Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HHS DID NOT FULLY COMPLY WITH FEDERAL REQUIREMENTS AND HHS POLICIES AND PROCEDURES WHEN AWARDING AND MONITORING CONTRACTS FOR VENTILATORS

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Office of Inspector General

https://oig.hhs.gov

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS Did Not Fully Comply With Federal Requirements and HHS Policies and Procedures When Awarding and Monitoring Contracts for Ventilators

Why OIG Did This Audit

HHS is one of the largest contracting agencies in the Federal Government. In fiscal year 2020, HHS awarded over $14 billion in contracts in response to the COVID-19 pandemic. Of these contracts, HHS's Administration for Strategic Preparedness and Response (ASPR) awarded 10 contracts between March 30, 2020, and May 28, 2020, totaling nearly $2.9 billion to supply approximately 198,000 ventilators for the Strategic National Stockpile (SNS) by the end of 2020.

Our objective was to determine whether ASPR awarded and monitored contracts for the production of ventilators in accordance with Federal requirements and HHS policies and procedures.

How OIG Did This Audit

We audited the five highest-dollar value contracts that ASPR awarded for the production of ventilators, totaling approximately $2.4 billion. We reviewed these firm-fixed price contracts and associated modifications, invoices, delivery documentation, and other documentation maintained by ASPR.

What OIG Found

ASPR did not consistently award and monitor contracts for ventilators for use in responding to the COVID-19 pandemic in accordance with Federal requirements and HHS policies and procedures. Specifically, ASPR did not establish roles and responsibilities for communication with other emergency response teams, did not always accurately report contract data, and did not always properly monitor contractor performance.

As a result, ASPR could not ensure compliance with applicable Federal requirements or that each contract's terms were economically and efficiently achieved; therefore, ASPR could not determine whether the use of taxpayer funds was reasonable. In addition, the Federal Government may have used inaccurate contract data supplied by ASPR to measure and assess the impact of Federal procurements on Coronavirus Aid, Relief and Economic Security (CARES) Act spending. Finally, ASPR potentially hindered the SNS's ability to meet anticipated ventilator demand in support of the Federal Government's COVID-19 pandemic response.

What OIG Recommends and ASPR Comments

We made a series of recommendations to ASPR, including that it establish written policies and procedures for communicating with federally established emergency response team lead agencies, accurately report contract data, and strengthen its policies and procedures to ensure proper monitoring of contractor performance.

In written comments on our draft report, ASPR did not indicate concurrence or nonconcurrence with our findings and recommendations; however, it stated that it looks forward to utilizing our findings and recommendations to strengthen future response efforts. We encourage ASPR to implement our recommendations in these efforts.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Department of Health and Human Services (HHS) is one of the largest contracting agencies in the Federal Government. In fiscal year (FY) 2020, HHS awarded over $14 billion in contracts in response to the COVID-19 pandemic. Of these contracts, HHS's Administration for Strategic Preparedness and Response (ASPR)[1] awarded 10 contracts totaling nearly $2.9 billion to supply approximately 198,000 ventilators for the Strategic National Stockpile (SNS) by the end of 2020.[2, 3]

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for HHS, the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.[4]

OBJECTIVE

Our objective was to determine whether ASPR awarded and monitored contracts for the production of ventilators in accordance with Federal requirements and HHS policies and procedures.

BACKGROUND

ASPR and Its Role in the National Response Framework

ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, health care coalitions, biotech firms, community members, State, local, Tribal, and territorial Governments, and other partners across the country to improve readiness and response capabilities. In accordance with the *National Response Framework* (NRF), HHS is designated as the Federal

[1] ASPR was formerly known as the Office of the Assistant Secretary for Preparedness and Response. On July 22, 2022, the office was elevated from a staff division to an operating division and renamed the Administration for Strategic Preparedness and Response.

[2] The SNS is part of HHS's Federal medical response infrastructure. It is a repository of vaccines, antibiotics, antidotes, antitoxins, medical devices (including ventilators), supplies, and medications meant to supplement and resupply State and local public health agencies in the event of a national emergency in the U.S. or its territories.

[3] SNS was originally funded by Congress in FY 1999 and operated by the Centers for Disease Control and Prevention. ASPR has been responsible for operating the SNS since 2018. The SNS stores and maintains a variety of ventilator models, each with different features.

[4] OIG's COVID-19 response and strategic plan activities can be accessed at HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG.

agency to lead the Federal Government's response to a public health emergency.[5] HHS, through ASPR, is the primary coordinator for emergency support functions related to public health and medical services. ASPR has previously led this emergency support function in response to previous public health emergencies, such as the Zika Virus outbreak in Puerto Rico and public health emergencies declared in response to various natural disasters. However, prior to the COVID-19 pandemic, ASPR had not acted as an emergency support function supporting agency in response to a public health emergency; rather, ASPR has historically been the primary coordinator for emergency support functions related to public health and medical services.

