state, territorial, and local health officials, and health care providers from January 6, 2021, through February 1, 2021. | GAO-21-443

Note: These challenges were examples identified collectively by stakeholders and not by every stakeholder interviewed.

^aPrior to the beginning of vaccine administration on December 14, 2020, approximately \$340 million had been made available from CDC to jurisdictions for vaccine preparedness. Of this \$340 million, the Department of Health and Human Services announced \$200 million would be awarded on September 23, 2020, and an additional \$140 million would be awarded on December 15, 2020.

^bFor the purposes of this report, vaccine hesitancy refers to a delay in acceptance of vaccines despite availability. Those who are vaccine hesitant are a middle group along a continuum that ranges between those who fully accept vaccines on one end and those who are strongly opposed to vaccines on the other. An individual's vaccine hesitancy can apply to all vaccines or to a specific vaccine.

Some stakeholders indicated these challenges were exacerbated by unanticipated changes from the federal government. For example, in December 2020, ACIP recommended that, when initial vaccine supplies were expected to be limited, vaccine doses should first be offered to health care personnel and long-term care facility residents. Next, vaccine doses should be offered to persons aged 75 and older and non-health care, frontline essential workers. As more vaccine doses became available, ACIP recommended vaccination be expanded to include persons aged 65 and older.⁵¹ However, during a press conference on January 12, 2021, the Secretary of Health and Human Services recommended that the target group be expanded to include those aged

⁵¹ACIP recommendations for phased allocation provide guidance for federal, state, and local jurisdictions while vaccine supply is limited. To inform policy options for ACIP, the committee's COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, held 28 meetings to review data regarding vaccine candidates, COVID-19 surveillance, modeling of allocation scenarios, and vaccination program implementation issues. In its deliberations, ACIP considered scientific evidence regarding COVID-19 epidemiology, ethical principles, and vaccination program implementation. ACIP recommendations are reviewed by the CDC Director and, if adopted, are published as official CDC/HHS recommendations in the *Morbidity and Mortality Weekly Report*, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152e2-H.pdf>.

65 and older and people under 65 with a documented co-morbidity before additional vaccine doses became available.

At the same time, jurisdictions experienced an unexpected decline in their second-week allocations of vaccine doses and some said they received mixed messages from the federal government on vaccine availability. See table 7 for changes made by the federal government regarding COVID-19 vaccinations that occurred during the initial vaccine implementation through mid-February 2021. Some stakeholders expressed frustration with these unanticipated changes and stressed the need for more predictable information and guidance going forward, underscoring the need for clear and consistent coordination and communication by the federal government to help ensure more effective vaccine implementation.

Table 7: Changes by the Federal Government to the Initial COVID-19 Vaccine Implementation between November 2020 and mid-February 2021

Change	Date	Event
Expansion of recommended target groups to receive initial supplies of vaccine doses beyond initial recommendations	Dec. 1-2, 2020	The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended that when supplies of COVID-19 vaccines are limited, vaccination should be offered in a phased approach. ACIP recommended that vaccines in the initial phase of the vaccination program (phase 1a) be offered to (1) health care personnel, and (2) residents of long-term care facilities. ^a The CDC Director adopted ACIP's recommendation for priority groups for the initial phase of the COVID-19 vaccination program. ^b
	Dec. 20-21, 2020	ACIP recommended that after phase 1a, vaccination should be offered in phase 1b to: (1) persons aged 75 and older and (2) frontline essential workers (non-healthcare); and in phase 1c to: (1) persons aged 65-74 years, (2) persons aged 16-64 years with high-risk medical conditions, and (3) other essential workers. The CDC Director adopted ACIP's updated recommendations for priority groups for allocation of COVID-19 vaccine doses. ^b
	Jan. 12, 2021	The Secretary of Health and Human Services announced at a press briefing that jurisdictions should open vaccination to all persons age 65 and older and all people under age 65 with a documented co-morbidity.
	Jan. 21, 2021	The White House released the <i>National Strategy for the COVID-19 Response and Pandemic Preparedness</i> (National Strategy) that encouraged jurisdictions to open vaccination to persons age 65 and older and essential workers. ^c

