Highlights of GAO-21-387, a report to congressional committees

#### Why GAO Did This Study

As of March 15, 2021, the U.S. had over 29 million reported cases of COVID-19 and more than 523,000 reported deaths, according to CDC. The country also continues to experience serious economic repercussions.

Five relief laws, including the CARES Act, were enacted as of January 31, 2021, to provide appropriations to address the public health and economic threats posed by COVID-19. As of January 31, 2021, of the \$3.1 trillion appropriated by these five laws for COVID-19 relief, the federal government had obligated a total of \$2.2 trillion and expended \$1.9 trillion, as reported by federal agencies.

Most recently, in March 2021, a sixth relief law, the American Rescue Plan of 2021, was enacted and provides additional federal assistance for the ongoing response and recovery.

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 the federal government's continued efforts to respond to and recover from the COVID-19 pandemic.

GAO reviewed data, documents, and guidance from federal agencies about their activities and interviewed federal and state officials, experts, and other stakeholders, including health care professionals.

#### What GAO Recommends

GAO is making 28 new recommendations for agencies that are detailed in this Highlights and in the report.

View GAO-21-387. For more information, contact A. Nicole Clowers, (202) 512-7114 or clowersa@gao.gov.

#### March 2021

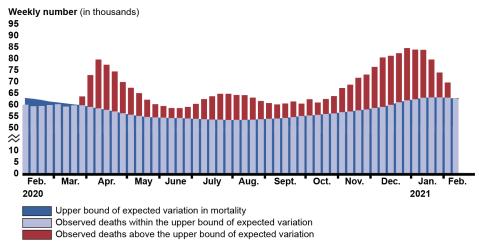
### COVID-19

# Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year

#### What GAO Found

More than a year after the U.S. declared COVID-19 a public health emergency, the pandemic continues to result in catastrophic loss of life and substantial damage to the global economy, stability, and security. According to data from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, about 520,000 more deaths occurred from all causes (COVID-19 and other causes) than would be normally expected from February 2020 through mid-February 2021, highlighting the effect of the pandemic on U.S. mortality (see figure). The pandemic also continues to cause economic challenges, particularly for the labor market. As of February 2021, there were about 10 million unemployed individuals, compared to nearly 5.8 million at the beginning of 2020.

#### Higher-Than-Expected Weekly Mortality in the U.S., February 2020 through Mid-February 2021



Source: GAO analysis of Centers for Disease Control and Prevention/National Center for Health Statistics data. | GAO-21-387

In the past year, GAO has made 44 recommendations for agency actions, 6 of which have been implemented. Since taking office, the new administration has taken some action consistent with GAO's recommendations, such as issuing the *National Strategy for the COVID-19 Response and Pandemic Preparedness* and issuing executive orders calling for the development of a pandemic supply chain resilience strategy and providing emergency economic relief. GAO will continue to monitor the administration's actions toward addressing GAO's recommendations in future reporting.

In this report GAO is making 28 new recommendations in the areas of public health, the economy, and program integrity. Implementing these 28 recommendations, as well as 38 of GAO's 44 prior recommendations that have not been fully implemented from CARES Act reports issued since June 2020, would improve the ongoing federal response to COVID-19.

GAO's new recommendations are discussed below.

Hospital and Pharmacy Perspectives on COVID-19 Vaccine Administration and Medical Supply Availability

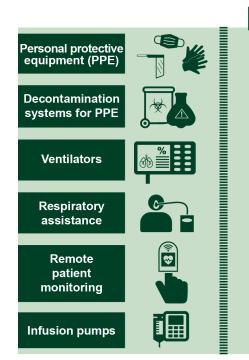
In February 2021, GAO surveyed hospitals and interviewed large retail pharmacy chains and an association of independent pharmacies to gain their perspectives on vaccine administration and medical supply availability. Providers expressed concerns about COVID-19 vaccine availability and limitations in the availability of certain key medical supplies for administering the vaccines—notably syringes and needles. For example, representatives from one retail pharmacy chain stated that the chain has the capacity to administer 25 million doses per month at 9,900 locations, but the chain's initial allocation of vaccines from the federal government was expected to be only 230,000 doses at 250 locations. Several retail pharmacy chain representatives also indicated that limited vaccine availability has led to uncertainty regarding the amount of vaccines their pharmacies can expect to receive each week. The new administration has taken steps to increase certainty and vaccine availability. For example, the White House announced at the end of January 2021 that the federal government would begin notifying states earlier about availability and shipments of vaccines, to give greater certainty for planning vaccination efforts.