Federal Efforts To Address COVID-19 and the Ventilator Shortage

On December 31, 2019, the World Health Organization (WHO) noted several cases of viral pneumonia in Wuhan, China. On January 20, 2020, the United States identified its first confirmed case of COVID-19, and on January 30, 2020, the WHO declared COVID-19 a Public Health Emergency of International Concern.[6]

As a result of confirmed cases of COVID-19, the HHS Secretary declared a public health emergency on January 31, 2020. At the time, hospitals were experiencing shortages of ventilators critical to providing treatment to COVID-19 patients. (See text box below.)

On March 13, 2020—2 days after the WHO declared COVID-19 a pandemic—the President proclaimed the pandemic a national emergency. On March 19, 2020, the White House Coronavirus Taskforce (WHCTF) designated, under Stafford Act authority (42 U.S.C. § 5121), the Federal Emergency Management Agency (FEMA) to lead the Federal response in combating the pandemic. FEMA's response involved coordinating with HHS and establishing a Unified Coordination Group (UCG) responsible for ensuring a whole-of-Government response to COVID-19. The UCG included the FEMA Administrator, the HHS ASPR Incident Manager, and the HHS Assistant Secretary for Health.

Early Demand for Ventilators

According to FEMA, early in the Federal Government's response to COVID-19, data models were still being developed to project the number of new COVID-19 cases and hospitalizations. In the face of such uncertainty, States prepared for the worst by asking for large numbers of ventilators from the SNS. Ventilator requests from March 16 to March 31, 2020, totaled 133,239—8 times the number of ventilators that the SNS had in stock.

On March 21, 2020, HHS's Program Support Center posted a Request for Information (RFI) on a Federal Government website to seek information

[5] The NRF is a guide to how the Nation responds to all types of disasters and emergencies and includes emergency support functions published by the Department of Homeland Security.

[6] A Public Health Emergency of International Concern is a formal declaration by the WHO of an extraordinary event determined to constitute a public health risk through the international spread of diseases and to potentially require a coordinated international response.

from the manufacturing community on the maximum number of ventilators that could be quickly produced and the cost for producing them.[7]

On March 25, 2020, the Under Secretary of Defense for Acquisition and Sustainment established the Joint Acquisition Task Force (JATF), which was comprised of acquisition professionals from the Department of Defense (DoD) and designed to support DoD's COVID-19 response for medical resources in coordination with FEMA and HHS.

One day later, on March 26, 2020, due to the urgency of the situation and the estimated demand for ventilators, ASPR began the process for quickly awarding ventilator contracts to vendors based on their responses to the RFI.[8]

The following day—March 27, 2020—The Coronavirus Aid, Relief and Economic Security (CARES) Act was signed into law. The law allocated approximately $25 billion to ASPR to procure personal protective equipment and ventilators for the SNS and to support State and local COVID-19 response.[9] Accordingly, ASPR's Office of Resource Management (ORM), SNS Contracting Branch entered into contracts with vendors to purchase ventilators for this purpose. In addition, the President used his authority under the Defense Production Act of 1950 (DPA) to direct HHS to facilitate the supply of materials for the production of ventilators to respond to the spread of COVID-19.[10]

The figure on the following page illustrates the timeline of key events described above.

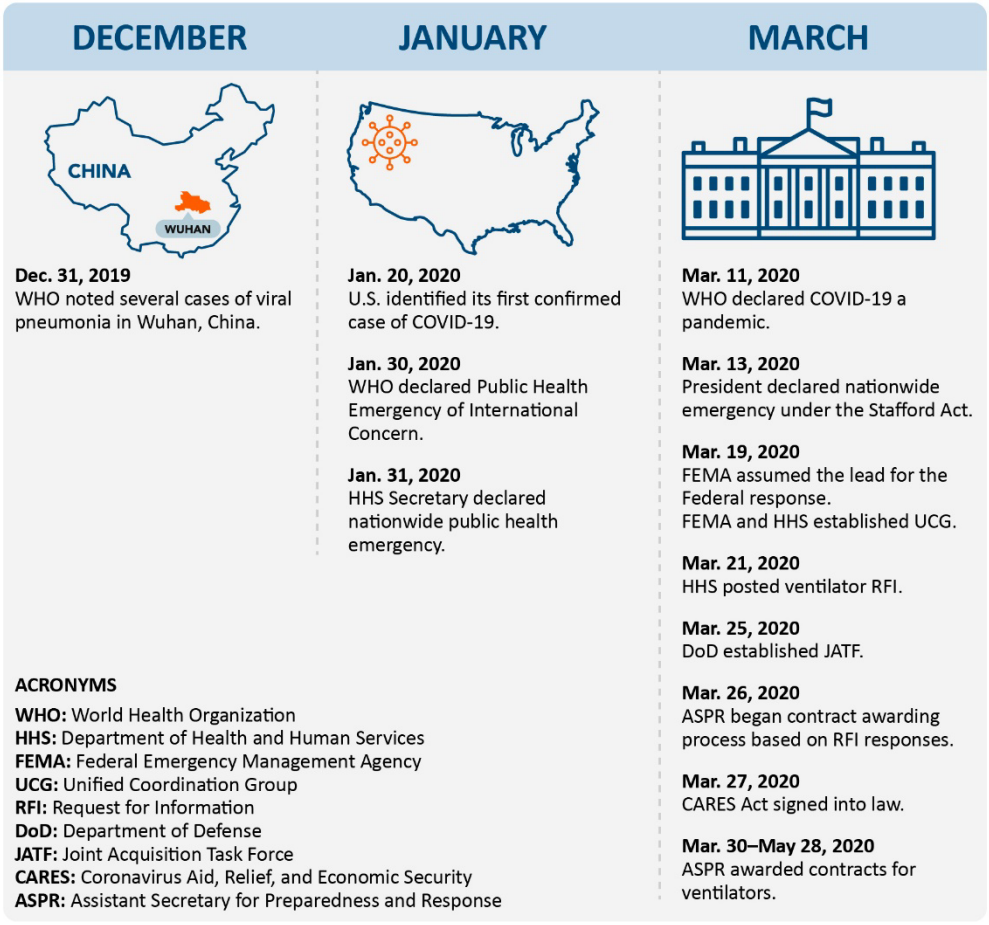
[7] In response to the RFI, ASPR received responses from 11 vendors that asserted to have the capacity to provide various models of ventilators to the SNS as early as Apr. 13, 2020.

