

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ASPR DID NOT CONSISTENTLY
COMPLY WITH FEDERAL
REQUIREMENTS FOR AWARDING
RESEARCH AND DEVELOPMENT
CONTRACTS**

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Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Date: July 2024

Report No. A-03-20-03003

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



Why OIG Did This Audit

A previous OIG investigation found that the Administration for Strategic Preparedness and Response (ASPR) was unable to demonstrate that funds to support advanced research and development by the Biomedical Advanced Research and Development Authority (BARDA) were used for appropriated purposes.

Our objective was to determine whether ASPR complied with Federal requirements in awarding research and development contracts from fiscal year (FY) 2017 through FY 2020. Specifically, we determined whether ASPR: (1) awarded these contracts using BARDA appropriations in accordance with the Federal Acquisition Regulation (FAR) and (2) used the ASPR Next and BARDA DRIVE programs to award contracts in accordance with the FAR and established policies and procedures.

How OIG Did This Audit

We reviewed a judgmental sample of 28 research and development contracts (out of 235 unique contracts): 26 contracts were awarded by ASPR with contract actions from FYs 2017 through 2020 and 2 contracts were awarded through the ASPR Next program. We reviewed the 28 contracts to identify the award type and determine whether awards were made in accordance with the FAR and other legal requirements.

ASPR Did Not Consistently Comply With Federal Requirements for Awarding Research and Development Contracts

What OIG Found

ASPR did not always award research and development contracts, including those awarded using the BARDA DRIVE and ASPR Next programs, in accordance with FAR and HHS Acquisition Regulation requirements. Specifically, the contracting officers did not: (1) complete novation procedures timely upon the contractor's sale of its business and (2) properly finalize one contract before authorizing work to begin. Further, ASPR did not properly document all key administrative matters, including contracting decisions or activities for nine contracts.

These errors occurred because ASPR did not have an established process for reviewing or monitoring contract files for completeness and accuracy, and ASPR's contractor failed to comply with the terms of its contract. Further, ASPR failed to adequately maintain oversight, did not finalize and obligate funds for another contract, and, while ASPR's internal contract administration policies specified the documentation that should be maintained within a contract file, ASPR's policies did not address the organization and maintenance of electronic records.

What OIG Recommends and ASPR Response

We made several recommendations, including that ASPR: (1) implement a review process to verify that Federal acquisition awarding procedures and contract funding are fully completed before contract performance begins; (2) correct the Recording Statute violation for the contract that was not properly finalized by ratifying the original contract and properly recording an obligation; (3) correct the time violation for the improperly created purchase order by using no-year funds or multi-year funds available for obligation and report an Antideficiency Act violation if the time violation cannot be corrected; (4) create policies and procedures for the maintenance and organization of electronic contract files; and (5) implement a periodic documentation review process to assess completeness of contract files and provide training to address deficiencies identified from the review. The full recommendations are in the report.

In written comments on our draft report, ASPR concurred with all of our recommendations and described the actions it had taken and planned to take in response to those recommendations. For example, ASPR has implemented an agency-wide process to ensure all required reviews and approvals occur prior to contract award to ensure compliance with acquisition requirements.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Audit	1
Objective	1
Background	1
The Administration for Strategic Preparedness and Response	1
ASPR Contracts.....	2
The Federal Acquisition Regulation	3
The Antideficiency Act	3
How We Conducted This Audit	4
FINDINGS.....	4
ASPR Did Not Comply With Federal Requirements for Two Contracts	5
Novation Procedures for One Government Contract Were Delayed.....	5
ASPR May Have Violated the Antideficiency Act By Authorizing Work To Begin Before the Contract Was Signed	7
ASPR Did Not Appropriately Complete or Document Contract Administrative Procedures.....	9
Federal and ASPR Requirements	9
Incorrect Contract Information Was Reported to the Federal Procurement Data System.....	10
Key Documents Relating to the Contract Awarding Process Were Missing.....	11
Proposal Evaluations Were Not Properly Completed or Maintained	12
Causes of Contract Administrative Errors.....	12
RECOMMENDATIONS	13
ASPR COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	13
APPENDICES	
A: Audit Scope and Methodology	15
B: Federal Requirements	17
C: The Antideficiency Act	21
D: Judgmentally Selected Contracts	22

E: The Novation Process	23
F: ASPR Comments.....	25

INTRODUCTION

WHY WE DID THIS AUDIT

The Administration for Strategic Preparedness and Response (ASPR), an Operating Division of the Department of Health and Human Services, leads the Nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR's Biomedical Advanced Research and Development Authority (BARDA) provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases.

ASPR used two similar funding programs known as ASPR Next and BARDA Division of Research, Innovation, and Ventures (DRIVE) to award contracts to spur innovation in the development of new technologies. Congressional funding for ASPR includes funds to support advanced research and development by BARDA. A previous Office of Inspector General investigation of accounting for funds that Congress intended for BARDA to use to respond to public health emergencies and other outbreaks found that ASPR was unable to demonstrate that the BARDA funds were used for their appropriated purposes.¹

OBJECTIVE

Our objective was to determine whether ASPR complied with Federal requirements in awarding research and development contracts from fiscal year (FY) 2017 through FY 2020. Specifically, we determined whether ASPR: (1) awarded these contracts using BARDA appropriations in accordance with the Federal Acquisition Regulation (FAR) and (2) used the ASPR Next and BARDA DRIVE programs to award contracts in accordance with the FAR and established policies and procedures.

BACKGROUND

The Administration for Strategic Preparedness and Response

ASPR leads the Nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR has operational responsibilities for the advanced research, development, and stockpiling of medical countermeasures as well as the coordination of the Federal public health and medical response to emergencies and disasters. 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.

¹ *Investigation into the Assistant Secretary for Preparedness and Response for Misuse of Congressional Appropriations* ([H-18-0-1183-8](#)), issued May 1, 2020.

BARDA, as part of ASPR, was established to aid in securing our Nation from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the Food and Drug Administration and inclusion in the Strategic National Stockpile.

ASPR Contracts

Within ASPR, the Office of the Head of Contracting Activity is responsible for awarding contracts.² To gather contract proposals, it may post a Broad Agency Announcement (BAA) to the System for Award Management website (SAM.gov).³ BAA requirements vary; however, a posted BAA will describe the agency's research interest and criteria for selecting the proposals, specify the period of time during which submitted proposals will be accepted, and contain instructions for the preparation and submission of proposals. Once potential contractors submit the documentation specified in the BAA, ASPR reviews the submissions and decides which proposals to accept.⁴ After acceptance, the potential contractor submits a full proposal, with abstract, for evaluation.