Change	Date	Event
Changes in number of doses, including in states' and other jurisdictions' second week allocations of the Pfizer and Moderna vaccines	Late Dec. 2020	<p>For 51 jurisdictions (93 percent of the 55 jurisdictions for which data were available), the number of Pfizer vaccine doses included in their second week's allocation was more than 25 percent lower than were included in their first week's allocation, according to CDC data.^d</p> <p>An Operation Warp Speed official explained that the number of doses available for allocation in the second week of the Pfizer vaccine implementation was lower [than initially understood] and so the actual allocations made were lower than had originally been communicated to jurisdictions.</p> <p>For 54 jurisdictions (98 percent of the 55 jurisdictions for which data were available), the number of doses available for allocation in the second week of Moderna vaccine implementation was about 65 percent lower than their first allocation.^e</p>
	Jan. 6, 2021	The Food and Drug Administration (FDA) determined six doses instead of five doses can be obtained from the Pfizer vaccine vials by using "low dead-volume" syringes. If standard syringes and needles are used, there may not be sufficient vaccine to extract a sixth dose. ^f
Changes in federal management of vaccines for second doses	Dec. 2, 2020	During a press conference, an Operation Warp Speed official said the federal government would not distribute the second dose of vaccine to jurisdictions to ensure that enough vaccine doses would be available for people to receive it. The official said the federal government would distribute the second dose of the vaccine either 3 or 4 weeks later, depending on the vaccine. ^g
	Dec. 9, 2020	During a press conference, an Operation Warp Speed official said the federal government set aside some vaccine doses from the initial total supply as part of a reserve. ^h This official said that as the federal government became more confident in the manufacturing and distribution process, a smaller reserve of vaccine doses would be maintained.
	Jan. 12, 2021	During a press conference, the Secretary of Health and Human Services said the federal government was releasing its entire supply of vaccine for jurisdictions to order rather than holding back second doses in a physical reserve until a 3- or 4-week time period had passed. This statement led some jurisdictional officials (e.g., state officials) to anticipate they would receive a larger weekly allocation of vaccine doses.
	Jan. 15, 2021	In a press interview, the Secretary of Health and Human Services clarified that the federal government did not have a stockpile of reserved second doses of vaccine.
	Jan. 21, 2021	The National Strategy stated that the administration planned to end the policy of holding back significant levels of vaccine doses. The National Strategy also noted that to ensure the availability of second doses of vaccine, the administration would hold a smaller reserve and closely monitor the development, production, and release of vaccine doses, and use the Defense Production Act as needed to ensure adequate supply.
Announced modifications to how vaccines would be allocated	Nov. 2020	In anticipation of the authorizations of the Pfizer and Moderna vaccines, Operation Warp Speed officials reported that allocations would be made based on jurisdictions' adult populations (i.e., those aged 18 years and older).

Change	Date	Event
	Jan. 12, 2021	In a press conference, the Secretary of Health and Human Services announced that beginning in 2 weeks, vaccines would be allocated to jurisdictions based on the percentage of doses each jurisdiction had administered along with the number of residents aged 65 years and older residing in the jurisdiction.
	Feb. 11, 2021	Department of Defense (DOD) and Department of Health and Human Services (HHS) partnership officials said the allocation policy for jurisdictions would be based on jurisdictions' adult populations (i.e., those 18 and older).

Source: GAO analysis of CDC data on vaccine allocations, federal planning and other documents, transcripts of press conferences with Operation Warp Speed officials, which included HHS and DOD officials, and interviews with federal officials. | GAO-21-443.

Note: COVID-19 vaccine implementation includes prioritization, allocation, distribution and administration of any authorized or licensed COVID-19 vaccine. Also, as of January 2021, the partnership between DOD and HHS has continued but is no longer referred to as Operation Warp Speed.

³CDC defines health care personnel as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. See Department of Health and Human Services, Centers for Disease Control and Prevention, "The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020," *Morbidity and Mortality Weekly Report*, (Atlanta, Ga.: Dec. 11, 2020), accessed on March 1, 2021, <https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm>.

