

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FDA SHOULD IMPROVE ITS
MANAGEMENT OF CONTRACTS FOR THE
ACQUISITION OF INFORMATION
TECHNOLOGY**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

January 2023
A-18-21-11100

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

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: January 2023

Report No. A-18-21-11100

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



Why OIG Did This Audit

HHS relies extensively on contractors to fulfill its mission, and OIG has identified ensuring the financial integrity of HHS programs, including HHS's oversight of contracts, as a top management challenge for HHS. This audit is part of a broad portfolio of HHS OIG audits examining various aspects of HHS contracting operations. Our focus was on the Food and Drug Administration's (FDA's) contract administration of large dollar information technology (IT) contracts with multiple task or delivery orders. FDA relies on contractors to facilitate the purchase and maintenance of IT products.

Our objective was to determine whether FDA administered contracts for the acquisition of IT in accordance with applicable Federal acquisition regulations and HHS acquisition regulations and policies.

How OIG Did This Audit

We reviewed five FDA orders totaling \$23.6 million paid to a contractor during fiscal years 2018 through 2020 for IT hardware and equipment. We examined acquisition planning documents, award documents, contract files and records, invoices, and supporting contract file documentation; reviewed FDA policies and procedures related to acquisitions, procurement, and supply management; and conducted virtual interviews with FDA on its governance, contracting processes, practices, controls, and management support activities.

FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology

What OIG Found

FDA contracting officers generally administered the delivery and call orders we reviewed for the acquisition of IT in accordance with Federal regulations and policies. However, we identified areas within FDA's management of these orders that were not conducted consistent with applicable Federal acquisition regulations and HHS acquisition regulations and policies. Specifically, the contracting officers did not: (1) properly designate a contracting officer's representative (COR), or did not complete all required duties for contracts for which there was no designated COR; (2) complete required contractor performance evaluations; (3) properly document all key contracting decisions or activities and obtain all required signatures on key documents; and (4) include the required acquisition strategy statement in the orders' acquisition plans. Additionally, FDA did not fully comply with the HHS Competition Advocacy Directive for fiscal years 2018 and 2019.

These conditions occurred because FDA did not always: (1) follow existing FDA acquisition and procurement policies and procedures, including ensuring the completeness of contract documents, and (2) work with HHS to meet its obligation to comply with an HHS directive.

What OIG Recommends and FDA Comments

We made procedural and administrative recommendations to improve compliance with Federal acquisition requirements related to COR duties, contractor performance assessments, documentation of contracting decisions and activities, and acquisition strategies. The full recommendations are in the report.

In written comments on our draft report, FDA concurred with all of our recommendations and described actions it has taken or plans to take to address the findings. FDA stated that it has increased its reviews and audits of the acquisition files to ensure that all applicable contract documentation is properly prepared and uploaded. FDA stated that it has updated its policies and procedures to ensure that all contracting decisions made by the contracting officer will be documented and that the documentation will include the rationale for any business judgments. FDA stated that it will assess the acquisition lifecycle process to ensure that all acquisition activities align with current policies and procedures and established best practices. FDA stated that it will continue to work with HHS to ensure FDA complies with the Competition Advocacy Directive.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Audit	1
Objective	1
Background	1
The Food and Drug Administration	1
Federal Requirements.....	2
FDA’s Contracting Process	2
How We Conducted This Audit	5
FINDINGS.....	6
Contracting Officers Did Not Properly Designate a Contracting Officer’s Representative.....	7
FDA Did Not Complete Contractor Performance Assessments.....	8
FDA Did Not Properly Document Key Contracting Decisions and Activities and Obtain Required Signatures for Key Decisions.....	9
FDA Did Not Include the Required Acquisition Strategy or Statement in the Acquisition Plans for Some Orders.....	11
FDA Did Not Fully Comply With the HHS Competition Advocacy Directive	12
RECOMMENDATIONS	13
FDA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	13
APPENDICES	
A: Audit Scope and Methodology	14
B: Federal Requirements	15
C: Contract Management Findings by FDA Center or Office	19
D: FDA Comments	20

INTRODUCTION

WHY WE DID THIS AUDIT

The Department of Health and Human Services (HHS) relies extensively on contractors to fulfill its mission, and the Office of Inspector General (OIG) has identified ensuring the financial integrity of HHS programs, including HHS's oversight of contracts, as a top management challenge for HHS. This audit is part of a broad portfolio of HHS OIG audits examining various aspects of HHS contracting operations, including payment accuracy, eligibility verification, management and administration, and data security. Our focus was on the Food and Drug Administration's (FDA's) contract administration of large dollar information technology (IT) contracts with multiple task or delivery orders.

We audited FDA's contracts for the acquisition of IT because FDA relies on contractors to facilitate the purchase and maintenance of IT products. During fiscal year (FY) 2020, FDA awarded contracts totaling \$682.7 million for IT equipment and services.

OBJECTIVE

Our objective was to determine whether FDA administered contracts for the acquisition of IT in accordance with applicable Federal acquisition regulations and HHS acquisition regulations and policies.