In 2018, ASPR created the BARDA DRIVE program to drive cutting-edge research, foster innovation, and facilitate ventures aimed at enhancing our Nation's preparedness against health threats. This effort is accomplished through awarding contracts using a BAA.

In addition, from August 2019 through June 2020, ASPR used the ASPR Next program which was designed to solicit proposals to spur innovation in the development of new technologies and

What Makes a BAA Unique?

A BAA is a notice from the Government that requests scientific or research and development proposals from private firms concerning certain areas of interest to the Government. A BAA is not related to the development of a specific system or hardware procurement. A BAA presents a problem statement and challenge in search of a solution and may lead to contracts or grants. A BAA is different from a Request for Proposal, which provides a standard Statement of Work.

² Within the Office of the Head of Contracting Activity, the Deputy Head of Contracting Activity oversees BARDA's Division of Contract Management and Acquisitions, which is responsible for awarding and overseeing BARDA contracts.

³ SAM.gov is an official website of the U.S. Government that entities seeking to do business with the U.S. Government can use to: (1) register to do business with the U.S. Government; (2) update, renew, or check the status of entity registration; (3) search for entity registration and exclusion records; and (4) search contract opportunities and contract data reports.

⁴ Each ASPR BAA posted to SAM.gov specifies the documentation that must be submitted for proposal consideration by ASPR. Each BAA provides specific requirements for layout, supporting documentation, and required information to be submitted.

products for revolutionary advancements in health security products, technologies, and innovations through an ASPR Next BAA posted to SAM.gov.⁵

The BARDA DRiVe program could be used for BARDA contracts only, while the ASPR Next program could be used for both ASPR and BARDA contracts.

The Federal Acquisition Regulation

The FAR is the primary regulation that all Federal Executive agencies must follow when acquiring goods and services with appropriated funds (FAR, 48 CFR chapter 1). The Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) supplements the FAR and provides the regulatory framework for conducting acquisitions across HHS (HHSAR, 48 CFR chapter 3). Both provide a framework for awarding contracts, paying contractor invoices, and conducting management and oversight of contractor performance.

Contracting officers, appointed by the agency head, are the only individuals authorized to enter into, administer, or terminate contracts (FAR, 48 CFR § 1.602). Contracting officers appoint contracting officer's representatives to assist in the technical monitoring and administration of a contract (FAR, 48 CFR § 1.604). The FAR provides policies and establishes responsibilities for recording and maintaining contract information (FAR, 48 CFR § 4.801 and 4.802).

The Antideficiency Act

An agency may obligate or expend appropriations for goods and services when: (1) the purpose of the obligation or expenditure is authorized (31 U.S.C. § 1301(a)), (2) the obligation occurs within the time for which the appropriation is available (31 U.S.C. § 1502(a)), and (3) the obligation or expenditure is within the amounts that Congress has established (31 U.S.C. § 1341(a)). Together these statutes are referred to as the main tenets of appropriations law requirements: purpose, time, and amount. According to the Recording Statute, an agency is required to record an obligation at the time it incurs a liability (31 U.S.C. § 1501(a)(1)).

The Antideficiency Act prohibits the agency from entering into contracts that exceed the amount of enacted appropriations for the year and from purchasing services and merchandise before appropriations are enacted (31 U.S.C. § 1341(a)(1)). Agencies must report Antideficiency Act violations to the President (through the Office of Management and Budget (OMB)), Congress, and the Comptroller General of the Government Accountability Office (GAO) (31 U.S.C. § 1351). OMB Circular A-11 prescribes the methodology for this reporting.

See Appendix B for a summary of the Federal requirements referenced in this report and Appendix C for further information about the Antideficiency Act.

⁵ The ASPR Next program only posted one BAA that solicited proposals from August 29, 2019, through June 30, 2020, resulting in a total of four awards.

HOW WE CONDUCTED THIS AUDIT

We reviewed a judgmental sample of 28 research and development contracts (out of 235 unique contracts): 26 contracts were awarded by ASPR with contract actions from FYs 2017 through 2020 and 2 contracts were awarded through the ASPR Next program.^{6, 7} Of the 26 ASPR contracts, 14 were awarded using standard contract awarding processes and 12 were awarded through the BARDA DRIVE program.⁸ The 28 contracts were associated with 24 different contractors and resulted in obligations totaling \$512.4 million from FY 2017 through FY 2020 (audit period).

We reviewed the 28 contracts to identify the award type and determine whether awards were made in accordance with the FAR and other legal requirements.

Although this audit was not designed to focus on contract management specifically related to COVID-19 efforts, our audit period includes research and development contracts awarded through FY 2020, the first full year of the COVID-19 pandemic.

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.

See Appendix A for the details of our audit scope and methodology and Appendix D for a list of reviewed contracts.

FINDINGS

ASPR did not always award research and development contracts, including those awarded using the BARDA DRIVE and ASPR Next programs, in accordance with FAR and HHSAR requirements. Specifically, ASPR did not begin novation procedures until nearly 2 years after a contractor's sale of its business, and ASPR contracting officers did not properly finalize one contract before

⁶ In general, a contract action is an action that results in the acquisition (purchase, rent, or lease) of equipment, services, or construction using appropriated dollars over the micro-purchase threshold. Modifications to previously awarded contracts are also contract actions. As a result, reviewed contracts may have been originally awarded prior to FY 2017. See FAR 4.601 for further information about contract actions.

⁷ Four awards were made through the ASPR Next program; however, only two were standard procurement contracts that were governed by the FAR and HHSAR and therefore within the scope of our audit.

⁸ Of the 26 ASPR-awarded contracts, 8 were orders for specific tasks that occurred during the performance period of an Indefinite Delivery, Indefinite Quantity (IDIQ)-type contract made using standard contract awarding processes. An IDIQ contract provides for an indefinite quantity, within stated limits, of supplies or services during a fixed period. During the fixed period, the Government places individual task or delivery orders for required supplies or services once a specified number of services or supplies is identified and required by the Government. The orders in total may not exceed the limits stated in the original IDIQ contract award.

authorizing work to begin. Further, ASPR did not properly document all key administrative matters, including contracting decisions or activities for nine contracts.

These errors occurred because ASPR did not have an established process for reviewing or monitoring contract files for completeness and accuracy, and ASPR's contractor failed to comply with the terms of its contract. Further, ASPR failed to adequately maintain oversight, did not finalize and obligate funds for another contract, and, while ASPR's internal contract administration policies specified the documentation that should be maintained within a contract file, ASPR's policies did not address the organization and maintenance of electronic records.