⁴ACIP recommendations are reviewed by the CDC Director and, if adopted, are published as official HHS/CDC recommendations in the *Morbidity and Mortality Weekly Report*. See <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html> (accessed March 1, 2021) for ACIP's current COVID-19 vaccine recommendations. For the purposes of ACIP's recommendation, non-healthcare frontline essential workers include firefighters, police officers, corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, those who are in the education sector (teachers and support staff), as well as daycare workers. According to CDC, about 49 million persons, including non-healthcare frontline essential workers and individuals aged ≥75 years are recommended for vaccination in phase 1b, and an additional 129 million persons are recommended for vaccination in phase 1c (including about 28 million individuals aged 65-74 years).

⁵White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021), accessed on January 21, 2021 at <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>.

⁶For COVID-19 vaccine implementation, there are 64 jurisdictions including all 50 states, territories, the District of Columbia, and local health programs in Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio that receive vaccine allocations from Operation Warp Speed and the continued HHS and DOD partnership. According to CDC, the Marshall Islands, Micronesia, and Palau did not receive doses of the Pfizer vaccine due to logistical considerations with ultra-cold storage requirements. American Samoa, Guam, and the Mariana Islands received their first and second doses simultaneously to optimize transportation logistics. Alaska was allocated vaccine doses the first and fourth weeks, but not the second or third week of Pfizer vaccine implementation. Houston and San Antonio had their allocations consolidated with Texas.

⁷According to CDC, for the Moderna vaccine, American Samoa, Guam, and the Mariana Islands received their first and second doses simultaneously to optimize transportation logistics. Alaska, the Marshall Islands, Micronesia, and Palau were allocated vaccine doses the third week but not the second week of Moderna vaccine implementation. Houston and San Antonio had their allocations consolidated with Texas.

⁸Department of Health and Human Services, Food and Drug Administration, "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization

(EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)", accessed January 11, 2021, <https://www.fda.gov/media/144413/download>.

⁹The second dose of the Pfizer vaccine should be administered 3 weeks after the first dose, and the second dose of the Moderna vaccine should be administered 1 month after the first dose, according to FDA.

^hThe federal government maintained this emergency reserve of vaccine doses based on recommendations from the National Security Council, according to federal officials.

The Federal Government Has Taken Some Steps to Help Improve COVID-19 Vaccine Implementation

In January 2021, HHS announced that CDC would provide more than \$3 billion in awards using funds provided under the Consolidated Appropriations Act, 2021, to jurisdictions to support vaccination-related activities.⁵² In addition, the American Rescue Plan Act of 2021, enacted in March 2021, provided additional resources for vaccination activities. For example, that act includes \$7.5 billion for CDC to carry out activities to plan, prepare for, promote, distribute, administer, monitor, and track COVID-19 vaccines.⁵³ With the release of the National Strategy, the federal government identified several specific initiatives for vaccine implementation, as part of the larger COVID-19 response.⁵⁴ Several examples of federal initiatives include:

Additional funding and resources for vaccine distribution and administration. In accordance with a January 21, 2021 Presidential Memorandum, the Federal Emergency Management Agency (FEMA) will reimburse states, territorial, local, and tribal governments for costs associated with COVID-19 response, which includes vaccine distribution and administration, through the Disaster Relief Fund, which had a

⁵²The \$3 billion in awards will be made through the CDC Immunization and Vaccines for Children cooperative agreement, and funds will be allocated by a population-based formula.

⁵³Pub. L. No. 117-2, § 2301, 135 Stat. 4, 37-38.

⁵⁴White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Washington, D.C.: Jan. 21, 2021), accessed on January 21, 2021 <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>.

balance of about \$61.4 billion, as of March 18, 2021, according to FEMA.⁵⁵

On February 18, 2021, FEMA also reported it could support establishing community vaccination centers and provide additional resources (e.g., clinical staff including nurses and emergency medical services personnel) and additional ancillary supplies (e.g., gloves, masks, and syringes). These community vaccination centers range from mobile sites that can support the administration of 250 vaccine doses a day to those that can support the administration of 6,000 vaccine doses a day.⁵⁶ According to FEMA, as of March 26, 2021, the agency had partnered with California, Florida, Georgia, Illinois, Michigan, New York, North Carolina, Ohio, Pennsylvania, and Texas to establish community vaccination centers and planned to partner with additional states in late-March and April 2021.⁵⁷

⁵⁵White House, *Memorandum to Extend Federal Support to Governors' Use of the National Guard to Respond to COVID-19 and to Increase Reimbursement and Other Assistance Provided to States*, (Washington D.C.: Jan. 21, 2021), accessed on February 4, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/extend-federal-support-to-governors-use-of-national-guard-to-respond-to-covid-19-and-to-increase-reimbursement-and-other-assistance-provided-to-states/>.