[8] Between Mar. 26, 2020, and the awarding of the first contract on Mar. 30, 2020, HHS anticipated that funds for contracts would be provided with the passage of the Coronavirus Aid, Relief and Economic Security Act and developed authorizations for contractors to proceed at risk.

[9] Of the $25 billion, not more than $16 billion was to be allocated for the SNS.

[10] The DPA designation prioritized vendor delivery of ventilators to the Federal Government and manufacturer access to ventilator components and parts.

Figure: Timeline of Key Events



ASPR Ventilator Contracting Process During the COVID-19 Pandemic

Between March 30, 2020, and May 28, 2020 (our audit period), ASPR awarded 10 contracts totaling nearly $2.9 billion to supply approximately 198,000 ventilators for the SNS by the end of 2020. ASPR's process for awarding ventilator production contracts included numerous acquisition and administrative activities. ASPR contracting officials[11] were responsible for developing a streamlined acquisition plan, a request for proposal, and ultimately awarding the contracts. After awarding the contracts, ASPR contracting officials administered the contracts, to include contract reporting, monitoring the contractors' performance, and reviewing and approving (or disapproving) contractors' requests for payment. See Appendix B for an overview of ASPR's ventilator contracting process during the COVID-19 pandemic.

[11] We use the term "contracting officials" to refer to the Head of Contracting Activities, Contracting Officers, and Contracting Officer's Representatives.

Federal Requirements Applicable to Acquisitions and Internal Controls

The Federal Acquisition Regulation (FAR) guides the acquisition process by which Federal executive agencies acquire goods and services through contracts using appropriated funds. The FAR requires Federal agencies to report contract actions (e.g., contract award dates, amounts, and modifications) in the Federal Procurement Data System (FPDS) (FAR § 4.606(a)(1)).[12] It also allows for acquisition flexibilities when responding to a national emergency, including limiting the number of sources from which the Government solicits in situations with an unusual and compelling urgency (FAR § 6.302(a)(2)). In response to COVID-19, HHS's Assistant Secretary for Financial Resources issued emergency guidance further simplifying HHS's acquisition process by allowing for certain contracting flexibilities.[13]

In March 2020, the Office of Management and Budget (OMB) directed Federal agencies to enter a specific action code in the FPDS for all procurement actions issued in response to the COVID-19 pandemic.[14] The action code has been used as a means to track acquisition costs of Federal agencies involved in the response to COVID-19.

The Federal Managers' Financial Integrity Act (P.L. No. 97-255) requires Federal executive branch entities, including HHS, to establish internal controls in accordance with standards prescribed by the Comptroller General. *Standards for Internal Control in the Federal Government* (issued by the Comptroller General and known as the Green Book) states that agencies should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objective.[15] Specifically, management should internally and externally communicate the necessary quality information to achieve the entity's objectives.[16, 17]

[12] The FPDS is the real-time, relational database that serves the government acquisition community as the authoritative source of contract information. It contains summary level data that is used for policy and trend analysis. Because contracts change over time and FPDS is a real-time, relational database, the numbers change in FPDS every day.

[13] One contracting flexibility included informally requesting quotes via telephone, email, or other electronic means.