ASPR DID NOT COMPLY WITH FEDERAL REQUIREMENTS FOR TWO CONTRACTS

Novation Procedures for One Government Contract Were Delayed

Federal Requirements

Federal regulations at 41 U.S.C. section 6305(a) expressly state that the party to whom the Federal Government gives a contract or order may not transfer the contract or order, or any interest in the contract or order, to another party. If a contractor's business is sold within the contract's period of performance, the contractor must submit a written request to the responsible contracting officer for the Government to recognize a successor and transfer the business's rights and obligations under the contract to the new owner (FAR 42). FAR 42 outlines the documentation that the original contractor must submit to the contracting officer for approval. If the agency, through the contracting officer, determines that it is in its best interest for a new contractor to assume responsibility for the entire contract, the contracting officer works with the original contractor to execute an agreement known as a novation. Contracting officers are not required to approve novation requests; instead, they approve novations only when the agency determines that it is in its best interest for a new contractor to assume responsibility for the entire contract. If approved, the previous contractor passes on the performance responsibility under the contract to the new business owner.

A Change-of-Name Agreement applies only when the contractor's name is the only change and that contractor's contractual rights and obligations remain unaffected. If a contractor transfers its assets (including the assets involved in the performance of the contract) to a new owner, then the contractor must follow the novation process.

Federal regulations at 48 CFR section 52.215-19 provide the requirements for notifying the contracting officer of ownership changes. In particular, the contractor must notify the contracting officer of the change in ownership within 30 days.

Contracting officers use the Contractor Performance Assessment Reporting System (CPARS) to record contractors' past performance for Government contracts (FAR 42.15). It is imperative that CPARS reporting is accurate as past performance is a mandatory and often deciding factor in awarding most Federal contracts and task orders. The CPARS report includes the contractor's

record of conforming to requirements and to standards of good workmanship during the completion of previous contracting work.

See Appendix E for a detailed explanation of the novation process.

Novation Was Delayed By Almost 2 Years

For one research and development contract, ASPR did not begin novation procedures until nearly 2 years after the sale of the company. Specifically, ASPR awarded an indefinite delivery/indefinite quantity (IDIQ) contract with a period of performance of September 2013 through September 2023. A subsequent delivery order was awarded to the original contractor with a period of performance of September 2013 through March 2019. In September 2017, the original contractor sold the company but did not notify the contracting officer of the sale within 30 days in accordance with the contract terms and did not submit a complete novation package as required.⁹

The new contractor inappropriately continued work on the delivery order under the name of the original contractor. Because novation had not been completed, the new contractor was working on the delivery order without a valid contract. The contracting officer did not know about the change in contractors until January 2019, when the new contractor inaccurately notified the contracting officer that the company had changed its name when in fact the company had been sold over a year previously.

After the contracting officer received notification of a name change, an additional 7 months passed before the contracting officer notified the new contractor that a name change was not appropriate in this circumstance and that the contractor would need to submit a novation agreement for review and approval. The new contractor, assuming the work of the original

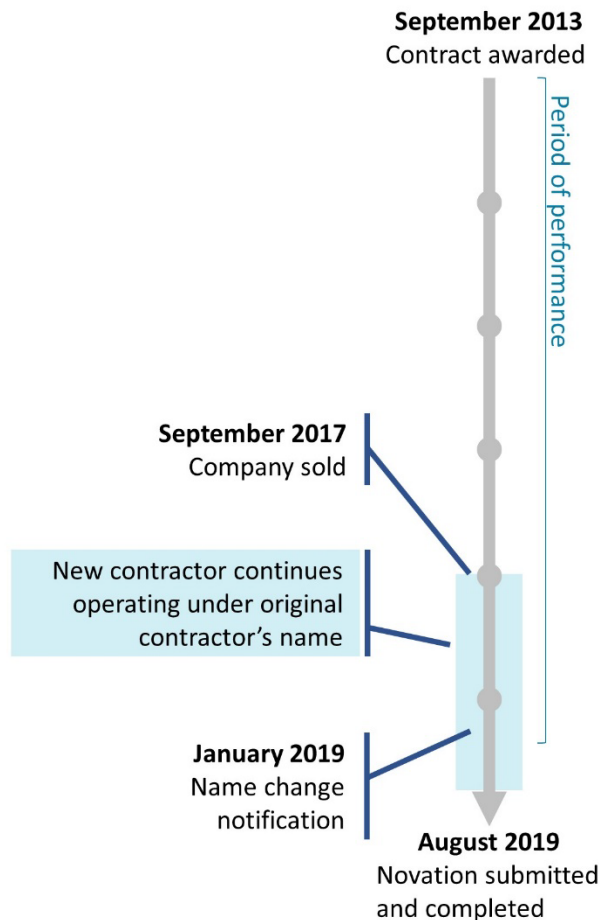
⁹ The contract properly incorporated 48 CFR section 52.215-19 by reference. However, although this section specifies the actions a contractor must take when the contractor becomes aware that a change in its ownership has occurred or is certain to occur, as we noted in this report, the original contractor did not notify the contracting officer that the company had been sold.

contractor, did not submit paperwork for the novation until August 2019. The Figure on the right provides a timeline of events for the novation process for this contract.

BARDA hosted a kickoff meeting with the new contractor in November 2019 (after the novation was finalized) to provide a clear understanding of Government expectations and to discuss pertinent terms and conditions and the technical path forward. However, because the original contractor failed to comply with the contract’s requirement to submit a written novation request to the responsible contracting officer after the sale of the company, the novation process was delayed, and the Government's interests were not adequately protected from September 2017 when the company was sold and August 2019 when the novation was approved.

Although BARDA discussed Government expectations with the new contractor, it did not report in CPARS that the original contractor failed to report the sale of the business interests and transfer of the contract in accordance with the requirements included within the contract. CPARS should include a contractor’s record of conforming to requirements and standards of good workmanship during the completion of previous contracting work. Contracting officials contemplating future awards must rely on clear and timely evaluations of contractor performance to make informed business decisions when awarding government contracts and orders. When CPARS is not updated with this type of information, contracting officers selecting a contractor for future work would not have complete past performance information for the original contractor.

Figure: Novation Timeline



ASPR May Have Violated the Antideficiency Act By Authorizing Work To Begin Before the Contract Was Signed

Federal Requirements

As stated in 48 CFR 1.602-2, contracting officers are responsible for ensuring performance of all necessary actions for effective contracting, ensuring compliance with the terms of the contract, and safeguarding the interests of the United States in its contractual relationships. Further, Federal statutes limit the time for which an appropriation may be used. The bona fide needs rule requires that a fiscal year appropriation be obligated only to meet a bona fide, or

legitimate, need arising in, or in some cases arising before but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). Bona fide needs may involve transactions that cover more than 1 fiscal year, depending on the nature of the services involved. When an agency does not follow the bona fide needs rule, an Antideficiency Act violation can occur. In 2013, GAO issued a decision that addressed, among other things, the proper application of the bona fide needs rule.¹⁰

The Recording Statute, 31 U.S.C. section 1501, requires agencies to promptly record obligations in their financial management system. The Statute further states the agency may not record an obligation until one has arisen and may not record an obligation until there is proper documentation, including a binding agreement between an agency and another person (including an agency) that is in writing, in a way and form, and for a purpose authorized by law.