Of the 146 surveyed hospitals that plan to or have begun administering COVID-19 vaccines, 40 hospitals reported at the time of GAO's survey being greatly concerned about having a sufficient quantity of syringes in the next 30 days for vaccine administration following the survey, and 43 hospitals were greatly concerned about having a sufficient quantity of needles. Additionally, shortages of personal protective equipment (PPE) and COVID-19 testing supplies also remain a challenge for some providers. GAO and other entities have documented persistent and evolving supply chain challenges throughout the pandemic, such as shortages of key supplies used for COVID-19 testing. GAO will continue to examine the medical supply chain, including the role of the Strategic National Stockpile, in future reporting, including actions to respond to GAO's previous recommendations.

#### **Emergency Use Authorizations**

Emergency use authorizations (EUA)—which allow for the temporary use of unapproved medical products—have been instrumental in increasing needed supply of certain devices, such as PPE, during the COVID-19 pandemic response (see figure). However, there have been instances of inconsistencies between EUAs issued by the Food and Drug Administration (FDA) and device guidance from CDC and the Department of Labor (DOL), which led to confusion and hesitancy among providers about using such devices, according to provider associations. **GAO recommends that FDA, CDC, and DOL work together to develop a process for sharing information to facilitate decision-making and guidance consistency related to devices with EUAs.** The Department of Health and Human Services (HHS)—which includes FDA and CDC—and DOL agreed with this recommendation.

Examples of Medical Devices Other Than Tests with Emergency Use Authorizations for COVID-19



#### **Description**

Protective clothing; helmets; gloves; face shields; goggles; masks; respirators, such as N95 respirators; or other equipment designed to protect the wearer from injury or the spread of infection or disease.

Devices intended to decontaminate certain medical devices (such as compatible respirators) so that they can be reused by health care personnel.

Devices that mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas.

Devices intended to help patients in need of support for breathing, removal of carbon dioxide, and therapy to reduce disuse atrophy of abdominal wall muscles.

Devices including (1) non-invasive remote monitoring devices that measure or detect common physiological parameters, and (2) non-invasive monitoring devices that wirelessly transmit patient information to their health care provider or other monitoring entities.

Devices that deliver fluids, such as nutrients and medications, into a patient's body in controlled amounts.

In addition, stakeholders—including associations representing manufacturers, distributors, and users of authorized devices, such as health care providers—raised concerns about what will happen to devices with EUAs after the declarations permitting their use for COVID-19 end. HHS has indicated that it intends to develop draft guidance for a transition plan for medical devices distributed under EUAs for COVID-19 by the end of fiscal year 2021. A plan for devices with EUAs that specifies a reasonable timeline and process for transitioning away from their use, taking into account stakeholder input, would help ensure a smooth transition. As HHS develops a transition plan for devices with EUAs, GAO recommends that the agency specify a reasonable timeline and process for transitioning authorized devices to clearance, approval, or appropriate disposition that takes into account input from stakeholders. HHS agreed with this recommendation.

#### COVID-19 Data for Health Care Indicators

Since June 2020, GAO has identified concerns with federal COVID-19 data and underscored that in the midst of a nationwide public health emergency, clear and consistent communication between the federal government and the public is critical given that effective response requires the public's participation. As part of its efforts to communicate with the public and stakeholders about the pandemic, several experts suggested that the federal government should improve the accessibility of its COVID-19 data by making these data available from a central location on the internet. HHS publishes its data on COVID-19 health indicators across several websites. However, the data it makes publicly available are not all located on, or available from website links on, one online location. As a result, the public, including stakeholders, may not be able to fully understand the extent of the pandemic and use the data to best inform their decision-making.