BACKGROUND

The Food and Drug Administration

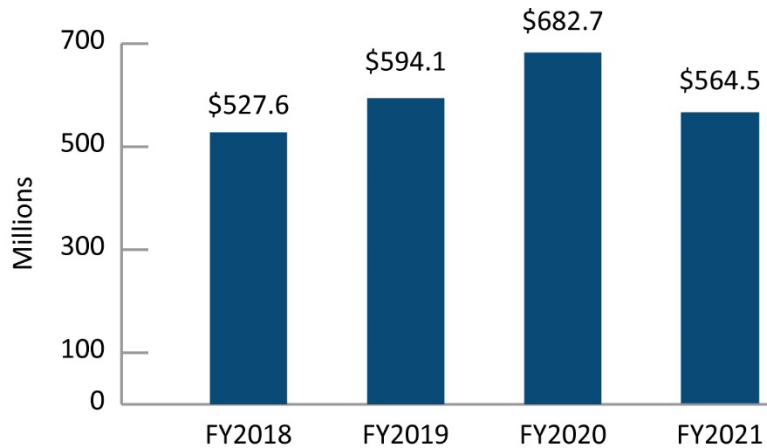
Within HHS, FDA's mission is to promote and protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological and tobacco products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA consists of 7 centers and 13 offices.¹ To support this mission, FDA relies upon IT and awards contracts to IT vendors to acquire the IT it requires.

FDA's Office of Information Management and Technology (OIMT) is responsible for FDA's IT Program, and its mission is to provide high quality, secure, and efficient IT solutions that enable FDA to promote and protect public health. Through the IT Program, OIMT provides the delivery of IT and enterprisewide solutions and is responsible for developing architecture, standards, policies, governance, best practices, and technology road maps that support FDA's business priorities. From FY 2018 through FY 2021, FDA spent over \$2.3 billion for IT products and services. See Figure 1 on the next page.²

¹ FDA began an agency reorganization in March 2019. Before the reorganization, FDA consisted of 9 centers and 13 offices.

² USASPENDING.gov is the source of the data used in Figure 1.

Figure 1: FDA Spending on IT Products and Services



Federal Requirements

The Federal Acquisition Regulation (FAR) is the primary regulation that all executive branch agencies must follow when acquiring products and services with appropriated funds (FAR, 48 CFR chapter 1). According to FAR 2.101, acquisition begins when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and technical and management functions directly related to the process of fulfilling agency needs by contract.

The HHS Acquisition Regulation (HHSAR) supplements the FAR and provides the regulatory framework for conducting acquisitions across HHS (HHSAR, 48 CFR chapter 3). The HHS Acquisition Policy, Guidance, and Instructions (HHS Acquisition PGI) provides internal instructions, procedures, and guidance for processing procurement-related activities. In addition, FDA directives known as FDA Staff Manual Guides provide documentation of FDA administrative and program policies, responsibilities, and procedures, including those that govern procurement.

These requirements provide a framework for awarding contracts, paying contractor invoices, managing contracts, and conducting management and oversight of contractor performance throughout FDA's contracting cycle.

Appendix B contains the Federal requirements referenced in this report.

FDA's Contracting Process

Office of Acquisition and Grants Services

The Office of Acquisition and Grants Services (OAGS) is the single organization within FDA with authority to award contracts. OAGS' mission is to provide high-quality acquisitions to FDA.

Specifically, OAGS provides acquisition support and technical expertise to FDA centers and offices throughout the contracting cycle.

Within OAGS, contracting officers are individuals with the authority to enter into and terminate contracts and make related determinations and findings.³ Before entering into a contract, contracting officers must ensure that all requirements of law, executive orders, regulations, and all other applicable procedures, including clearances and approvals, have been met.⁴ The contracting officer may designate a contracting officer's representative (COR) in writing and thus give the COR the authority to assist in the monitoring and administration of the contract. A COR possesses technical knowledge of the type of work being done so as to be able to adequately oversee the contractor's work, to direct technical aspects of its work, and to notify the contracting officer if there are any deviations in performance from what is required by the contract.

Acquisition Management Systems

The Federal Procurement Data System (FPDS) is the Government repository for information on Government contracts. FPDS collects contract data from all executive branch agencies. Congress and Federal departments and agencies use FPDS to track small business goals, report numbers, amounts of contracts, geographical locations of contracts, and contract data for each contractor, among other things, in accordance with FAR 4.11 and 52.204. FDA collects and reports its contract data to FPDS.

Until December 2019, FDA used the Departmental Contract Information System (DCIS), which transmitted FDA contract information to FPDS. DCIS was used to support the acquisition-related mission needs of HHS. HHS no longer actively uses DCIS to track new contract actions.⁵ However, FDA personnel can still use DCIS data as a resource since it is still available and contains contract information from before January 2020.

HHS currently utilizes the acquisition processing and management functionality of the Purchase Request Information System (PRISM), a commercial off-the-shelf application that allows end users to formulate, administer, and distribute contract documents subject to the FAR. PRISM provides a single solution for integrating acquisitions with financial management.

³ The FAR, 48 CFR § 1.602, lists the authority and responsibilities of contracting officers.

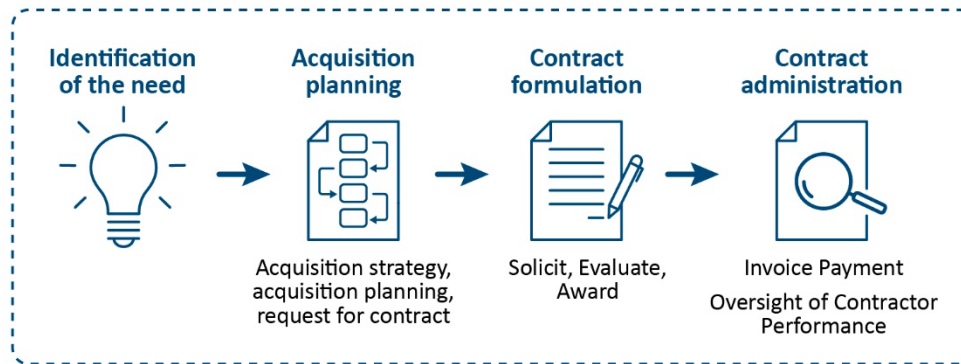
⁴ Ibid.