ASPR Authorized Work To Begin Without a Signed Contract and May Have Violated the Antideficiency Act

In October 2017, ASPR began the process of awarding a \$14,000 contract to procure the services of an independent appraiser. Approximately 2 years after the work was completed and after a new contracting officer was assigned to the contract, the new contracting officer was informed that the original contract had not been finalized and funds had not been obligated. Instead, the original contracting officer had inappropriately provided the contractor with verbal authorization for work to begin but did not finalize the contract. As a result, ASPR was unable to provide us with an original signed contract for this BARDA contract.

A memo, dated February 11, 2020, from the newly assigned contracting officer stated that the original contracting officer failed to release the contract into the electronic contracting system and provided verbal authorization for the contractor to begin work on the contract. Without proper documentation in the electronic contracting system, ASPR was unable to record obligations totaling \$14,000 as required. As ASPR never released the contract into the electronic contracting system, there was no obligation from which to pay the contractor when the work was complete.

In September 2019, once the new contracting officer discovered that a contractor completed work for the Government without a signed contract or funding obligation, the Head of Contracting Activity could have ratified the original contract.¹¹ Instead, in February 2020, the new contracting officer inappropriately created a new purchase order obligating FY 2020 funds to pay for purchases for which a bona fide need began in FY 2018. This new purchase order did not refer to the original contract period and also specified a delivery date of March 2020 for

¹⁰ GAO, *Department of Health and Human Services—Multiyear Contracting and the Bona Fide Needs Rule* (B-322455), published August 16, 2013.

¹¹ Ratifying a contract is the act of approving the terms and conditions of the document.

work that had actually been completed in FY 2018. In doing so, ASPR incorrectly used FY 2020 funds to pay for services with a bona fide need that arose in FY 2018.

Because the contract was not properly finalized or ratified, ASPR violated the Recording Statute and time requirement and may have violated the Antideficiency Act. At the time the error was discovered, ASPR could have used either remaining FY 2018 funds or no-year funds available for obligation to properly record the obligation. However, FY 2018 funds were only available for obligation through September 30, 2023, thus, only no-year funds or, potentially, multi-year funds are available to correct the original error.

ASPR DID NOT APPROPRIATELY COMPLETE OR DOCUMENT CONTRACT ADMINISTRATIVE PROCEDURES

Of the 28 contracts reviewed, ASPR did not appropriately complete or was missing documentation for 8 different contracts. Specifically, three contracts were incorrectly reported within the Federal Procurement Data System (FPDS), three contracts were missing required documentation, and four contracts did not have technical evaluations appropriately completed or maintained.¹²

Federal and ASPR Requirements

Federal regulations at 48 CFR subpart 4.8 provide the requirements for establishing, maintaining, and disposing of contract files, stating that the head of each contracting office is required to establish files with complete histories of all contractual actions and decisions and ensure that these files are readily accessible to principal users, and that contract files must be maintained to ensure effective documentation of contract actions. Technical evaluations are considered part of the contract file and should be maintained and readily accessible to principal users. The documentation in the files must be sufficient to constitute a complete history of the transaction for the purposes of: (1) providing a complete background as a basis for informed decisions at each step in the acquisition process; (2) supporting actions taken; (3) providing information for reviews and investigations; and (4) furnishing essential facts in the event of litigation or congressional inquiries.

Internal ASPR contract administration policies also specify the documentation that should be maintained within a contract file. Further, the policy states that all contract files must be uniform in structure (ASPR-AMCG-1017.01).

Executive agencies use the FPDS to maintain publicly available information about all unclassified contract actions exceeding the micro-purchase threshold and any modifications to those actions that change previously reported contract action report data, regardless of dollar value (FAR, 48 CFR § 4.603).

¹² Some contracts had more than one error.

Federal requirements at 48 CFR subpart 4.606 specify the actions that must be reported to the FPDS. At a minimum, agencies must report the contract actions defined in FAR, 48 CFR § 4.603.

The FAR, Part 10, states that contracting officers are to conduct market research appropriate to the circumstances before developing required acquisition documents and soliciting offers with an estimated value above the simplified acquisition threshold. Market research involves obtaining information specific to the product or service being acquired and may vary depending on such factors as urgency, estimated dollar value, complexity, and the contractor's past experience. The contracting officer may use market research conducted within 18 months before the award of any task or delivery order if the information is still current, accurate, and relevant.

The FAR, Part 35.016 states that proposals received as a result of a BAA will be evaluated in accordance with evaluation criteria specified within the posted BAA through a peer or scientific review process. Written evaluation reports on individual proposals are necessary, and proposal acceptance is based on technical aspects, its importance to agency programs, and fund availability. Cost realism and reasonableness must also be considered to the extent appropriate.

Incorrect Contract Information Was Reported to the Federal Procurement Data System

For 3 of 28 contracts, contract actions were incorrectly reported within the FPDS:

- For one contract, ASPR failed to appropriately report one contract action related to a delivery order. For this delivery order, three modifications were completed during our audit period, but only two were reported to the FPDS. The first modification obligated \$1.9 million to the contract but was never reported to the FPDS.
- For a second contract, the contractor completed a corporate name change within a modification to the contract. This corporate name change included a change to the Dun & Bradstreet (DUNS) number associated with the contractor.¹³ However, the FPDS records for that modification and the next eight modifications after that continued to reflect the original DUNS number.
- For a third contract, the contractor completed a corporate name change within a modification to the contract, but the FPDS records for both the name change modification and the next modification failed to reflect the name change. Instead, the

¹³ The DUNS number is a unique nine-digit identifier for a business. On Apr. 4, 2022, after our audit period, the unique identifier used across the Federal Government changed from the DUNS number to a Unique Entity ID generated by SAM.gov upon registration.

records for these modifications continued to reflect the original name of the contractor.¹⁴

Failure to post accurate information within the FPDS negatively affects trust and transparency in Federal spending. Further, the award information in FPDS is used by the President, Congress, GAO, and other agencies to form policy decisions and to report on trends. Therefore, it is important that data in FPDS is accurate, complete, and timely.¹⁵