On February 2, 2021, the administration announced it would retroactively reimburse states fully for FEMA-eligible services—including masks, gloves, emergency feeding actions, sheltering at risk populations, and mobilization of the National Guard—back dated to the beginning of the pandemic in January 2020 in the United States, according to FEMA. White House, *Memorandum on Maximizing Assistance from the Federal Emergency Management Agency*, (Washington D.C.: Feb 2, 2021), accessed on February 4, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/02/memorandum-maximizing-assistance-from-the-federal-emergency-management-agency/>.

According to FEMA, as of March 31, 2021, it had provided more than \$4.49 billion to 42 states, the District of Columbia, five territories, and four Tribes for expenses related to COVID-19 vaccination efforts.

⁵⁶Federal Emergency Management Agency, *Community Vaccination Centers Playbook, Version 4.0* (Washington, D.C.: Mar. 26 2021), accessed on March 30, 2021, https://www.fema.gov/sites/default/files/documents/fema_community-vaccination-centers_playbook_03-26-2021.pdf.

⁵⁷See FEMA's website on its support of COVID-19 vaccination efforts, accessed on February 26, 2021, <https://www.fema.gov/disasters/coronavirus/vaccine-support>.

According to FEMA, the sites are selected based on data analysis including the CDC's Social Vulnerability Index and other Census data as well as input from state and local partners.

The National Strategy also proposed augmenting the number of health care providers available to administer vaccines by, for example, utilizing the Army and Navy Medical Corps. According to FEMA, as of March 26, 2021, 6,838 federal personnel were deployed to 997 federally supported vaccination sites across the country, including 2,905 DOD personnel and 2,108 FEMA and Department of Homeland Security personnel who were directly supporting vaccination efforts. There were also an additional 2,800 personnel serving in non-clinical operational roles. In addition, as of March 26, 2021, U.S. National Guard Bureau personnel were supporting the COVID-19 response, including 1,916 vaccinators.

Earlier advance notice on vaccine allocations and increased amounts of projected supply. On January 26, 2021, the White House announced that the federal government would begin providing states, Tribes, and territories with reliable vaccine allocation estimates 3 weeks in advance—instead of the one-week look-ahead they had been receiving—to give state and local leaders greater certainty around supply so they can plan their vaccination efforts.⁵⁸ In addition, on March 9, 2021, the White House announced that it would increase the overall weekly vaccine supply to states, Tribes, territories, and others to more than 20 million doses. This amount was up from an earlier weekly vaccine supply of 8.5 million doses.

Initiation of a federal retail pharmacy program. In January 2021, CDC announced a federal partnership with retail pharmacies, including 21 national pharmacy partners and networks of independent pharmacies, representing over 40,000 pharmacy locations nationwide. Described in CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex* (annex), CDC noted that not all pharmacy locations would receive vaccine doses in the initial stages of implementation, but

⁵⁸White House, *Fact Sheet: President Biden Announces New Steps to Boost Vaccine Supply and Increase Transparency for States, Tribe, and Territories* (Washington, D.C.: Jan. 26, 2021), accessed on February 4, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/26/fact-sheet-president-biden-announces-new-steps-to-boost-vaccine-supply-and-increase-transparency-for-states-tribes-and-territories/>.

instead, jurisdictions were to select one or more pharmacy partners, based on a pre-selected list of partners.⁵⁹

According to CDC, the pre-selected pharmacy partners were chosen based on CDC analysis that they could provide vaccine to those in greatest need, including those at highest risk of becoming severely ill from COVID-19 and those who are socially vulnerable. According to the annex, as the vaccine supply increases, the number of participating retail pharmacies will also increase. Selected pharmacies received their initial vaccine doses, which were separate from vaccine allocations provided to jurisdictions, on February 11, 2021, according to the White House. On February 16, 2021, the White House announced that 2 million doses would be going to pharmacies that week.