⁵ A contract action is an oral or written action that results in the purchase, rent, or lease of supplies, equipment, services, or construction using appropriated dollars over a certain threshold. Contract actions do not include grants, cooperative agreements, other transactions, real property leases, requisitions from Federal stock, training authorizations, and other non-FAR based transactions.

FDA's Contracting Cycle

The contracting cycle for FDA-awarded contracts consists of four phases: identification of the need, acquisition planning, contract formulation, and contract administration. See Figure 2.

Figure 2: FDA Contracting Cycle



The contracting cycle begins when an agency identifies a need. In identifying a need, an agency describes and justifies the purpose of a proposed acquisition in terms of the function to be performed, the performance requirements, or the essential physical characteristics of the proposed product or service.

Acquisition planning is the process through which the efforts of all personnel responsible for an acquisition are coordinated and integrated through a comprehensive plan for fulfilling an agency need in a timely manner and at a reasonable cost. As part of acquisition planning, the agency develops the acquisition strategy, which is a high-level description of how the program or project will procure the necessary resources to satisfy an agency need. The acquisition strategy provides sufficient detail to allow senior leadership and other decision makers to assess whether the strategy makes good business sense. The acquisition strategy is the overall strategy for managing the acquisition and is meant to effectively implement laws and policies and accurately reflect management priorities. An acquisition strategy typically serves as the foundation for the development of multiple acquisition plans to support a specific program or project.

Acquisition planning also includes developing an acquisition plan that documents all cost, schedule, technical, business, management, and other considerations that will govern a specific acquisition. The acquisition plan is derived from the acquisition strategy. The acquisition plan summarizes the acquisition planning discussions and identifies milestones in the acquisition process. According to the FDA Staff Manual Guide, General Administration, Volume III, every acquisition plan must relate back to and fall under an approved acquisition strategy.

The final activity in the acquisition planning phase is the preparation of the Request for Contract, which is completed by the FDA center or office requesting the acquisition. The Request for Contract serves as the official request for initiating a contract action. The Request

for Contract contains all preliminary documents, approvals, and authorizations for a planned contract action. The Request for Contract also identifies administration details and provides funding commitment information (e.g., type and amount of available funds, or account classification codes). Program personnel (i.e., the program or project manager or an individual who will eventually serve as the COR) must complete and electronically submit the Request for Contract to OAGS to formally initiate a specific contract action.

Once acquisition planning is complete, contract formulation can begin. Contract formulation begins with the agency's solicitation for contractors to submit offers or quotations to the Government. Among other things, a solicitation identifies what the agency wants to buy and how a contractor's proposal will be evaluated and includes a deadline for contractors to submit their proposals.

After receiving the contractors' proposals, the agency evaluates the proposals, assessing the proposals and the offerors' ability to perform the prospective contract successfully. Contract formulation results in the award of a contract, which occurs when the Government accepts a contractor's agreement to furnish and deliver the items or to perform services to the extent stated in the solicitation.

After the contract is awarded, the contracting officer administers the contract. During this contract phase, the agency pays contractor invoices and conducts oversight of the contractor's performance. If the contracting officer designates a COR, the COR is responsible for technical monitoring of the contract and assessing contractor performance (HHSAR, 48 CFR § 302.101(b)). If the contracting officer does not designate a COR, the contracting officer retains the responsibility for performing all COR tasks.

FDA has a contract file checklist for each contract and contract file step. For example, there is a checklist for task order awards that cover contract file steps such as the Award Document; Pre-solicitation; Determination and Pre-solicitation Clearances; Pre-award Documentation, Funding and Clearances; and Invoices and Other Financial Information.

When the contract is physically complete and the contracting officer has received evidence of complete receipt of property or services, the contract is closed out as required by the FAR and HHS regulations. A contract is closed once the contractor has completed contract requirements and the Government has completed all required administrative actions.

HOW WE CONDUCTED THIS AUDIT

We reviewed four delivery orders placed under an indefinite delivery, indefinite quantity contract and one call order placed against a blanket purchase agreement totaling \$23.6 million paid to a contractor (CSP Enterprise) during FYs 2018 through 2020 (audit period) for IT

hardware and equipment.⁶ Of the five orders selected, three were with OIMT, one was with the Center for Devices and Radiological Health, and one was with the Center for Biologics Evaluation and Research.

To accomplish our objective, we examined acquisition planning documents, award documents, contract files and records, invoices, and supporting contract file documentation. We reviewed FDA policies and procedures related to acquisitions, procurement, and supply management; and conducted virtual interviews with FDA on its governance, contracting processes, practices, controls, and management support activities. We communicated to FDA our preliminary findings in advance of issuing our draft report.

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 describes our audit scope and methodology.

FINDINGS

The FDA contracting officers generally administered the delivery and call orders we reviewed for the acquisition of IT in accordance with Federal regulations and policies. However, we identified areas within FDA's management of these orders that were not conducted consistent with applicable Federal acquisition regulations and HHS acquisition regulations and policies. Specifically, the contracting officers did not:

- properly designate a COR, or did not complete all required duties for the orders for which there was no designated COR;
- complete required contractor performance evaluations;
- properly document all key contracting decisions or activities and obtain all required signatures on key documents; and
- include the required acquisition strategy statement in the orders' acquisition plans.

Additionally, FDA did not fully comply with the HHS Competition Advocacy Directive for FYs 2018 and 2019 because it did not submit an Annual Competition Advocate Report (ACAR).

⁶ FAR 16.501 defines a delivery-order contract as a contract for supplies that does not procure or specify a firm quantity of supplies (other than a minimum or maximum quantity) and that provides for the issuance of orders for the delivery of supplies during the period of the contract. A task-order contract is a contract for services that does not procure or specify a firm quantity of services (other than a minimum or maximum quantity) and that provides for the issuance of orders for the performance of tasks during the period of the contract.