[14] Memorandum to the Heads of Executive Departments and Agencies, M-20-18, issued Mar. 20, 2020. Available online at https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf. Accessed on Feb. 1, 2022. The guidance was intended to assist the acquisition workforce as it addresses impacts due to COVID-19.

[15] Green Book ¶ 3.02.

[16] Green Book ¶ 14.01.

[17] Communications should enable personnel to perform key roles in achieving objectives, addressing risks, and supporting the internal control system. In these communications, management should assign internal control responsibilities for key roles (Green Book ¶ 14.03). Further, management should develop and maintain documentation of its internal control system (Green Book ¶ 3.09).

HOW WE CONDUCTED THIS AUDIT

We audited the five highest-dollar value contracts that ASPR awarded for the production of ventilators between March 30, 2020, and May 28, 2020 (our audit period). These firm-fixed-price contracts, totaling approximately $2.4 billion of the nearly $2.9 billion in total contracts awarded, were awarded to procure 139,474 ventilators by December 31, 2020.[18]

We obtained an understanding of the Federal contracting process and the flexibilities granted under emergency guidance. To determine whether contracts were awarded and monitored in accordance with Federal requirements and HHS policies and procedures, we reviewed contracts and associated modifications, invoices, delivery documentation, and other documentation maintained by ASPR. We conducted this performance audit 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.

Appendix A contains the details of our audit scope and methodology. Appendix C contains a summary of the ventilator contracts awarded by ASPR during our audit period.

FINDINGS

ASPR did not consistently award and monitor contracts for ventilators for use in responding to the COVID-19 pandemic in accordance with Federal requirements and HHS policies and procedures. Specifically, ASPR did not establish roles and responsibilities for communication with other emergency response teams, did not always accurately report contract data, and did not always properly monitor contractor performance.[19, 20]

[18] The SNS ultimately received 71,739 ventilators because, as of Aug. 31, 2020, 3 of the contracts were partially terminated prior to completion. As of the end of our fieldwork, in April 2022, termination settlement negotiations for one of these three partially terminated contracts were still ongoing and two were completed. Excess funds of approximately $905 million for these three contracts were deobligated.

[19] We note that the Department of Homeland Security, Office of Inspector General recommended that FEMA, working with HHS, issue clarifying guidance defining agencies' pandemic response roles and responsibilities under Stafford Act declarations (*Lessons Learned from FEMA's Initial Response to COVID-19*, OIG-21-64, Sept. 21, 2021).

[20] We note that the Government Accountability Office (GAO) has identified what it described as persistent deficiencies in HHS's preparedness and response efforts in several areas, including: (1) establishing clear roles and responsibilities for the wide range of key Federal, State, local, Tribal, territorial, and nongovernmental partners; (2) collecting and analyzing complete and consistent data to inform decision making as well as future preparedness; and (3) establishing transparency and accountability to help ensure program integrity and build public trust. (See GAO*, COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO 22-105291, Jan. 27, 2022.)

As a result, ASPR could not ensure compliance with applicable Federal requirements or that each contract's terms were economically and efficiently achieved; therefore, ASPR could not determine whether the use of taxpayer funds was reasonable. In addition, the Federal Government may have used inaccurate FPDS data supplied by ASPR to measure and assess the impact of Federal procurements on CARES Act spending. Finally, ASPR potentially hindered the SNS's ability to meet anticipated ventilator demand in support of the Federal Government's COVID-19 pandemic response.

ASPR DID NOT ESTABLISH ROLES AND RESPONSIBILITIES FOR COMMUNICATION WITH OTHER EMERGENCY RESPONSE TEAMS WHEN AWARDING VENTILATOR CONTRACTS

The FAR requires an agency head or a designee to prescribe procedures for ensuring that acquisition planners address the requirement to specify needs, develop specifications, and solicit offers in such a manner as to promote and provide for full and open competition with due regard to the nature of the supplies and services to be acquired.[21] Further, the Green Book states that management should: (1) assign responsibility and internally and externally communicate the necessary quality information to achieve the entity's objectives,[22] and (2) develop and maintain documentation of its internal control system.[23]

ASPR did not assign clearly defined roles and responsibilities for communicating with outside agencies designated as emergency response leads or federally established emergency response teams related to the awarding of ventilator production contracts. Specifically, ASPR did not develop procedures for documenting the decision-making process used by FEMA or the JATF in their determination of certain contract details communicated to ASPR. Thus, ASPR could not ensure compliance with full and open competition.