Initiation of a federal partnership with federally qualified health centers. The National Strategy described a federal partnership with federally qualified health centers, and during the week of February 22, 2021, federally qualified health centers began directly receiving vaccine allocations from the federal government.⁶⁰ Similar to the federal partnership with retail pharmacies, this program began with a phased-in approach, initially including 25 sites. The health centers initially chosen include those that serve a large volume of disproportionately affected populations, including individuals experiencing homelessness, migrant or seasonal agricultural workers, and those with limited English proficiency, according to the Health Resources and Services Administration.⁶¹ Across this initial phase, the goal is to allocate 1 million doses, according to a White House COVID-19 Response Team statement on February 9,

⁵⁹Department of Health and Human Services, Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex* (Atlanta, Ga.: Jan. 11, 2021), accessed on February 4, 2021, <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vaccination-program-playbook-annex.pdf>.

According to CDC, pharmacies will be administering COVID-19 vaccine in accordance with the prioritization groups determined by the appropriate public health authority (e.g., the state or local health department in coordination with the state governor).

⁶⁰These allocations to federally qualified health centers are separate from the allocations provided to jurisdictions.

⁶¹See the Health Resources and Services Administration's Ensuring Equity in COVID-19 Vaccine Distribution—Engaging Federally Qualified Health Centers website, accessed on February 26, 2021, <https://www.hrsa.gov/coronavirus/health-center-program>.

2021.⁶² As of March 8, 2021, 199 health centers were participating and 51 additional health centers were invited to participate in this program, according to the Health Resources and Services Administration.

Enhancing the number of eligible vaccinators and expanding eligibility for vaccination to all adults in the U.S. by April 19, 2021.

On March 11, 2021, the administration announced plans to allow other qualified health care providers to administer COVID-19 vaccine, including dentists, midwives, optometrists, paramedics, veterinarians, and medical and nursing students.⁶³ The White House also announced expectations that all eligibility restrictions would be lifted by May 1, 2021, making all adults in the U.S. eligible for vaccination. On April 6, 2021, the White House announced it was moving that date up, from May 1, 2021, to April 19, 2021. The White House also expects to launch various tools to make it easier for individuals to identify where they can be vaccinated. These federally supported tools include a “Find a Vaccination Website” and a 1-800 number for a call center that will provide guidance and assistance to those who may lack internet access. In addition, the administration stated it would deploy technology teams to states who need assistance in improving the websites their states’ are using to schedule vaccination appointments.

Information published on vaccine safety. In January and February 2021, CDC published results from its analysis of COVID-19 vaccine safety monitoring, including allergic reactions reported after receipt of the Pfizer and Moderna vaccines in its *Morbidity and Mortality Weekly Report* and in medical articles, including data on reported cases of anaphylaxis,

⁶²See <https://www.whitehouse.gov/briefing-room/press-briefings/2021/02/09/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-2/>, accessed on February 26, 2021.

⁶³White House, *Fact Sheet: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th*. (Washington, D.C.: Mar. 11, 2021), accessed on March 15, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/11/fact-sheet-president-biden-to-announce-all-americans-to-be-eligible-for-vaccinations-by-may-1-puts-the-nation-on-a-path-to-get-closer-to-normal-by-july-4th/>.

frequently reported adverse events, and deaths.⁶⁴ CDC also posted a series of communication resources on its website, including tool kits for health care providers, long term care facilities, employers of essential workers, and community-based organizations that provide educational information about the benefits of COVID-19 vaccination and address common questions and concerns.⁶⁵

Additional guidance on equitable access promoting vaccination.

CDC's January 2021 annex provided tools to jurisdictions on how to increase vaccine confidence in priority populations. The document, which focused, in part, on balancing equitable access with demand for vaccine, included new guidance to jurisdictions on when and how to transition from initial target populations to other priority populations and how to promote increased vaccination.