To make the data more easily accessible, GAO recommends that HHS make its different sources of publicly available COVID-19 data accessible from a centralized location on the internet. HHS neither agreed nor disagreed with this recommendation, but agreed that COVID-19 data should be made accessible to support communication with the public about the pandemic.

#### **COVID-19 Health Disparities**

GAO previously reported that communities of color have been disproportionately affected by the pandemic. According to HHS, as of February 8, 2021, data collected from states and jurisdictions on COVID-19 vaccine recipients were missing data on race and ethnicity for almost half of recipients. Without complete information on the race and ethnicity of those vaccinated, HHS may have difficulty determining whether vaccines are distributed equitably to communities of color. **GAO recommends that HHS take steps to ensure the complete reporting of race and ethnicity information for recipients of COVID-19 vaccinations.** HHS neither agreed nor disagreed with this recommendation.

HHS's July 2020 COVID-19 Response Health Equity Strategy has a goal to reduce health disparities by using data-driven approaches to attain the highest level of health possible for all individuals, including communities of color. However, the strategy lacks important elements of an effective national strategy. For example, HHS's strategy does not provide specific actions that the agency will take to determine whether or where it needs to increase access to testing for populations at increased risk for COVID-19—an essential first step before taking steps to increase testing access. **GAO recommends that HHS incorporate key elements of a national strategy to implement the agency's COVID-19 Response Health Equity Strategy, including determining how intermediate outcomes should be prioritized.** HHS agreed with this recommendation.

#### **Nursing Homes**

Collecting detailed information on vaccinations for nursing home populations is important for tracking and transparency, particularly because nursing homes have been an epicenter of the COVID-19 pandemic and HHS has recommended priority vaccinations for this group. HHS established a pharmacy partnership program for vaccinating staff and residents of long-term care facilities, and publicly reports the number of vaccination doses, by state, provided to residents and staff of all long-term care facilities participating in the program. However, HHS does not report data showing vaccination rates specifically for nursing homes and does not collect or report data for nursing homes not participating in the program. To improve the monitoring and transparency of nursing home vaccination efforts, GAO recommends that HHS collect data specific to COVID-19 vaccination rates in nursing homes and make these data publicly available. HHS neither agreed nor disagreed with this recommendation.

In addition, as of January 2021, HHS had not specified whether nursing homes would be required to offer COVID-19 vaccinations as they have with other vaccines and how these vaccinations would be incorporated into the agency's nursing home quality strategy. Data on COVID-19 vaccinations in nursing homes will also be important for HHS's ongoing efforts to monitor nursing home quality. **GAO recommends that HHS require nursing homes to offer COVID-19 vaccinations to residents and staff and design and implement associated quality measures.** HHS neither agreed nor disagreed with this recommendation.

#### Veterans Health Care

According to the Department of Veterans Affairs (VA), many veterans enrolled in VA's health care system are at a higher risk of infection or severe disease from COVID-19 due to their age or underlying health conditions. GAO identified several areas where VA can improve its vaccination efforts:

- VA does not have metrics related to staff and veterans who do not show (no-shows) for their vaccination appointments. Without data on no-shows, VA may be at risk for not being able to determine the extent to which staff and veterans are not showing up for appointments for their second vaccinations, and may miss opportunities to better target outreach to individuals not showing up for appointments.
- VA lacks targets for when it will move from one vaccination phase to another or within one phase for when the agency will move from one group of veterans to another, making it difficult for the department to assess progress.
- VA is utilizing a phased vaccine rollout; however, VA's current metrics do not capture vaccine data by phases. As a
  result, VA is not able to determine which facilities may be at an earlier phase than others and direct resources or
  assistance to those facilities.

GAO recommends that VA (1) collect data on the number of staff and veterans who do not show up for a vaccination appointment to better monitor for completion of the second dose of the vaccine; (2) develop preliminary vaccination targets for when it will move from one vaccination phase to another; or within one phase, from one group of veterans to another; and (3) develop metrics to assess the number of vaccines administered by vaccine rollout phase to better assess progress and make any necessary adjustments. VA agreed with the first and third recommendations and agreed in principle with the second recommendation.