Beginning March 19, 2020, FEMA rather than ASPR was designated to lead the Federal response to COVID-19; accordingly, FEMA determined what equipment and supplies were required, the necessary quantities and specifications, and which vendors would be awarded contracts to supply these critical lifesaving medical supplies, including ventilators. Normally, ASPR contracting officers would be responsible for making these types of decisions under FAR parts 7 (acquisition planning), 12 (commercial item contracting), and 13 (simplified acquisition procedures). In the weeks that followed, ASPR, whose role was to support the Federal response led by FEMA, awarded ventilator contracts that included details such as ventilator specifications and required quantities communicated to ASPR by FEMA and the JATF without ASPR's knowledge of how decisions regarding these critical contract details were made. ASPR contracting officials stated that they did not know how the JATF made these determinations. ASPR had historically been the primary coordinator for emergency support functions related to public health and medical services. ASPR officials stated that, prior to the COVID-19 pandemic,

[21] FAR 7.103(c), 10 U.S.C. 2305(a)(1)(A) and 41 U.S.C. 3306(a)(1).

[22] Green Book ¶ 14.03.

[23] Green Book ¶ 3.09.

ASPR never had a need to develop procedures for documenting the decision-making process of outside agencies. Despite serving as a supporting agency in the Federal Government's emergency response, ASPR retained the responsibility of awarding and monitoring the contracts in accordance with applicable Federal requirements.

Because ASPR was unable to document the decision-making process used by FEMA or the JATF to establish ventilator specifications or the quantities that vendors were required to provide, it could not ensure compliance with the acquisition planning process or that each contract's terms were economically and efficiently achieved. Therefore, ASPR cannot determine whether the use of taxpayer funds was reasonable.

ASPR MONITORING OF SELECT VENTILATOR CONTRACTS DID NOT ENSURE ACCURATE REPORTING OF CONTRACT DATA IN THE FEDERAL PROCUREMENT DATA SYSTEM

The FAR requires agencies to report contract actions in the FPDS and any modification to contract actions that change previously reported contract action data, regardless of dollar value.[24] Further, per OMB guidance, agencies are directed to assign a specific action code to all procurement actions reported into the FPDS for actions issued in response to the COVID-19 pandemic.[25]

ASPR's monitoring of select ventilator contracts did not ensure accurate reporting of contract data in the FPDS. Specifically, for 4 of the 5 contracts we audited, ASPR entered a total of 11 incorrect contract signature dates in the FPDS related to when contracts were signed and modified. The difference between the dates entered into FPDS and the actual signature dates ranged from 2 days prior to the actual signature date to 191 days after the actual signature date. Also, for the same four contracts, ASPR reported nine inaccurate contract obligations or deobligations in the FPDS. Differences between the reported and actual contract obligations or deobligations ranged from $34 million in obligations to $543 million in deobligations.[26] Finally, for one of the four contracts, ASPR did not assign the required action code in the FPDS to facilitate tracking Federal agencies' acquisition costs for responding to COVID-19.

ASPR stated that it did not always accurately report contract obligations and did not assign the required action code for one contract due to human error and that the associated data would be corrected once final negotiated settlement modifications related to the contract are entered into FPDS. ASPR did not provide an explanation for why it reported inaccurate data for the

[24] FAR § 4.606(a)(1).

[25] Memorandum to the Heads of Executive Departments and Agencies, M-20-18, issued Mar. 20, 2020.

[26] Examples of these differences include: (1) a no cost modification incorrectly reported in FPDS as a $543 million deobligation, and (2) a $1.4 million deobligation incorrectly reported in FPDS as a no cost change in obligation amount.

three other contracts or if the errors we identified would be corrected during contract closeout.[27]

In fulfilling its financial stewardship responsibilities, the Government needs to understand where tax dollars are spent. The ability to look at contracts across Government agencies, in greater detail, is a key component in establishing trust in our Government and credibility in the professionals who use these contracts. Further, it provides opportunity for the Government to better assess where its money is being spent, thereby offering opportunities to better determine how to most effectively and efficiently expend those resources. FPDS contains contracting data that allows for this kind of insight. FPDS data are also used to create recurring and special reports to the President, Congress, the Government Accountability Office, Federal executive agencies, and the general public. Because ASPR reported incorrect information, these reports may have been inaccurate. Therefore, the Federal Government may have used inaccurate FPDS data to measure and assess the impact of Federal procurements on the nation's economy.

ASPR DID NOT ALWAYS PROPERLY MONITOR CONTRACTOR PERFORMANCE

Despite serving as a supporting agency in the Federal Government's emergency response, ASPR retained the responsibility of awarding and monitoring the contracts in accordance with applicable Federal requirements. In accordance with the FAR, ASPR designated Contracting Officer's Representatives (CORs) for each of the contracts. The CORs' duties, as detailed in their COR appointment memos,[28] included completing interim evaluations of contractors' performance and reviewing contractors' monthly invoices in a timely manner to ensure that the invoices accurately reflected the work completed and were in accordance with the terms of the contracts.[29] Contract terms and conditions included a COVID-19 specific requirement for the contractors to notify ASPR in writing "as soon as it is reasonably possible" if they became aware of a circumstance beyond their control that may result or resulted in nonperformance, partial performance, or delay in performance.[30]

ASPR did not always properly monitor contractor performance during the period of performance for two of the five contracts we audited. Specifically, ASPR did not complete

[27] As of Mar. 16, 2022, ASPR had not corrected FPDS for any of these errors.