These conditions occurred because FDA did not: (1) follow existing FDA acquisition and procurement policies and procedures, including ensuring the completeness of contract documents, and (2) work with HHS to meet its obligation to comply with the HHS Competition Advocacy Directive. As a result, some of the areas of noncompliance with FDA acquisition and procurement policies could lead to repeat nonconformity with Federal acquisition and procurement requirements in the administration and management of orders and missed opportunities to further improve competition for IT procurements within FDA.

Appendix C identifies the contract management findings for each FDA center or office.

CONTRACTING OFFICERS DID NOT PROPERLY DESIGNATE A CONTRACTING OFFICER'S REPRESENTATIVE

The FAR requires contracting officers to designate and authorize, in writing in the *FAC-COR Appointment Memorandum* (COR Memo)⁷ and in accordance with agency procedures, a COR for all contracts and orders, unless the contracting officer retains and executes the COR duties.⁸ Additionally, FDA's Acquisition Policy and Oversight Branch requires a contracting officer or contract specialist to also designate the COR in PRISM.⁹

For three of the five orders examined, FDA contracting officers did not properly designate a COR or retain and complete COR duties. For two contracts, a COR was not designated using a COR Memo, although FDA designated the individuals as CORs in the PRISM contract file. For the third order, the contracting officer's required signature was missing from the COR Memo. Although the individuals performed COR duties such as invoice and solicitation document reviews and completed a COR Certification and Completion Statement, the designation of the COR was not compliant with the FAR and with FDA's Acquisition Policy and Oversight Branch requirements.

Further, the FDA centers and offices failed to complete contract file checklists, which are intended to ensure that contract administration requirements, such as the completion of a COR memo, have been accomplished. An individual serving as a contract's COR without a signed COR Memo that establishes duties to perform and the actions not authorized to perform could impact the effectiveness of FDA's oversight of the technical and programmatic aspects of the contract and the reliability and timely completion of contractor performance assessments and could result in the Federal Government incurring additional contract costs.

⁷ The COR Memo is the contracting officer's written designation and authorization of a COR. It details the role, specific authorities, responsibilities, and limitations required of the appointment. COR responsibilities included monitoring contractor performance and reviewing contractor invoices. COR limitations included the inability to change the contract terms or create additional financial obligations.

⁸ FAR 1.602-2(d).

⁹ PRISM is the approved contract filing system at FDA.

FDA DID NOT COMPLETE CONTRACTOR PERFORMANCE ASSESSMENTS

The FAR requires that agencies collect contractor performance information, complete an evaluation of contractor performance, and report on the contractor's performance at the time the work under the contract is completed.¹⁰ FAR 42.1501(b) instructs agencies to use the Contractor Performance Assessment Reporting System (CPARS) to create and measure the quality and timely reporting of performance information and specifies that CPARS is the official source for past performance information. According to the FAR, "[p]ast 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."¹¹ FDA also requires a contractor performance assessment¹² be completed within 90 days after the date when contracted work is completed.

For two of the five orders examined, FDA did not complete a contractor performance assessment and report it in CPARS for contracted work completed in June 2018 and September 2020. Although FDA had procedures and automated notifications to ensure that the contractor performance assessment is completed timely and reported in CPARS once a contract or order is completed, the assessing official¹³ and assessing official's representative¹⁴ failed to ensure that the contractor performance assessment was completed and reported in CPARS.

According to FDA, there was high staff turnover during the previous 3 years, and it was likely that the individuals responsible for completing contractor performance assessments and reporting them in CPARS had left OAGS before the assessments were ready for their review. The CPARS information is critical to ensuring that the Federal Government only does business with companies that provide quality products and services in support of the agency's missions. According to HHS's *Reporting of Contractor Performance Information Guidance*, collecting and reporting contractor performance information is critical because officials can use this data to make informed business decisions when awarding Government contracts and orders. Not completing the contractor's performance assessment could lead to future contract awards decisions being made without the benefit of contractor performance information. It also minimizes the effectiveness of CPARS as a tool to deter fraud, waste, and abuse by a contractor.

¹⁰ FAR 42.1502.

¹¹ FAR 42.1501.

¹² The contractor performance assessment includes FDA's ratings and narratives that reflect the contractor's performance during the specified period of work.

¹³ The assessing official is responsible for preparing, reviewing, signing, and processing the evaluation.

¹⁴ The assessing official representative provides a timely, accurate, quality, and complete narrative supporting the evaluation rating of contractor performance.

FDA DID NOT PROPERLY DOCUMENT KEY CONTRACTING DECISIONS AND ACTIVITIES AND OBTAIN REQUIRED SIGNATURES FOR KEY DECISIONS

The FAR requires the head of each contracting office to establish files with complete histories of all contractual actions and decisions and ensure that these files are readily accessible to principal users.¹⁵ Documentation in the files should provide a full history of each transaction, including a complete basis for the decisions made at each stage of the contracting process and support for any actions taken.¹⁶ According to FDA's *Standard Operating Procedures for Electronic File Management in FDA's Office of Acquisitions and Grants Services (OAGS)*, the procedures that implement FAR 4.8, "file management is crucial to successfully dealing with electronic records." FDA procedures identify key documentation that should be maintained and state that "upon award/release of a contract action, ALL final supporting documents must be uploaded" into PRISM with a completed FDA file checklist. PRISM is FDA's approved contract filing system. Additionally, FDA requires its staff to complete contracting documents for approval and authorization as part of contract planning requirements and the contracting cycle.