#### **Nutrition Assistance**

The U.S. Department of Agriculture (USDA) administers a number of federal nutrition assistance programs to vulnerable populations. Recent legislative and executive actions made several changes to these programs as the negative economic effects of the COVID-19 pandemic have continued. However, until recently, USDA had released minimal data about participation in these programs during the pandemic, and when the department released data in late January 2021, it did not publicly share sufficient information about data quality. In August 2020, USDA announced it had identified significant issues with the quality of state-reported data on two programs. As it worked to identify the root causes of the issues, USDA opted not to release participation data for any of its other nutrition assistance programs from July 2020 until late January 2021. When USDA released the data, the department did not explain how it resolved the data quality issues it previously disclosed, nor did it share necessary context to help stakeholders and the public understand and interpret the data.

As a result, stakeholders and the public lack sufficient information and appropriate context to interpret key program data and understand the effects of the pandemic on the programs. GAO recommends that USDA (1) provide sufficient context to help stakeholders and the public understand and interpret data on federal nutrition assistance programs during the pandemic and (2) disclose potential sources of error that may affect data quality during the pandemic, such as manual processing. USDA generally agreed with these recommendations.

#### Disaster Relief Fund and Assistance to Tribal Governments

Available data from HHS indicate that tribes are among communities of color bearing a disproportionate burden of COVID-19 positive tests, cases, hospitalizations, and deaths. The Federal Emergency Management Agency (FEMA), within the Department of Homeland Security (DHS), plays a key role in the ongoing COVID-19 pandemic response effort, including using the Disaster Relief Fund to provide Public Assistance grants to reimburse tribal governments, among others, for pandemic costs, such as testing supplies, PPE, and vaccine distribution.

Several tribal organizations reported challenges related to completing administrative requirements to request and receive Public Assistance. For example, two tribal officials told GAO that when requesting technical assistance from FEMA to help with disaster activities such as developing a Public Assistance Administrative Plan, FEMA did not have staff to assist. FEMA's initial assessment report of its response to the pandemic noted challenges and recommended that FEMA develop a tribal nation engagement strategy that includes providing the resources and personnel throughout each region required to support program delivery for all tribal nations. However, as of March 2021, FEMA had not developed this strategy.

GAO recommends that FEMA provide timely and consistent technical assistance to support tribal governments' efforts to request and receive Public Assistance as direct recipients, including providing additional personnel, if necessary, to ensure that tribal nations are able to effectively respond to COVID-19. DHS agreed with this recommendation.

FEMA's 2019 *Tribal Consultation Policy* specifies the process for consulting with tribes throughout the four phases that guide the agency in how to conduct regular and meaningful collaboration with tribes (see figure). However, GAO found that FEMA did not follow the tribal consultation process while developing an interim policy detailing eligible items for

reimbursement under the Public Assistance program. If tribes had been formally consulted earlier in the process, they could have been in a better position to provide meaningful input to FEMA on how its policy might impact tribes. Further, there may have been less confusion on which items were considered eligible for reimbursement during the early months of the pandemic, and tribes could have made more informed decisions. **GAO recommends that FEMA adhere to the agency's protocols listed in the updated 2019** *Tribal Consultation Policy* by obtaining tribal input via the four phases of the tribal consultation process when developing new policies and procedures related to COVID-19 assistance. DHS agreed with this recommendation.

Overview of FEMA's Tribal Consultation Policy Process

#### Phase 1

#### Phase 2

## Phase 3

#### Phase 4

FEMA will identify if an agency action has tribal implications and will determine if the action requires tribal consultation.

Once FEMA identifies the need to conduct tribal consultation on an action, FEMA will notify the affected tribal governments.

FEMA determines the process for communicating and collaborating with tribal governments to exchange information, receive input, and consider the views of tribes on actions that have tribal implications.

FEMA then follows up with all tribal officials who were engaged in consultation and communicates how tribal input was used to inform the final decision.