[28] The COR appointment memo authorizes a COR to perform certain duties with respect to acquisition planning, execution, management, and closeout matters within the scope of the contract. The COR is authorized, subject to limitations, to act on behalf of ASPR in all matters related to monitoring the programmatic aspects of the contract.

[29] FAR § 1.602-2 requires Contracting Officers to ensure compliance with contract terms and conditions as well as to designate and authorize a COR.

[30] Notices of delays in performance were required to include: (1) the identified cause of the delay, (2) the known particulars of the delay, (3) the actions being taken by the contractor to immediately address and mitigate the delay, (4) the anticipated duration of the delay, and (5) the projected and actual impact of the delay on the vendor's delivery schedule.

interim evaluations of the vendors' delivery schedules (including quantities and dates) or delivery delays throughout the period of performance. Rather, ASPR only reconciled deliverables to established delivery schedules when the contracts were completed or terminated. As a result, ASPR did not identify when vendors did not meet contracted delivery schedules or deliveries of insufficient quantities of ventilators.[31] Further, ASPR did not always ascertain the reasons for, and extent of, delays or determine whether the vendors' delays in delivering ventilators were excusable under contract terms and conditions.

The following examples illustrate how ASPR did not always properly monitor contractor performance:

Example 1: ASPR Did Not Act on Ventilator Delays Despite Acting on Other Contract Delays

ASPR provided no documentation or explanation for why one vendor did not deliver its initial quota of ventilators on time. Specifically, the vendor was contracted to deliver 3 specific items, including an initial quota of 1,200 ventilators during April 2020; however, the vendor delivered only 299 ventilators during this period. The vendor delivered the remaining ventilators during May 2020. At no point did the vendor request a bilateral contract modification to the schedule or ask ASPR for approval of an excusable delay for the delivery shortage. On May 21, 2020, the vendor requested an excusable delay related to one of the other contracted items, which ASPR acted on by removing that item from the contract 5 days later. However, ASPR did not ascertain why the vendor's delivery of ventilators was delayed. It also did not determine whether the vendors' failure to timely deliver ventilators was excusable under contract terms and conditions.

Example 2: ASPR Did Not Act on Delays of Ventilator Upgrade Kits

ASPR did not properly monitor one vendor's contract delays. Specifically, the contract contained three specific deliverable items—ventilators, disposable resupply kits, and ventilator upgrade kits—each of which had its own delivery schedule. The delivery schedule called for the vendor to provide 7,603 ventilator upgrade kits during August 2020; however, the vendor did not deliver its first order until September 8, 2020. Final delivery was made nearly 1 month late, on September 24, 2020. At no point did the vendor request a bilateral contract modification to the schedule or ask ASPR to approve an excusable delay for the final delivery. Further, ASPR did not ascertain why the vendor's delivery of

[31] The two vendors did not always meet agreed-upon delivery schedules and did not always request excusable delays in accordance with contract terms and conditions, nor did they request modifications to delivery schedules via bilateral contract modifications with ASPR.

ventilator upgrade kits was delayed. It also did not determine whether the vendors' failure to timely deliver the kits was excusable under contract terms and conditions.

Although the CORs' duties, as detailed in the COR appointment memos, included the completion of interim evaluations to ensure that vendors' contractual delivery schedules were met or delays were excusable in accordance with specific contract terms and conditions, ASPR's policies and procedures did not ensure contracting officials completed interim evaluations of deliverables throughout each vendor's period of performance.

ASPR's failure to monitor whether vendors met contracted delivery schedules potentially hindered the SNS's ability to meet anticipated ventilator demand in support of the Federal Government's COVID-19 pandemic response. Additionally, failure to perform the COR's duties (e.g., completing interim evaluations of contractors' performance) may lead to acceptance and full payment of submitted invoices when such payment would otherwise not be justified.

RECOMMENDATIONS

We recommend that the Administration for Strategic Preparedness and Response:

- establish written policies and procedures regarding the roles and responsibilities for organizational communication between ASPR and federally established emergency response team lead agencies;

- make corrections in the FPDS for the four contracts for which ASPR reported inaccurate contract data, as detailed in our report;

- develop and implement policies and procedures to help ensure the accurate reporting of contract data in FPDS; and

- strengthen its policies and procedures to ensure CORs monitor contractor performance in accordance with duties detailed in COR appointment memos, including timely completing interim evaluations of performance and determining whether delays were excusable in accordance with specific contract terms and conditions.

ASPR COMMENTS

In written comments on our draft report, ASPR did not indicate concurrence or nonconcurrence with our findings and recommendations; however, it stated that it looks forward to utilizing our findings and recommendations to strengthen future response efforts. We encourage ASPR to implement our recommendations in these efforts.