FDA policies and procedures state that a severability¹⁷ and funding determination is always required, and that completion of a *Severability & Funding Determination* document is mandatory, including signatures for the completion, submission, and approval of a contract request and all contract actions above the simplified acquisition threshold.¹⁸ The *Severability & Funding Determination* document requires signatures from three different FDA representatives: (1) the program official, (2) the contracting officer, and (3) the budget analyst. In addition, FDA requires that the *Recommendation for Award*, an internal document, be completed and signed in support of an award decision. The *Recommendation for Award* document requires signatures from three different FDA representatives in three distinct fields: (1) the contract specialist's signature in the "Prepared by" field, (2) the contracting officer's signature in the "Approved by" field, and (3) the supervisor or team lead's signature in the "Concur by" field.

For four of the five orders examined, FDA did not document all key contracting decisions or activities in PRISM and obtain all required signatures in FDA's internal review and approval for

¹⁵ FAR 4.801 and FAR 4.802.

¹⁶ FAR 4.803.

¹⁷ Whether a contract is severable or non-severable affects how an agency may optimize appropriations to fund a contract. Severable services must be funded during the period of appropriation availability in which the work is performed. Non-severable services must be fully funded by an appropriation current at the time the contract is awarded.

¹⁸ The simplified acquisition threshold in place at the time of the contracts was \$150,000. All contracts at the time were above the simplified acquisition threshold of \$150,000.

the *Severability & Funding Determination* document and the *Recommendation for Award* document. Specifically:

- the analysis of the contractor's price or technical quotation and price evaluation or record of price reductions or discounts sought was not stored in PRISM for three orders,¹⁹
- award decision documentation was not stored in PRISM for two orders,
- the pre-award review was not stored in PRISM for two orders,²⁰
- the System for Award Management verification was not stored in PRIMS for three orders,²¹
- the FPDS contract data report was not stored in PRISM for two orders,²²
- the contracting officer's signature was missing from the *Severability & Funding Determination* document for two orders,²³
- both the program budget analyst's signature for a funding determination and the contracting officer's signature were missing from the *Severability & Funding Determination* document for one order, and
- the "Concur by" field was not signed by the supervisor/team lead in the *Recommendation for Award* document for one order.

¹⁹ The analyses are evaluation factors and significant subfactors that apply to an acquisition and are the basis for the award decision. Evaluation factors and significant subfactors represent the key areas of importance and emphasis to be considered in the source selection decision and support meaningful comparison and discrimination between and among competing proposals.

²⁰ Pre-award review is a review and approval activity for proposed contract actions to ensure that contractual documents conform to the law, established policies and procedures, and sound business practices; contract actions properly reflect the mutual understanding of the parties; and the contracting officer is informed of deficiencies and items of questionable acceptability, and takes corrective action.

²¹ System for Award Management verification checks whether a contractor is registered in the System for Award Management for contractor eligibility. The System for Award Management is a Federal Government system that collects, validates, stores, and disseminates information on individuals or entities eligible for contract awards.

²² The FPDS contract data report contains information on contract actions for the acquisition and is used to provide transparency in Federal spending.

²³ The contracting officer's completion of the *Severability & Funding Determination* and signature represented the contracting officer's determination that they had no reason to believe that information provided in the *Severability & Funding Determination* document was incorrect or incomplete or required revision and that the funding approach and type and source of funds to be used complied with applicable fiscal law and acquisition policy requirements.

Although OAGS had existing standard procedures to ensure contract documents were uploaded timely into the PRISM contract file, OAGS staff, acquisition workforce personnel, and program officials did not consistently follow FDA procedures. If a dispute occurs during the performance of a contract, the lack of documentation could make it difficult for FDA to defend a protest against the Government. If there is a protest of the contract award, the Government would likely lose the protest if it was unable to provide contemporaneous documentation of its decision-making process. Also, the Government could be forced to stop the contracting process and not award the contract, which would delay contract performance or put the contract on hold throughout the duration of the protest. Both scenarios could put the Government behind schedule and necessitate either going without the services or products required or procuring them on a temporary basis until the protest is resolved. Regarding the lack of appropriate signatures on internal review and approval documents, there was no assurance that all parties responsible for making approvals, determinations, and recommendations for the acquisition concurred. If an acquisition is continued without the appropriate signatures or complete approval, it may lead to the inappropriate approval of contract actions, including improper funding for awards.

FDA DID NOT INCLUDE THE REQUIRED ACQUISITION STRATEGY OR STATEMENT IN THE ACQUISITION PLANS FOR SOME ORDERS

Beginning in 2015, HHS's *Directive For the Acquisition Strategy* and the HHS Acquisition PGI both require an acquisition strategy for all programs and projects that are augmented by contract services or support.²⁴ The acquisition strategy defines the mission and business needs for the portfolio or program and provides a critical foundation necessary to guide the execution of the program throughout the program's life cycle.²⁵ FDA Administrative Action Memorandums 2017.02-002 and 2017.05-010 state that, if an approved and documented acquisition strategy does not exist, the contracting officer should insert a specific statement into the Statement of Need section of the contract's or order's acquisition plan.²⁶ The contracting officer must ensure that the required statement is included in the appropriate section of the acquisition plan.

Three of the five orders examined for the IT Program were awarded during FYs 2018 and 2019, before the IT Program had an HHS-approved acquisition strategy, and therefore should have had the FDA-required statement in their acquisition plans.

Developing and getting approval for acquisition strategies was not a top priority for FDA, but FDA stated that it has been working towards the development and approval of IT-related

²⁴ HHS Acquisition PGI part 301.

²⁵ HHS' *Directive For the Acquisition Strategy*.