Source: GAO analysis of Federal Emergency Management Agency documentation. | GAO-21-387

#### K-12 Education

The Department of Education (Education) has taken steps to track state and school district spending of certain COVID-19 relief funds, but the data give an incomplete picture of the status of funds and understate the rate at which funds are being used. According to data collected by Education, as of February 28, 2021, states and territories have spent about \$6.1 billion of the approximately \$75 billion appropriated through the Education Stabilization Fund for states' and territories' education needs. However, federal spending data alone provide an incomplete picture of states' and school districts' spending, as there are several factors that influence the rate at which funds appear to be spent. For example, there is often a significant gap between when a district "uses" the funds (i.e., orders, contracts for, installs, and pays for goods or services, such as information technology equipment) and when those funds are reported as "spent" in state and federal reporting systems, as is common in federal grants management processes.

According to Education officials, states award applicable funds to school districts so that the school districts can obligate those funds for specific purposes. The state does not transfer funds to the district until the district requests payment for services or deliverables received. Education officials do not consider the funds spent until the state requests payment for expenses. Given this gap between when a district uses funds and funds are recorded as spent, absent information on obligations, policymakers will not have complete information on how these funds are being used to address the pandemic-related education needs of America's schoolchildren. GAO recommends that Education regularly collect and publicly report information on school districts' financial commitments (obligations), as well as outlays (expenditures) in order to more completely reflect the status of their use of federal COVID-19 relief funds. For example, Education could modify its annual report on state and school district spending data to include obligations data in subsequent reporting cycles. Education agreed with this recommendation.

#### Small Business Assistance Programs

The Consolidated Appropriations Act, 2021, appropriated additional funding for the creation of the Targeted Economic Injury Disaster Loan (EIDL) Advance program and authorized additional Paycheck Protection Program (PPP) loans, among other things, highlighting the continued need for ensuring program integrity. Since March 2020, the Department of Justice has publicly announced charges in numerous fraud-related cases associated with loans made through these programs. As a result of concerns about program integrity, GAO has added Small Business Administration (SBA) loans to GAO's High Risk List. SBA has taken some steps to mitigate fraud risks to EIDL and PPP, but it has not taken a strategic approach to managing fraud risks to both programs. GAO recommends that SBA (1) implement a comprehensive oversight plan to identify and respond to risk in the EIDL program to ensure program integrity, achieve program effectiveness, and address potential fraud; (2) conduct and document a fraud risk assessment for the EIDL program and PPP; (3) develop a strategy that outlines specific actions to address assessed fraud risks in the EIDL program; and (4) outline specific actions to monitor and manage fraud risks in PPP on a continuous basis. SBA agreed with these recommendations.

#### **Unemployment Insurance Programs**

GAO continues to have concerns about overpayments and potential fraud in the unemployment insurance (UI) system, including the federally funded Pandemic Unemployment Assistance (PUA) program, which authorizes UI benefits to certain individuals not otherwise eligible for these benefits, such as self-employed and certain gig economy workers. As of

March 15, 2021, DOL reported that states had identified more than \$3.6 billion in PUA overpayments from March 2020 through February 2021. In response to a recommendation in GAO's January 2021 report, DOL has taken steps to collect data on states' recovery of PUA overpayments. However, the Consolidated Appropriations Act, 2021, enacted in December 2020, provided states with authority to waive certain PUA overpayments. Thus, additional data on the amounts of PUA overpayments states have waived are also needed to effectively monitor the recovery of overpayments. GAO recommends that DOL collect data from states on the amount of overpayments waived in the PUA program, similar to the regular UI program. DOL agreed with this recommendation.

This report contains additional recommendations related to transparency and accountability in the following areas: relief for health care providers, economic impact payments, federal contracts and agreements, audits of nonfederal entities receiving federal pandemic assistance, and employer tax relief and payroll tax deferrals.

GAO is also examining the federal government's COVID-19 vaccine efforts, which will be the focus of an upcoming report. Finally, GAO will review actions federal agencies have taken in response to the American Rescue Plan of 2021 in future reporting.