ASPR noted that, in order to quickly execute numerous contracts, it partnered with the DoD to assist in the acquisition process. ASPR stated that, from March to June 2020, many functions

and processes were transferred between various Federal agencies, resulting in some confusion of roles and responsibilities. Finally, ASPR stated that the HHS Secretary recently approved ASPR's transition from a staff division to an operating division to allow ASPR to strengthen administrative capabilities, including hiring and contracting.

ASPR also provided technical comments, which we addressed as appropriate. ASPR's comments, excluding the technical comments, are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the top five highest-dollar value contracts awarded for the acquisition of ventilators for the SNS in response to the COVID-19 pandemic (COVID-19). These contracts related to $2,432,716,089 (84 percent) of the $2,894,048,058 in total contracts that ASPR awarded for ventilators between March 30, 2020, and May 28, 2020 (our audit period). We reviewed ASPR's process of awarding and monitoring contracts for the production of ventilators.

We assessed ASPR's policies, procedures, and practices applicable to awarding and monitoring contracts for the acquisition of ventilators in response to COVID-19. Our assessment would not necessarily disclose all material weaknesses in this control structure. However, it disclosed weaknesses in ASPR's monitoring of certain contract details. We discussed these weaknesses in the body of this report.

We conducted our audit work from November 2020 through April 2022.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal requirements;
- interviewed ASPR contracting officials to gain an understanding of and to document its processes for awarding Government contracts using emergency funding and for mitigating risks associated with making such awards;
- completed an internal control assessment to document ASPR's internal controls applicable to our audit objective;
- interviewed ASPR and HHS Program Support Center contracting officials to obtain an understanding of the contracting process and flexibilities granted due to the effects of the pandemic;
- determined contracts awarded by ASPR and reviewed copies of selected contracts and accompanying contract files;
- reviewed documentation to determine if ASPR followed established policies and procedures related to Federal Government contracting and the DPA;
- reviewed contract information that ASPR reported to the FPDS;

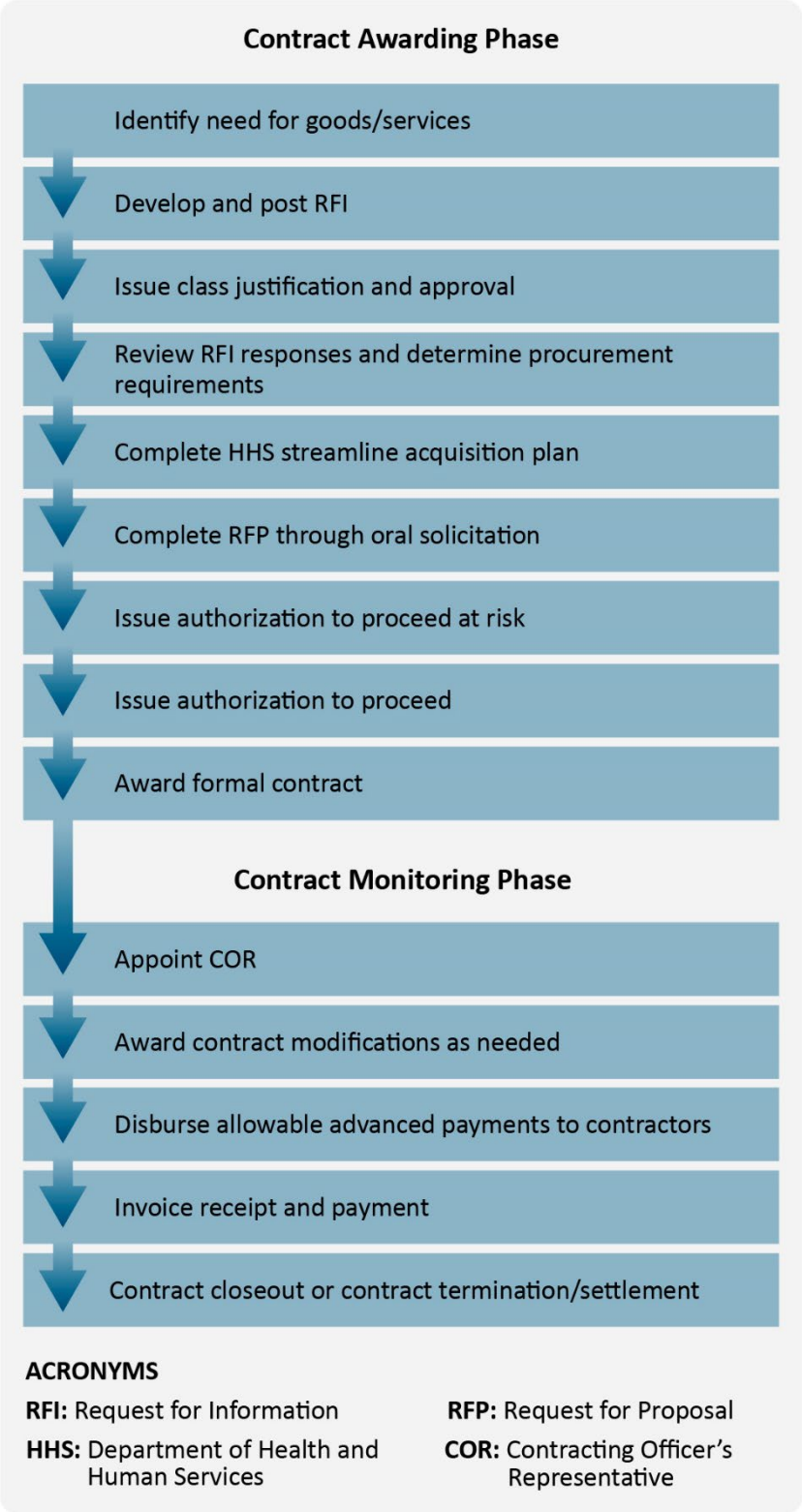
- determined if selected vendors met contract terms and conditions;