Key Documents Relating to the Contract Awarding Process Were Missing

For 3 of 28 contracts, the contracting officer was unable to locate and provide required contract documentation:

- For one sampled sole source contract, the contracting officer was unable to locate and provide an unredacted justification for exception to fair opportunity (JEFO).¹⁶ While ASPR provided a justification, it was partially redacted, and the final approving signature was dated 6 months before the task order was awarded. Although the contracting officer posted the justification on SAM.gov as required, it was access-controlled, and our office was unable to view the posted JEFO. To determine whether the justification was proper, we would need to be provided an unredacted, properly signed justification. Further, the contracting officer was also unable to provide documents related to an independent Government cost estimate that should have been developed by the contracting officer's representative prior to award.
- For a second sampled contract, the contracting officer was unable to provide documentation relating to the market research conducted and a signed, completed copy of a modification to the contract. During our review period, a total of \$33.8 million had been obligated to the contract. This total amount included \$818,656 that was deobligated through a modification, a signed copy of which the contracting officer was unable to provide.
- For a third contract awarded through the BARDA DRIVE program, the contracting officer was unable to provide the abstract submitted by the proposed contractor. The

¹⁴ This contract was not subject to novation, as the contractor's name was the only change and the contractor's contractual rights and obligations were unaffected.

¹⁵ [FPDS User's Manual and Data Dictionary](#), Version 1.5, January 2024.

¹⁶ The contracting officer must provide each awardee a fair opportunity to be considered for each order exceeding the micro-purchase threshold. When every awardee is not provided a fair opportunity and specific statutory exceptions apply, the contracting officer must complete a written justification for exception to fair opportunity (FAR 16.505). Fair opportunity is a requirement that U.S. Government agencies purchasing goods or services under a multi-award contract give all companies that hold that contract an equal opportunity to respond to a request for proposal (RFP).

contracting officer stated that the abstract was lost during the transition to an electronic filing system.

Having complete documentation protects the legal and financial rights of the Government and the individuals directly affected by Government activities. Further, having complete documentation provides institutional memory, which makes informed decisions possible to facilitate future actions.

Proposal Evaluations Were Not Properly Completed or Maintained

For four sampled BARDA DRIVE contracts, ASPR did not appropriately complete or maintain technical evaluations in accordance with requirements outlined in the BAAs. Specifically, for one sampled contract, the contracting officer was unable to provide a signed copy of the Technical Evaluation Report. For an additional three sampled contracts, the overall determinations were marked as acceptable; however, for all three contracts, at least one area within the cost realism section was marked unacceptable by the reviewer. While the BAA states that the only possible overall evaluation results are acceptable or unacceptable, the Offeror Compliance Checklist used by technical reviewers is more specific and states that if the proposal is unacceptable in any of the three cost realism criteria, the overall evaluation would be unacceptable. According to ASPR, however, the Offeror Compliance Checklist language is not accurate, as ASPR could still consider the proposal acceptable despite the unacceptable rating in the cost realism section.

If it is not complete and comprehensive, the contract record loses its integrity. This record, upon which nearly every bid protest is resolved, is essential to a fair and equitable procurement process. Therefore, both having incomplete records and failing to maintain records jeopardize the Government's ability to protect its legal and financial rights.

Causes of Contract Administrative Errors

Administrative errors made during the contract awarding process generally occurred because ASPR did not have an established process for reviewing or monitoring contract files for completeness and accuracy and did not have policies and procedures for the maintenance and organization of electronic records. Further, ASPR personnel stated that policies specifying how electronic records should be organized and maintained would only be implemented once electronic records became mandatory towards the end of 2023. By delaying the development and implementation of policies addressing the organization and maintenance of electronic records, ASPR created the conditions that gave rise to the documentation errors identified in this report.

On numerous occasions and for different contracts, we were told that documents were unavailable because the individual who created the document had since changed position. It is essential that documents are immediately incorporated into the electronic record when they are created and finalized. Because many contracting personnel change positions frequently

and ASPR did not have policies outlining how contract documents are to be maintained, documentation for each contract may be incomplete.

RECOMMENDATIONS

We recommend that the Administration for Strategic Preparedness and Response:

- note on the CPARS assessment report for the original contractor that the contractor failed to submit the novation to report the sale of the business interests and transfer of the contract;
- provide technical assistance or education to the new contractor regarding novation procedures;
- implement a review process to verify that Federal acquisition awarding procedures and contract funding are fully completed before contract performance begins;
- correct the Recording Statute violation for the contract that was not properly finalized by ratifying the original contract and properly recording an obligation;
- correct the time violation for the improperly created purchase order by using no-year funds or multi-year funds available for obligation and report an Antideficiency Act violation if the time violation cannot be corrected;
- create policies and procedures for the maintenance and organization of electronic contract files; and
- implement a periodic documentation review process to assess completeness of contract files and provide training to address deficiencies identified from the review.

ASPR COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, ASPR concurred with our recommendations and described the actions it had taken and planned to take in response to those recommendations.

Specifically, ASPR stated that it has noted in CPARS that the original contractor failed to submit the novation to report the sale of the business and, going forward, will support having consistent training on novation procedures for all contracting officers. Further, ASPR has implemented an agency-wide process to ensure all required reviews and approvals occur prior to contract award to ensure compliance with acquisition requirements. ASPR also stated that it is coordinating with ASPR's Office of Finance to identify the appropriate funds available for obligation and process the documentation needed to modify the improperly created purchase order to correct the both the Recording Statute and time violations and the FPDS record. Further, ASPR is currently developing policies and procedures to address electronic contract file compliance with all Federal record keeping requirements. Additionally, ASPR is in the process

of identifying funding to contract for an external third-party review of ASPR contracting actions to identify weaknesses for future action planning to address those weaknesses.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed a judgmental sample of 28 research and development contracts (out of 235 unique contracts): 26 contracts were awarded by ASPR with contract actions from FYs 2017 through 2020 and 2 contracts were awarded through the ASPR Next program. Of the 26 ASPR contracts, 14 were awarded using standard contract awarding processes and 12 were awarded through the BARDA DRIVE program. The 28 contracts represented 24 different contractors and resulted in obligations totaling \$512,395,855.

We reviewed the 28 contracts to determine whether they were awarded in accordance with the FAR and other legal requirements. We limited our review of internal controls to those in place to ensure compliance with requirements for awarding contracts and accounting for contract obligations and expenditures. We established reasonable assurance of the authenticity, accuracy, and completeness of the data obtained from ASPR. However, we did not independently verify that the contracts that ASPR identified represent all of the contracts that were awarded during our audit period.

We conducted our audit from July 2020 through February 2024.