²⁶ The statement should identify the FDA program the acquisition supports, state that an acquisition strategy is in development to comply with the requirement, and state that the acquisition plan will be updated to include the acquisition strategy when the acquisition strategy is approved.

acquisition strategies. A lack of adequate strategic planning could lead to unnecessary and costly contracting expenditures that are inconsistent with the program or project's strategic direction and objectives.

FDA DID NOT FULLY COMPLY WITH THE HHS COMPETITION ADVOCACY DIRECTIVE

Each HHS operating and staff division's competition advocate must prepare and submit to the HHS competition advocate an Annual Competition Advocate Report (ACAR) covering the prior fiscal year in accordance with the requirements of FAR 6.502(b)(2). Federal law (41 U.S.C. § 1705(b)(4)) states that the advocate for competition of an executive agency must prepare and transmit to the senior procurement executive an annual report describing the advocate's activities under this section, new initiatives required to increase competition, and remaining barriers to full and open competition. The ACAR describes the status of the operating or staff division's efforts to promote competition for the procurement of goods and services at fair and reasonable prices without reducing quality, readiness, or safety throughout HHS, and it addresses: (1) any steps the operating or staff division had taken during the previous fiscal year to remedy any organizational problems, policies, or procedures that inhibit competition; (2) hinderances to the acquisition of commercial items; and (3) opportunities and actions taken to improve the quality of planning, executing, and managing task and delivery orders, among other efforts.

FDA did not prepare and submit ACARs for FYs 2019 and 2020 and therefore did not comply with the HHS Competition Advocacy Directive for those 2 years.

FDA stated that HHS did not send the applicable instructions and data to draft the FY 2019 and FY 2020 ACARs and that it was waiting for instructions and data from HHS to complete the ACARs. However, the data FDA needed to address the requirements at FAR 6.502(b)(2) and from which the ACAR originates were available for FDA to retrieve from FPDS. The lack of instructions from HHS did not negate the requirement for FDA to complete the ACARs.

Without FDA's annual competition advocate report, the HHS Department Competition Advocate is not able to fully comply with Federal law (41 U.S.C. § 1705(b)(4) and FAR 6.502(b)(2)), and perform all Department Competition Advocate responsibilities established in the HHS Competition Advocacy Directive. In addition, FDA may have missed opportunities to further improve its overall competitive contract performance within HHS and to identify trends and emerging challenges in competition that reduce quality, readiness, or safety of products and services.

RECOMMENDATIONS

We recommend that the Food and Drug Administration:

- consistently implement its existing policies and procedures and use existing checklists to ensure that:
 - contracting officer's representatives (CORs) are appointed using the required COR Memo if the contracting officer does not retain and complete all COR duties,
 - contractor performance assessments are completed and uploaded to the Contractor Performance Assessment Reporting System timely,
 - the appropriate contracting documents and supporting documents are uploaded to the Purchase Request Information System (PRISM), and
 - the *Severability & Funding Determination and Recommendation for Award* approvals are properly completed;
- evaluate internal procedures and documents for key contracting decisions and activities to verify that all supporting contract documents are based on current HHS and FDA policies and procedures; and
- prepare and submit timely Annual Competition Advocate Reports (ACARS) to HHS in accordance with the requirements of FAR 6.502(b)(2) and the HHS Competition Advocacy Directive.

FDA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, FDA concurred with all of our recommendations and described actions it has taken or plans to take to address the findings. FDA stated that it has increased its reviews and audits of the acquisition files to ensure that all applicable contract documentation is properly prepared and uploaded into PRISM. FDA stated that it has updated its policies and procedures to ensure that all contracting decisions made by the contracting officer will be documented and that the documentation will include the rationale for any business judgments. FDA stated that it will assess the acquisition lifecycle process to ensure that all acquisition activities align with current policies and procedures and established best practices. FDA stated that it will continue to work with HHS to ensure the timely preparation and submission of ACARS.

FDA's comments are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered five FDA orders totaling \$23,674,513 paid to a single contractor (CSP Enterprise) for IT hardware and equipment during FYs 2018 through 2020. Of the five orders selected, three were with OIMT, one was with the Center for Devices and Radiological Health, and one was with the Center for Biologics Evaluation and Research. We evaluated these orders for compliance with the FAR, HHSAR, and HHS Acquisition PGI, and relevant FDA acquisition and procurement policies.

We did not assess FDA's overall internal controls. Rather, we limited our review of internal controls to those applicable to our audit objective. Specifically, we assessed the policies, procedures, and practices applicable to FDA awarding orders for the acquisition of IT.

We conducted our audit from March 2021 through September 2022.

METHODOLOGY

To accomplish our objective, we:

- interviewed FDA management and OAGS, OIMT, Center for Devices and Radiological Health, and Center for Biologics Evaluation and Research staff on FDA governance, contracting process, controls, and management support activities;
- examined acquisition planning documents, award documents, invoices, justifications, and supporting documentation, including FDA centers' and offices' internal acquisition determinations, recommendations, approvals, and evaluations;
- reviewed HHS and FDA policies and procedures related to acquisitions and procurement and supply management;
- verified the implementation of processes, procedures, and review and approval activities; and
- discussed the results of our audit with FDA 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 the findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL REQUIREMENTS

FEDERAL ACQUISITION REGULATION

48 CFR § 1.301(a)(1)

. . . an agency head may issue or authorize the issuance of agency acquisition regulations that implement or supplement the FAR and incorporate, together with the FAR, agency policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process or otherwise control the relationship between the agency, including any of its suborganizations, and contractors or prospective contractors.

48 CFR § 1.602-1(b)

No contract shall be entered into unless the contracting officer ensures that all requirements of law, executive orders, regulations, and all other applicable procedures, including clearances and approvals, have been met.