- reviewed vendors' invoices to determine whether they included data required by the FAR and were approved by the required contracting officials; and

- discussed the results of our audit with ASPR officials.

We conducted this performance audit 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.

APPENDIX B: OVERVIEW OF ASPR'S VENTILATOR CONTRACTING PROCESS DURING THE COVID-19 PANDEMIC



APPENDIX C: VENTILATOR CONTRACTS AWARDED BY ASPR BETWEEN MARCH 30, 2020, AND MAY 28, 2020

Vendor	Contract Amount	Number of Ventilators
Philips North America, LLC	$646,683,750	43,000
Hamilton Medical, Inc.	552,007,147	25,574
General Motors, LLC	476,143,048	30,000
Vyaire Medical, Inc.	407,904,453	22,000
Zoll Medical Corporation	349,977,691	18,900
Subtotal - Five Highest-Dollar Value Ventilator Contracts Audited	**$2,432,716,089**	**139,474**
Datex-Ohmeda, Inc. (General Electric)*	$336,000,000	50,000
Datex-Ohmeda, Inc. (General Electric)†	64,134,631	2,410
Resmed, Inc.	31,982,100	2,550
Hill-Rom Holdings, Inc.	20,097,400	3,400
Covidien Sales, LLC (Medtronic)	9,117,838	560
Subtotal – Other Ventilator Contracts Awarded	**$461,331,969**	**58,920**
Total Ventilator Contracts Awarded	**$2,894,048,058**	**198,394**

* Contract to provide pNeuton Model A-E ventilators.

† Contract to provide Carescape R860 ventilators.

APPENDIX D: ASPR COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Administration for Strategic Preparedness and Response
Washington, D.C. 20201

DATE: 08/11/2022

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of the Inspector General

FROM: Dawn O'Connell
Assistant Secretary for Preparedness and Response
Administration for Strategic Preparedness and Response

SUBJECT: OIG Draft Report: *HHS Did Not Fully Comply With Federal Requirements and HHS Policies and Procedures When Awarding and Monitoring Contracts for Ventilators*, A-02-20-02002

The Administration for Strategic Preparedness and Response (ASPR) welcomes the audit conducted by the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) which reviewed contracts for ventilator purchases during the COVID-19 pandemic. ASPR notes that in the early days of the response, specifically March to June 2020, many functions and processes were transferred between various agencies and Departments, resulting in some confusion on roles and responsibilities. As the response progressed through the summer, the Trump Administration stood up task forces and supporting operational components, such as the Joint Coordination Group, were put in place to enhance control, transparency and monitoring of previous awards and purchases.

ASPR as an organization is continually looking to learn lessons from past responses to improve its future response efforts. As noted in this report, in Fiscal Year 2020, HHS as a whole awarded over $14 billion in contracts to respond to the COVID-19 pandemic. Of these, ASPR awarded 10 contracts between March 30, 2020 and May 28, 2020, totaling nearly $2.9 billion to supply approximately 198,000 ventilators to the Strategic National Stockpile (SNS) by the end of 2020. In order to execute so many contracts so quickly, ASPR partnered with the Department of Defense to assist in the acquisition process. This was an unprecedented effort in an unprecedented response for ASPR, including ASPR's partnership with the Department of Defense. We look forward to utilizing findings and recommendations provided by OIG to strengthen our future response efforts.

ASPR would also like to note that the Secretary recently approved the transition of the Office of the Assistant Secretary for Preparedness and Response from a Staff Division to an Operating Division. As such, we are now the Administration for Strategic Preparedness and Response. One critical reason we requested this change, and the Secretary approved it, to allow us to strengthen our administrative capabilities, including hiring and contracting. These enhanced capabilities will help us ensure moving forward that APSR has the people in place to support critical mission

efforts as well as fully execute contracting requirements without relying on other partners for support. This additional capability will help us apply the lessons learned from this report.