METHODOLOGY

To accomplish our objectives, we:

- reviewed Federal appropriations laws, Federal requirements, and contract requirements;
- obtained and reviewed ASPR and BARDA policies and procedures for awarding research and development contracts;
- determined which components of internal control and the underlying principles were relevant for the purposes of this audit;
- selected a judgmental sample of 28 contracts for review from the 235 unique contracts that had contract actions during our period of review based on the following criteria:
 - high dollar contracts,
 - the variety of contractor types, and
 - unique item descriptors that explained the reason for the procurement;
- reviewed selected ASPR contracts to determine whether they were awarded in accordance with FAR and HHSAR requirements;

- determined whether selected contracts awarded using the ASPR Next and BARDA DRIVE programs complied with established FAR and HHSAR policies; and
- discussed the results of our audit and provided the detailed potential Antideficiency Act violations to 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: FEDERAL REQUIREMENTS

The FAR, 48 CFR Part 1.6, General Information About the Authority and Responsibilities of Contracting Officers

This section describes the authority and responsibilities of contracting officers that are received from the appointing authority, including limitations of their authority. This section also addresses the role of the contracting officer's representative and documentation requirements related to the delegation of authority received from the contracting officer.

The FAR, 48 CFR Part 3, Improper Business Practices and Personal Conflicts of Interest

This part prescribes policies and procedures for avoiding improper business practices and personal conflicts of interest and for dealing with their apparent or actual occurrence. Government business is to be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none.

The FAR, 48 CFR Part 4.8, Government Contract Files

This subpart prescribes the requirements for establishing, maintaining, and disposing of contract files.

The FAR, 48 CFR Part 5, Publicizing Contract Actions

This part prescribes policies and procedures for publicizing contract opportunities and award information. Contracting officers must publicize contract actions to: (1) increase competition; (2) broaden industry participation in meeting Government requirements; and (3) assist small business concerns, veteran-owned small business concerns, service-disabled-veteran-owned small business concerns, HUBZone small business concerns, small, disadvantaged business concerns, and women-owned small business concerns in obtaining contracts and subcontracts.

The FAR, 48 CFR Part 6, Competition Requirements

This part prescribes policies and procedures to promote full and open competition in the acquisition process and to provide for full and open competition, full and open competition after exclusion of sources, other than full and open competition, and advocates for competition. Competitive procedures available for use in fulfilling full and open competition requirements include sealed bids and competitive proposals. Further, competitive selections for basic and applied research and the part of development not related to a specific system or hardware procurement is considered a competitive procedure if the award results from a BAA that is general in nature identifying areas of research interest, including the criteria for selecting proposals and soliciting the participation of all offerors capable of satisfying the Government's needs.

The FAR, 48 CFR Part 10, Market Research

Market research is used to arrive at the most suitable approach to acquiring, distributing, and supporting supplies and services. Acquisitions begin with a description of the Government's needs stated in terms sufficient to allow conduct of market research. Market research is then conducted to determine whether commercial products, commercial services, or readily available items are available to meet the Government's needs or could be modified to meet the Government's needs. Market research results must be documented in a manner appropriate to the size and complexity of the acquisition.

The FAR, 48 CFR Part 16, Types of Contracts

This part describes types of contracts that may be used in acquisitions. It prescribes policies and procedures and provides guidance for selecting a contract type appropriate to the circumstances of the acquisition. The contract types are grouped into two broad categories: fixed-price contracts and cost-reimbursement contracts. The specific contract types range from firm-fixed-price, in which the contractor has full responsibility for the performance costs and resulting profit (or loss), to cost-plus-fixed-fee, in which the contractor has minimal responsibility for the performance costs and the negotiated fee (profit) is fixed.

The FAR, 48 CFR Part 35, Research and Development Contracting

This section specifies the primary purpose of contracted research and development programs is to advance scientific and technical knowledge and apply that knowledge to the extent necessary to achieve agency and national goals. It states that unlike contracts for supplies and services, most research and development contracts are directed toward objectives for which the work or methods cannot be precisely described in advance. The contracting process is to be used to encourage the best sources from the scientific and industrial community to become involved in the program and must provide an environment in which the work can be pursued with reasonable flexibility and minimum administrative burden.

The FAR, 48 CFR Part 42, Contract Administration and Audit Services

This section specifies the recognition of a successor in interest to Government contracts when contractor assets are transferred as well as the execution of novation agreements and change-of-name agreements by the responsible contracting office (48 CFR § 42.12). Further, 48 CFR section 42.15 states that past performance information (including the ratings and supporting narratives) is relevant information, for future source selection purposes, regarding a contractor's actions under previously awarded contracts or orders. Past performance information is to be entered into the Contractor Performance Assessment Reporting System, the Governmentwide evaluation reporting tool for all past performance reports on contracts and orders. Past performance evaluations are to be prepared at least annually and at the time the work under a contract or order is completed. These evaluations are generally for the entity, division, or unit that performed the contract or order.

The FAR, 48 CFR Part 43.102, General Information About Contract Modifications

This section describes the contracting officer's role in executing contract modifications and stipulates that other Government personnel do not have the authority to execute contract modifications or ask contractors to perform additional work.

The FAR, 48 CFR Part 52.215-19, Notification of Ownership Changes

This section states the contractor will notify the administrative contracting officer in writing within 30 days when the contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records.

31 U.S.C. § 1301(a), Application

This section states that appropriations will be applied only to the objects for which the appropriations were made except as otherwise provided by law.

31 U.S.C. § 1501(a)(1), Documentary evidence requirement for government obligations

This section states that agencies should record an obligation against a currently available appropriation for the authorized purpose in an amount reflecting the liability incurred as a result of a binding written agreement.

31 U.S.C. § 1502(a), Balances available

This section states that the balance of an appropriation is limited for obligation to a definite period and is available only for payment of expenses properly incurred during the period of availability. Further, the appropriation or fund is not available for expenditure for a period beyond the period otherwise authorized by law.

31 U.S.C. § 1517, Prohibited obligations and expenditures

This section states that an officer or employee of the U.S. Government or of the District of Columbia Government may not make or authorize an expenditure or obligation exceeding: (1) an apportionment or (2) the amount permitted by regulations.

31 U.S.C. § 1552(a), Procedure for appropriation accounts available for definite periods

A fixed appropriation account is closed 5 years after the period of availability during which the funds were available for obligation. At that time, the appropriation account is closed, and the balance is canceled and is no longer available for further obligation or expenditure.