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. . . . Contracting officers shall –

- (d) Designate and authorize, in writing and in accordance with agency procedures, a contracting officer's representative (COR) on all contracts and orders other than those that are firm-fixed price, and for firm-fixed-price contracts and orders as appropriate, unless the contracting officer retains and executes the COR duties.

48 CFR § 4.801

- (a) The head of each office performing contracting, contract administration, or paying functions shall establish files containing the records of all contractual actions.
- (b) The documentation in the files (see 4.803) shall be sufficient to constitute a complete history of the transaction for the purpose 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.

48 CFR § 4.802(a)

- (a) A contract file should generally consist of—
 - (1) The contracting office contract file, that documents the basis for the acquisition and the award, the assignment of contract administration (including payment responsibilities), and any subsequent actions taken by the contracting office.

48 CFR § 4.802(c)

Files must be maintained at organizational levels that ensure -

- (1) Effective documentation of contract actions;
- (2) Ready accessibility to principal users; . . .
- (5) Conformance with agency regulations for file location and maintenance.

48 CFR § 42.1502(a)

Past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed. . . . Past performance information shall be entered into CPARS, the Governmentwide evaluation reporting tool for all past performance reports on contracts and orders.

HHS ACQUISITION POLICY, GUIDANCE, AND INSTRUCTION

Part 307.104-70, Acquisition strategy

An acquisition strategy (AS) is required for all programs/projects that are augmented by contract services/support in order to provide the conceptual basis of the overall mission and business need.

Part 306.503, Annual Competition Advocate Report

Each OPDIV/STAFFDIV Competition Advocate (CA) must submit an ACAR report to the Department CA by the 15th of November annually (or the following business day if November 15th is not a normal business day). The ACAR report is based upon instructions from the Department CA which will be sent on or about October 1 annually.

HHS DIRECTIVES

Directive for the Acquisition Strategy, § 1.6, Requirement for a Written Acquisition Strategy

In accordance with the FAR and HHS policy, a written AS is required for all [programs/projects] that will be augmented by contractor support.

HHS Competition Advocacy Directive, § 2.3, Agency Operating Division and Staff Division Competition Advocate

Each OPDIV and STAFFDIV Competition Advocate shall prepare an Annual Competition Advocate Report (ACAR), covering the prior fiscal year, in accordance with the requirements of FAR 6.502(b)(2) and provide it to the HHS Competition Advocate in accordance with instructions sent by the HHS Competition Advocate on or about the 1st of October. HHS requires that each ACAR be prepared in a standard format. The template for the report will be included with the instructions sent by the HHS Competition Advocate on or about the 1st of October.

FDA POLICIES

Policy and Procedure Memorandum (PPM) 2019.06-001

[Contracting officers] must appoint a COR for Non-firm-fixed-price acquisitions, regardless of dollar value and complexity of the action. In addition, the PPM states that the contracting officer or contract specialist shall also designate the COR in PRISM for the acquisition.

FDA Staff Manual Guide No. 2610.1, Volume III - General Administration, Procurement and Supply Management

This section states that a severability and funding determination is always required.

Standard Operating Procedures for Electronic File Management in FDA's OAGS

This section states that file management will be accomplished through PRISM and that "upon award/release of a contract action, ALL final supporting documents must be uploaded" into its approved contract filing system with a completed FDA file checklist.

Administrative Action Memoranda 2017.02-002 and 2017.05-010

This section states that for any acquisition plan that is not supported by an approved acquisition strategy, "Insert and complete the following statement in the [acquisition plan] Section, entitled, "FAR 7.105 (a)(1) Statement of Need": The subject acquisition supports the FDA Program entitled _____ - _____. An Acquisition Strategy document is currently being developed as required by _____.

the Acquisition Alert 2015-01: New Acquisition Guides and Templates, dated March 26, 2015. When the [acquisition strategy] is approved, this [acquisition plan] will be updated to note the approved [acquisition strategy].”

APPENDIX C: CONTRACT MANAGEMENT FINDINGS BY FDA CENTER OR OFFICE

Order	Center or Office	COR Not Properly Designated	Contractor Performance Assessments Missing	Key Decisions Not Properly Documented or Required Signatures Not Properly Obtained	No Approved Acquisition Strategy
1	CBER	X	–	X	X
2	OIMT	X	X	X	–
3	CDRH	–	–	–	–
4	OIMT	–	X	X	X
5	OIMT	X	–	X	X

FDA Center/Office:

CBER – Center for Biologics Evaluation and Research

OIMT – Office of Information Management and Technology

CDRH – Center for Devices and Radiological Health

An 'X' in a box denotes a finding in that area.

APPENDIX D: FDA Comments



DATE: December 20, 2022

TO: Amy J. Frontz
Deputy Inspector General
Audit Services

FROM: Lisa Rovin, Director, Public Health Strategy and
Analysis, *for*:

Lisa B. Rovin
-S
Digitally signed by Lisa B.
Rovin -S
Date: 2022.12.21
08:33:24 -05'00'

Beethika Khan, Ph.D.
Associate Commissioner for Economics and Analysis
Director, Office of Economics and Analysis
Office of Policy, Legislation, and International

SUBJECT: ~~Office~~ Draft Report, A-18-21-11100

Attached are the general comments to the Office of Inspector General's November 21, 2022 draft report entitled *FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology*. The Food and Drug Administration does not have technical comments to the draft report. Thank you for the opportunity to provide feedback.

Attachments

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA's General Comments

OIG Draft Report: FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology, A-18-21-11100

FDA appreciates the opportunity to review and comment on OIG's draft report. The Office of Acquisitions and Grants Services (OAGS) has no additional comments beyond those previously submitted. OAGS appreciates the recommendations and for each concurrence has provided a statement on the nature of the corrective action taken or planned to be taken.

