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INSPECTOR GENERAL

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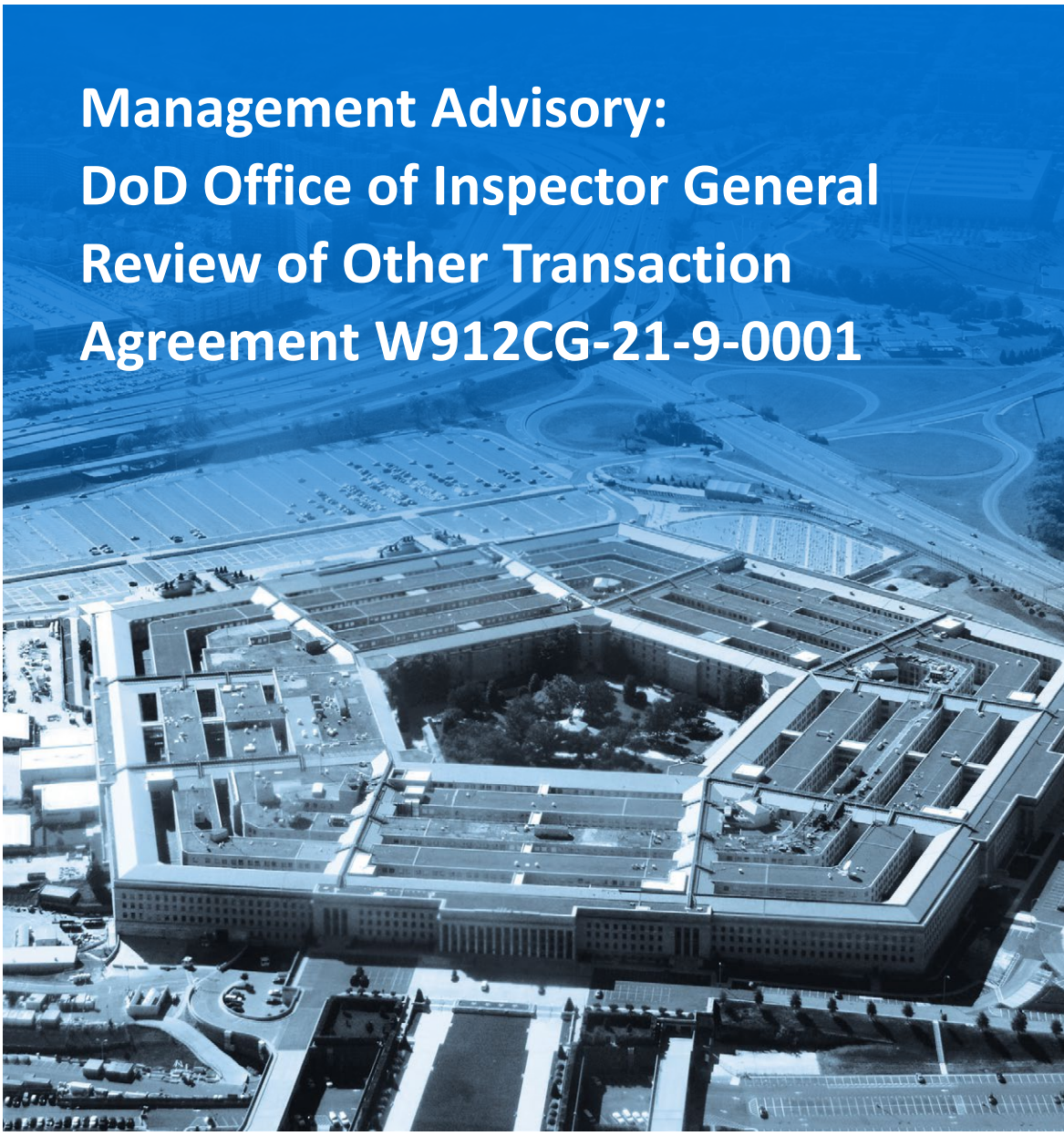
SEPTEMBER 26, 2023

Management Advisory: DoD Office of Inspector General Review of Other Transaction Agreement W912CG-21-9-0001



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September 26, 2023

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT
UNDER SECRETARY OF DEFENSE FOR POLICY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Management Advisory: DoD Office of Inspector General Review of Other Transaction Agreement W912CG-21-9-0001 (Report No. DODIG-2023-125)

We are providing this management advisory to inform DoD and Army Contracting Command leadership of a review the DoD Office of Inspector General (OIG) conducted of other transaction (OT) agreement W912CG-21-9-0001. The DoD awarded the OT agreement to KPMG, LLP on March 1, 2021, to develop a process for accelerating access to the monoclonal antibody treatments for high-risk COVID-19 patients.

The OIG's review was in response to a congressional inquiry that requested that the DoD OIG identify the DoD office that was tasked or partnered with the Department of Health and Human Services (HHS) to solicit bids and award the OT agreement, and determine DoD and HHS roles with respect to the following actions:

- defining the government's requirements,
- soliciting bids,
- evaluating bids,
- awarding the OT agreement,
- monitoring the program (including ongoing evaluations of whether KPMG was meeting program goals),
- reaching the decision to pause the program, and
- reaching the decision to cancel the program.