These and other steps the federal government has initiated may take time to implement at the federal, state, and local levels. Thus, it is too soon to determine to what extent, these and other efforts outlined in the National Strategy might help facilitate vaccine distribution and administration going forward. As we have reported since June 2020, coordination and clear and consistent communication across all levels of government and with all stakeholders remains a critical component of a successful response to the COVID-19 pandemic.

⁶⁴See, for example Department of Health and Human Services, Centers for Disease Control and Prevention, "First Month of COVID-19 Vaccine Safety Monitoring—United States, December 14, 2020—January 13, 2021, *Morbidity and Mortality Weekly Report* (Atlanta, Ga.: Feb. 19, 2021), accessed February 26, 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm>; "Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine—United States, December 21, 2020—January 10, 2021, *Morbidity and Mortality Weekly Report* (Atlanta, Ga.: Jan. 22, 2021), accessed on February 26, 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm>; "Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine—United States, December 14-23, 2020, *Morbidity and Mortality Weekly Report* (Atlanta, Ga.: Jan. 6, 2021), accessed on February 11, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w%E2%80%8B; and T.T. Shimabukuro, M. Cole, J. R. Su, "Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021" *JAMA*. Vol. 325, no. 11 (2021): pp. 1101–1102. <https://jamanetwork.com/journals/jama/fullarticle/2776557?resultClick=1> (accessed April 5, 2021).

⁶⁵See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits.html>, accessed February 26, 2021.

Finally, the Consolidated Appropriations Act, 2021, required the CDC Director to provide Congress with an updated and comprehensive COVID-19 vaccine distribution strategy within 30 days of the law's enactment (by January 26, 2021).⁶⁶ In March 2021, CDC prepared an initial submission of the strategy that provides a high-level description of the agency's ongoing and planned distribution activities. For example, it highlights enhancements for vaccine distribution that include efforts to vaccinate high-risk and underserved populations (including ethnic minority populations and rural communities). The strategy states that, to date, CDC has provided \$3 billion of the at least \$4.29 billion it intends to use as grants to state, local, tribal, and territorial jurisdictions for COVID-19 vaccine distribution. According to the distribution strategy, details of CDC's efforts are still under development and will be included in subsequent reports to Congress.

Agency Comments

We provided a draft of this report to DOD, HHS, and FEMA for review and comment. DOD, HHS, and FEMA provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Defense, FEMA, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Alyssa M. Hundrup at (202) 512-7114 or hundrupa@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix I.



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Acting Director, Health Care

⁶⁶Pub. L. No. 116-260, div. M, tit. III, 134 Stat. 1182, 1912 (2020). This strategy is to be updated and provided to Congress every 90 days through the end of fiscal year 2021.

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Vice Chairman
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United States Senate

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Appendix I: GAO Contact and Staff Acknowledgments

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In addition to the contact named above Kelly DeMots (Assistant Director), Alison Goetsch (Analyst in Charge), Nora Adkins, Darnita Akers, Jennie Apter, La Sherri Bush, Kaitlin Farquharson, Ryan Han, Nicolaus Heun, Katheryn Hubbell, Gay Hee Lee, Jason Lee, Jeff Mayhew, Linda McIver, Christopher Murray, Patrick Netherclift, Angie Nichols-Friedman, Miranda Riemer, Ethiene Salgado-Rodriguez, Fatima Sharif, Meghan Shrewsbury, Will Simerl, and Kim Yamane made key contributions to this report.

Related GAO Products

COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year. [GAO-21-387](#). Washington, D.C.: March 31, 2021.

Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Manufacturing Challenges. [GAO-21-319](#). Washington, D.C.: February 11, 2021.

Operation Warp Speed Dashboard, <https://ows.gaoinnovations.gov/>

COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention. [GAO-21-265](#). Washington, D.C.: January 28, 2021.

COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response. [GAO-21-191](#). Washington, D.C.: November 30, 2020.

COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations. [GAO-21-207](#). Washington, D.C.: November 17, 2020.

COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions. [GAO-20-701](#). Washington, D.C.: September 21, 2020.

COVID-19: Opportunities to Improve Federal Response and Recovery Efforts. [GAO-20-625](#). Washington, D.C.: June 25, 2020.

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