Consistently implement its existing policies and procedures and use existing checklists to ensure that:

- **contracting officer's representatives (CORs) are appointed using the required COR Memo if the contracting officer does not retain and complete all COR duties,**
- **contractor performance assessments are completed and uploaded to the Contractor Performance Assessment Reporting System timely,**
- **the appropriate contracting documents and supporting documents are uploaded to the Purchase Request Information System, and**
- **the *Severability & Funding Determination and Recommendation for Award* approvals are properly completed.**

FDA concurs with this recommendation.

- It is the FDA's position that the CO does not need to appoint a Contracting Officer's Representative (COR) for every order and should only do so in compliance with FAR 1.602-2. The FDA established "agency procedures" through Policy and Procedure Memorandum (PPM) 2019.06-001, which specifically gives Contracting Officers (COs) "discretion as to when it is most appropriate to appoint a COR to an acquisition" (Section 4.1.1). PPM 2019.06-001 explicitly cites FAR 1.602-2 and establishes the framework which does not require a CO to appoint a COR on every acquisition, including on every firm-fixed-price contract and order, and a CO appointing a COR is not in the best interest of the Government for many acquisitions in consideration of the terms and conditions of the acquisition. To increase visibility when a COR is appointed, FDA now tracks COR Appointments through a dedicated data field in PRISM. Also, OAGS has increased its reviews of Acquisition Files, including COR Appointment documentation, within operational supervisory chains of command, as well as greater Acquisition File audits and other reviews by the Acquisition Policy and Oversight Branch. Additionally, last year, the FDA issued PPM 2021.01-001, Technical Points of Contact Appointment (TPOC), which "**mandates the appointment of a Technical Point of Contact**" when a CO does not appoint a COR to an acquisition. Through PPM 2021.01-001, the FDA formalized the roles and responsibilities of TPOCs, which strengthened the FDA's procedures and

controls in helping ensure there is adequate oversight of acquisition activities. OAGS has conducted and will continue to host training and other outreach events to emphasize the importance of appropriately appointing and documenting CORs and TPOCs.

- FDA accepts the OIG's finding regarding file documentation. FDA's OAGS has implemented Standard Procedures for Electronic File Management (eSOP) to ensure contract documents are uploaded timely into the PRISM contract file. OAGS recognizes that uploading contract documentation to the PRISM electronic contract file has been problematic since moving from paper to electronic contract files. Therefore, in FY22 OAGS implemented a policy requiring that all OAGS Directors, Branch Chiefs, Contracting Officers, Team Leaders, and Contracts Specialist ensure all contract documentation is uploaded into the PRISM Contract File in accordance with the eSOP. OAGS has also incorporated performance factors in everyone's FY22 Performance Management Plans. The Division Directors have been tasked to conduct weekly reviews of contracts being awarded that all contract documents have been uploaded. This new process has dramatically increased compliance with the eSOP.
- FDA agrees with the OIG that CPARS evaluations were not conducted for a couple of the actions that were reviewed. OAGS has procedures, tracking systems, and performance matrixes to ensure that timely completion CPARS once the contract or task order has been completed and the government has accepted all of the products and services called out for in the contract. On a monthly basis, a report is generated and provided to the Approving Official (AO) and the Approving Official Representative (AOR) identifying the CPARS evaluations due to be completed. The first line leaders within OAGS are tasked with the responsibility of tracking completion. Greater emphasis will be placed on tracking completion. Note: The Department of Health and Human Services provides quarterly reports on OPDIV completion of CPARS.
- FDA agrees with the OIG that a number of the Severability & Funding Determination were not signed in accordance with FDA policy. The Severability & Funding Determination is an internal FDA policy and failure to sign has no direct impact on the contract award nor does it mean that FDA is not following the core procurement processes, policies, principles outlined in the Federal Acquisition Regulations. The document only states if the action severable or not. OAGS will remind COs of their responsibility to review supporting documentation provided for the contract file and ensure proper signatures are obtained.

Evaluate internal procedures and documents for key contracting decisions and activities to verify that all supporting contract documents are based on current HHS and FDA policies and procedures.

FDA concurs with this recommendation.

All contracting decisions made by the CO shall be documented, and the documentation shall include the rationale for any business judgments. It is the CO's responsibility to ensure this document and other supporting contract documents are included in the contract file and follow

current HHS and FDA guidance. The FDA does not require any specific “Recommendation for Award” template through its official guidance or applicable acquisition regulation. Additionally, the FDA does not require, through its official guidance or applicable regulation, “Recommendations for Award” to “Prepared by,” “Approved by,” or “Concurred by” any specific individuals and does not prohibit one person serving as a “submitter,” “reviewer,” and “approver.” In contrast, a CO often is the “submitter,” “reviewer,” and “approver” of acquisition documents, such as “Recommendations for Award” type documents. FDA guidance allows for flexibility in the process without diminishing the decision making of the CO. The FDA will assess the acquisition lifecycle process to ensure all acquisition activities aligned with current policies and procedures and established best practices.

Prepare and submit timely Annual Competition Advocate Reports to HHS in according with the requires of FAR 6.502(b)(2) and the HHS Competitions advocacy Directive.

FDA concurs with this recommendation.

The completion of the Annual is Competition Advocate Report (ACAR) done in collaboration with HHS who provides the FDA with the applicable instructions and data to draft those reports in accordance with Chapter 2, Section 2.1 of the HHS Competition Advocacy Directive. FDA will continue to work with HHS to ensure the timely preparation and submission of ACARs. If the instruction and data is not provided to ensure timely submission, FDA will be proactive in reaching out to HHS to obtain the needed information.