We conducted the work on this management advisory with integrity, objectivity, and independence, as required by the Council of the Inspectors General on Integrity and Efficiency's Quality Standards for Federal Offices of Inspector General.

While performing the review, we determined that DoD contracting officials did not maintain documentation to support that HHS conducted market research or that, during the market research, it identified three prospective contractors for white paper requests. Therefore, without the necessary documentation, we were unable to determine whether the OT agreement complied with section 2371b, title 10, United States Code or the Office of the Under Secretary

of Defense for Acquisition and Sustainment OT Guide, which requires the DoD to use competitive procedures to the maximum extent practicable and to document the rationale for making Government investment decisions.

This management advisory has no direct recommendations; however, we refer to open recommendations from a previous DoD OIG audit that addresses the issues identified in this advisory.[1]

If you have any questions, please contact me at [redacted]. We appreciate the cooperation and assistance received during the review.

FOR THE INSPECTOR GENERAL:

Carmen J. Malone
Assistant Inspector General for Audit
Acquisition, Contracting, and Sustainment

[1] DoD OIG Report No. DoDIG-2021-077, "Audit of Other Transactions Awarded Through Consortiums," April 21, 2021.

Introduction

In November 2022, the DoD OIG received a congressional inquiry regarding Other Transaction (OT) agreement W912CG-21-9-0001 awarded to KPMG, LLP (KPMG) on March 1, 2021. Specifically, the request was for the DoD OIG to identify the DoD office that was tasked or partnered with the HHS to solicit bids and award the OT agreement, and to determine DoD and HHS roles in awarding and executing the OT agreement.

We coordinated with the HHS OIG to determine whether it had ongoing audits specific to this request and it did not. Therefore, our review only included information from the DoD perspective.

Background

On March 11, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and subsequently the President of the United States declared the COVID-19 outbreak a national emergency. A pandemic is a global outbreak of a disease that grows exponentially and covers a wide area, affecting several countries and populations. In November 2020, the U.S. Food and Drug Administration issued an emergency use authorization for monoclonal antibody (mAb) therapies which aid in the body's immune response to fight COVID-19.[2] The emergency use authorization stated that the U.S. Government was responsible for the fair and transparent allocation and distribution of mAb therapeutics to treat COVID-19. The increased transmission of COVID-19 caused an urgent need to develop a process for mAb infusion center capabilities for COVID-19 patients in high-risk communities within the United States. The U.S. Government was looking for support for the rapid implementation of an "infusion center model" that would minimize the risk associated with patients at a high risk of mortality. Specifically, the U.S. Government was interested in solutions that could be rapidly scaled nationwide, where the contractor would act as the integrator. Therefore, the DoD and HHS partnered to solicit bids and award an OT agreement. On March 1, 2021, the Army Contracting Command–Aberdeen Proving Ground Orlando (ACC-APG Orlando) awarded OT agreement W912CG-21-9-0001 to KPMG. After the award, Army Contracting Command consolidated its COVID-19-related acquisition efforts under a single division and the Army Contracting Command-Aberdeen Proving Ground Joint COVID-19 Response Division (ACC-APG JCRD) took over responsibility for the OT agreement.[3]

To conduct the review of OT agreement W912CG-21-9-0001, we met with officials from the ACC-APG JCRD and the ACC-APG Orlando. We also obtained access to the DoD OT agreement file and reviewed the available solicitation, evaluation, award, and termination documentation. In

[2] Monoclonal antibody treatments were laboratory-produced proteins created to bind to SARS-CoV2, the virus that caused COVID-19, and prevented it from attaching to human cells.

[3] ACC-APG JCRD was comprised of members from five different Army Contracting Command centers and supported the COVID acquisition efforts of the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), in conjunction with HHS.

addition, we reviewed written communications between DoD and HHS officials regarding the OT agreement and examined Federal and DoD policy related to Other Transaction Authorities.

Other Transaction Authority Competitive Procedures

Section 2371, title 10, United States Code (10 U.S.C. § 2371) and section 2371b, title 10, United States Code (10 U.S.C. § 2371b), now sections 4021 and 4022, title 10, United States Code (10 U.S.C. § 4021) and (10 U.S.C. § 4022), provide authority for the DoD to enter into OTs.[4] The law states that the DoD is required to use competitive procedures to the maximum extent practicable to award OT agreements.

Under Secretary of Defense for Acquisition and Sustainment Other Transaction Guide Competitive Procedures

The OT Guide issued by the Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD[A&S]), November 2018, provides advice and lessons learned on the planning, publicizing, soliciting, evaluating, negotiating, awarding, and administering of Other Transactions.[5] The guide states that agencies are free to create their own process to solicit and assess potential solutions, so long as the process is fair and transparent, provides for competitive procedures to the maximum extent practicable, and documents the rationale for making Government investment decisions.