31 U.S.C. § 1553(b), Availability of appropriation accounts to pay obligations

After a fixed appropriation account is closed and canceled, an agency may charge an obligation or an adjustment to an obligation chargeable to the canceled account to a current-year appropriation account available for the same purpose. However, the amount charged may not exceed 1 percent of the current appropriation.

31 U.S.C. § 1554, Audit, control, and reporting

This section requires the head of each agency to report to the President and the Secretary of the Treasury any obligation adjustments that the agency made during the year pursuant to section 1553.

41 U.S.C. § 6305, Prohibition on transfer of contract and certain allowable assignments

This section states that the party to whom the Federal Government gives a contract or order may not transfer the contract or order, or any interest in the contract or order, to another party.

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION

48 CFR Chapter 3, Subpart 301.602, Contracting officers

The Head of Contracting Activity is the official authorized to ratify an unauthorized commitment. No other re-delegations are authorized. The Head of Contracting Activity will coordinate the request for ratification with the Office of General Counsel, General Law Division and submit a copy to the senior procurement executive.

GOVERNMENT ACCOUNTABILITY OFFICE DECISION

Bureau of Customs and Border Protection—Automated Commercial Environment Contract—Multiyear Contracting, B-302358 (Dec. 27, 2004)

This GAO opinion examined the recording of an obligation for a contract awarded by the Bureau of Customs and Border Protection. The opinion stated that Customs should have recorded the obligation in its obligational accounting records at the time of contract award. The opinion stated that consistent with 31 U.S.C. § 1501(a)(1), commonly referred to as the recording statute, Customs should have recorded an obligation against a currently available appropriation for the authorized purpose in an amount reflecting the liability incurred as a result of a binding written agreement at the time the contract was awarded. The opinion further stated to ensure the integrity of Customs' obligational accounting records needed for a variety of reasons not least of which is compliance with the Antideficiency Act.

See Appendix C for further explanation of the Antideficiency Act and related Federal regulations.

APPENDIX C: THE ANTIDEFICIENCY ACT

Congress determines the amount of funding available to an agency by enacting appropriations to cover programs, projects, purchases, and services needed by the agency during the period for which the funds are made available. An agency is required to record an obligation in the agency's accounting system against an appropriation currently available for the authorized purpose in an amount that reflects the Government's liability as a result of a contract or contract modification (31 U.S.C. § 1501(a)). The Antideficiency Act prohibits the agency from entering into contracts that exceed the amount of enacted appropriations for the year and from purchasing services and merchandise before appropriations are enacted (31 U.S.C. § 1341(a)(1)).¹⁷ Agencies must report Antideficiency Act violations to the President (through OMB), Congress, and the Comptroller General of GAO (31 U.S.C. § 1351). OMB Circular A-11 prescribes the methodology for this reporting.

After fiscal year appropriations expire, they remain available to record, adjust, and liquidate obligations properly chargeable to the appropriation account for up to 5 years. After 5 years, the appropriation account is closed and any remaining balance (whether obligated or not) is canceled (31 U.S.C. § 1552(a)). If fiscal year funds are no longer available because an account has been closed, an agency may charge the obligation to the current fiscal year appropriation account available for the same purpose (31 U.S.C. § 1553(b)(1)). The amount to be charged to the current fiscal year appropriation account may not exceed 1 percent of the appropriation (31 U.S.C. § 1553(b)(2)). After the close of each fiscal year, the head of each agency must report to the President and the Secretary of the Treasury any adjustments that the agency made to appropriation accounts during the year, including any obligation adjustments made in accordance with 31 U.S.C. section 1553 (31 U.S.C. § 1554(b)).

When the Office of Inspector General identifies possible violations of the Antideficiency Act, it is the responsibility of the agency to investigate or audit the possible violations and attempt to correct them by making adjustments, and it is the responsibility of the agency head to report any Antideficiency Act violations that cannot be corrected (OMB Circular A-11 § 145). Further, OMB Circular No. A-11, section 145: Requirements for Reporting Antideficiency Act Violations, defines an Antideficiency Act violation and provides the appropriate requirements for reporting an Antideficiency Act violation to the President (through the Director of OMB), Congress, and the Comptroller General of GAO.¹⁸

¹⁷ Antideficiency Act violations can occur during the apportionment as well as allocation level of the budget process. (31 U.S.C § 1517).

¹⁸ OMB Circular No. A-11, *Preparation, Submission, and Execution of the Budget*, July 1, 2016.

APPENDIX D: JUDGMENTALLY SELECTED CONTRACTS

Sample No.*	Contract Purpose	Award Date	Total Contract Obligations through FY 2020
B1	Assess equipment fair market value	2/12/2020	\$14,000
B2	Develop Flu Medical Countermeasures	2/11/2020	1,125,000
B3	Develop Vaccine	8/16/2016	849,451
B4	Develop Flu Vaccine	9/30/2019	15,836,078
B5	Develop Medical Countermeasure	9/28/2012	33,803,118
B6	Develop Flu Vaccine	1/1/2007	184,041,664
B7	Research for Specific Treatments	9/30/2019	21,463,543
B8	Maintain National Stockpile Storage	7/22/2018	800,856
B9	Procure National Stockpile Supply	8/1/2018	628,079
B10	Maintain Flu Egg Supply	8/27/2018	38,395,013
B11	Acquire Colony Stimulating Factor	9/13/2018	154,394,550
B12	Develop Sepsis Treatment	9/30/2018	11,942,818
B13	Purchase Flu Vaccine Bulk Lots	9/22/2017	7,989,513
B14	Formulate Single Dose Vials	1/1/2017	2,722,638
BD1	Complete Biomarker Assay Validation	9/28/2018	749,000
BD2	Advanced Research for Sepsis Diagnosis	9/30/2019	7,240,843
BD3	Develop Vaccine Patches	9/30/2019	700,000
BD4	Develop Sepsis Detection/Prediction	9/30/2019	3,513,790
BD5	Evaluate Solid Dose Flu Vaccine	4/15/2019	688,863
BD6	Develop Sepsis Early Development	12/1/2018	749,000
BD7	Develop Health Artificial Intelligence	12/6/2018	599,000
BD8	Develop Medical Software Device	2/1/2019	699,376
BD9	Develop Prediction Model	1/24/2019	326,454
BD10	Develop online Sepsis portal	2/1/2019	547,248
BD11	Develop Rapid Forecast Algorithm	7/1/2019	749,000
BD12	Develop Sepsis Treatment	1/31/2019	744,739
AN3	Supply Chain Management	3/16/2020	682,221
AN4	Create Analytics Platform Dashboards	3/27/2020	20,400,000
		TOTAL	\$512,395,855

*B = BARDA award, BD = BARDA DRiVe award, AN = ASPR Next award

APPENDIX E: THE NOVATION PROCESS

Government contracts are not automatically transferred to a new owner when a contractor's business is sold. Instead, the original contractor must follow FAR 42 to begin a process called novation to transfer the business's rights and obligations under the contract to the new owner.

When a contract is transferred through novation, it protects the Government's interests and releases the original contractor from its obligations under the contract. Certain contract modifications may not be processed until an applicable novation has been approved. Payment issues may also arise if a novation is not processed at the time of the change.

Novation begins when the original contractor submits documentation to start the process.

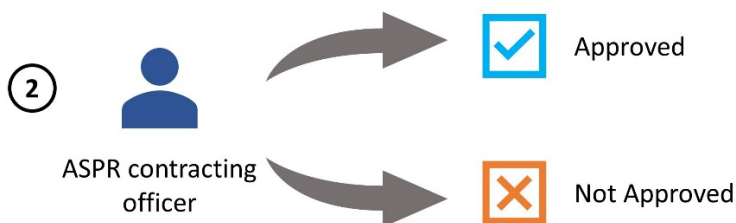


FAR 42 outlines the documentation that the original contractor must submit to process a novation. This required documentation consists of:

- three signed copies of the proposed novation agreement,
- one copy of the document describing the proposed transaction,
- a list of all affected contracts between the original contractor and the Government,
- evidence of the new business owner's capability to perform contract responsibilities, and
- any other relevant information requested by the responsible contracting officer.

Without such documentation, the contracting officer cannot approve the novation and create a contract modification showing the transfer of responsibility to the new contractor.

Federal regulations at 48 CFR section 52.215-19 provide the requirements for notifying the contracting officer of ownership changes. In particular, the contractor must notify the contracting officer of the change in ownership within 30 days.



Contracting officers are not required to approve novation requests; instead, they approve novation only when the agency determines that it is in its best interest for a new contractor to assume responsibility for the entire contract.



Approved

If a business that has a Government contract is sold and the contracting officer approves the existing contract novation request under FAR 42.1204, the previous contractor passes on the performance responsibility to the new business owner.



Not Approved

If the Government does not approve the novation, the original contractor remains responsible for all contract actions. If the Government does not approve the novation and the original contractor does not perform the contract actions, the original contractor can be terminated for default (FAR, 48 CFR § 42.1204).

APPENDIX F: ASPR COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Administration for Strategic
Preparedness and Response

Administrator and Assistant Secretary
for Preparedness and Response
Washington, D.C. 20201

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

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

SUBJECT: Office of the Inspector General Draft Report: *ASPR Did Not Consistently Comply with Federal Requirements for Awarding Research and Development Contracts*, A-03-20-03003

DATE: May 24, 2024

The Administration for Strategic Preparedness & Response (ASPR) appreciates the opportunity to review and comment on this draft report issued by the HHS Office of the Inspector General (OIG) on its evaluation of whether ASPR complied with Federal requirements in awarding research and development contracts from fiscal year (FY) 2017 through FY 2020. ASPR acknowledges the findings and recommendations included in this report. ASPR recommends closing three of the seven recommendations based on efforts and activities implemented post the timeframe of the OIG review that strengthen operations, training, and system notes.

Recommendation 01: Note on the Contractor Performance Assessment Reporting System (CPRS) assessment report for the original contractor that the contractor failed to submit the novation to report the sale of the business interests and transfer of the contract.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation closed.
- **Action:** ASPR has noted in CPRAS for the Indefinite Delivery, Indefinite Quantity Contract that the original contractor failed to submit the novation to report the sale of the business interests and transfer of the contract.

Recommendation 02: Provide technical assistance or education to the new contractor regarding novation procedures.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation closed.
- **Actions:** OIG should be aware that the contract under review and related to this recommendation ended in 2023. Going forward, ASPR/BARDA is supporting consistent training for all Contracting Officers on novation procedures. ASPR/BARDA is also using opportunities like the contract kickoff meeting to remind new contractors of their responsibility to make novation requests to Contracting Officers when there is a change in ownership.

Recommendation 03: Implement a review process to verify that Federal acquisition awarding procedures and contract funding are fully completed before contract performance begins.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation closed.
- **Actions:** ASPR's Office of Head of Contracting Activity (OHCA) implemented an agency-wide Acquisition Threshold Review Guidance on October 7, 2022, to ensure all required reviews and approvals occur prior to contract award to ensure compliance of all ASPR contracting actions. The BARDA's Division of Contract Management & Acquisitions & Business Planning & Strategy (DCMA), Compliance and Local Policy Branch reviews all actions that require HCA approval or above. Under existing processes, the Contracting Officer and their leadership are responsible for reviewing contracts to ensure the contract is awarded in accordance with established procedures, including the Acquisition Threshold Review Guidance. Routine compliance reviews are also conducted by the Compliance and Local Policy Branch.

Recommendation 04: Correct the Recording Statute violation for the contract that was not properly finalized by ratifying the original contract and properly recording an obligation.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation open.
- **Actions:** BARDA is coordinating with the ASPR's Office of Finance to identify the appropriate funds available for obligation and to process the documentation needed to modify the contract in order to correct the Recording Statute violation and the FPDS record.

Recommendation 05: Correct the time violation for the improperly created purchase order by using no-year funds or multi-year funds available for obligation and report an Antideficiency Act violation if the time violation cannot be corrected.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation open.
- **Actions:** BARDA is coordinating with the ASPR's Office of Finance to identify the appropriate funds available for obligation and to process the documentation needed to modify the contract in order to correct the Recording Statute violation and the FPDS record.

Recommendation 06: Create policies and procedures for the maintenance and organization of electronic contract files.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation open.
- **Actions:** In September 2023, ASPR's OHCA implemented an electronic contract file system using the Department's Work Smarter platform. Training, policies, and

procedures are currently being developed for the ASPR contracting officials to ensure that the system is utilized in full compliance with all Federal record keeping requirements.

Recommendation 07: Implement a periodic documentation review process to assess completeness of contract files and provide training to address deficiencies identified from the review.

- **General Comments:** ASPR concurs with this recommendation and considers this recommendation open.
- **Actions:** In September of 2023, ASPR completed its first internal acquisition management review. ASPR's OHCA is now in the process of identifying funding for a contract that would support an external third-party review of ASPR contracting actions. This contract would support an annual requirement for a random sample of contracting actions to be pulled for review and a report developed which identifies weaknesses for future action planning to address those weaknesses.



Dawn O'Connell
Administrator and Assistant Secretary for Preparedness and Response

Attachments:

- Technical Comments on the Draft Report
- Acquisition Threshold Review Guidance
- CPARS Evaluation