Offices within the DoD and HHS Responsible for the OT Agreement

We confirmed that the DoD and the HHS partnered to solicit bids and award the OT agreement to KPMG. The DoD offices were the Joint Program Executive Office–Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), ACC-APG JCRD, and ACC-APG Orlando. The HHS offices were the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

Actions the DoD and HHS Performed to Solicit and Award the OT Agreement

According to DoD OT agreement documentation and our meetings with officials from the ACC-APG JCRD, the HHS initiated the program to create an infusion center model to increase the administration of mAb therapeutics infusions for COVID-19 patients, provided the funding, and later made the decision to terminate the OT agreement. In addition, ASPR

[4] Public Law 117-81, "National Defense Authorization Act for FY2022," issued December 27, 2021, renumbered 10 U.S.C. § 2371b to 10 U.S.C. § 4022.

[5] The OUSD (A&S) OT Guide was updated in July 2023; however, we performed this review in accordance with the November 2018 OUSD (A&S) OT Guide which was applicable at the time of this OT agreement award.

and BARDA partnered with JPEO-CBRND, ACC-APG JCRD, and ACC-APG Orlando to define the mAb therapeutics infusion program requirements, solicit white papers, evaluate bids, and monitor contractor performance. See below for details on responsible agencies for each part of the process.

Defining Government Requirements

On July 30, 2020, HHS officials issued a broad agency announcement on the SAM.gov website to solicit pre-proposals for potential procurement contracts, OTs, and technology investment agreements for COVID-19 therapeutics to identify the best available science for protecting against contracting COVID-19 and for treating those who contracted COVID-19. ACC-APG JCRD officials stated that the specific requirements for the program to create an infusion center model to increase mAb therapeutics infusions for COVID-19 patients were then defined through a collaborative effort between the JPEO-CBRND, ASPR, and BARDA.

Soliciting Bids

ACC-APG JCRD officials stated that following the HHS publication of the broad agency announcement, HHS officials conducted market research to determine capabilities in the therapeutics market and identified three contractors that were capable of meeting program requirements. ACC-APG Orlando officials issued a request for white papers to those three contractors on February 16, 2021, with a due date of the following day, February 17, 2021. Two of the contractors responded to the request, one of which was KPMG.

Neither ACC-APG JCRD officials nor the DoD OT agreement file had documentation to support that HHS officials conducted the market research.[6] In accordance with 10 U.S.C. § 2371b, the DoD is required to use competitive procedures to the maximum extent practicable to award OT agreements. In addition, the OUSD(A&S) OT Guide, November 2018, states that agencies are free to create their own process to solicit and assess potential solutions, provided it is fair and transparent, provides for competitive procedures to the maximum extent practicable, and documents the rationale for making Government investment decisions. However, we determined that the DoD OT agreement file did not contain support that the HHS or the DoD conducted market research or the rationale for sending the request for white papers to the three contractors.

Evaluating Bids

According to ACC-APG JCRD officials and the DoD OT agreement file, JPEO-CBRND, ACC-APG Orlando, and ASPR officials evaluated the white paper proposals received and selected KPMG's white paper. In the DoD OT agreement file, the evaluation team documented that KPMG's white paper was the preferred option based on KMPG's stated ability to successfully address

[6] We did not request supporting documentation from the HHS; therefore, we were unable to determine whether the documentation existed in HHS files.

each area outlined in the announced statement of objectives. Specifically, the U.S. Government was looking for support for the rapid implementation of an "infusion center model" that would minimize risk associated with patients at high risk of mortality. The U.S. Government was interested in solutions that could be rapidly scaled nationwide, where the contractor would act as the integrator.

OT Award Process

On February 23, 2021, ACC-APG Orlando officials issued a letter of intent to execute an OT agreement to KPMG and on March 1, 2021, requested that KPMG provide a full cost proposal. However, ACC-APG JCRD officials stated that the request for the full cost proposal and negotiation process would unduly delay the long lead time process in establishing the mAb infusion centers and therefore, they decided to issue an undefinitized prototype agreement (UPA) before receiving the full cost proposal from KPMG.[7] On March 1, 2021, OT agreement officials from the ACC-APG Orlando issued an undefinitized prototype agreement for the not-to-exceed value of $150 million to KPMG and incrementally funded the agreement for $75 million. After receiving the full cost proposal and completing negotiations, ACC-APG Orlando officials definitized the agreement on June 17, 2021, for $142.7 million for the period of performance from March 2021 to February 2022.

Program Monitoring

ACC-APG JCRD officials stated that officials from the JPEO-CBRND, ACC-APG-JCRD, ACC-APG Orlando, ASPR, and BARDA monitored KPMG's performance. The agreement officer's representative (AOR) was a DoD employee assigned to the Army Contracting Command but detailed to the HHS office for the Federal COVID Response Therapeutics team. The AOR stated that his team, including ASPR and BARDA officials, monitored the implementation of the program at multiple locations to ensure KPMG was meeting requirements and the work was meeting the intent of the program. The AOR also stated that KPMG officials sent his team monthly program reviews that tracked the number of patients infused at the infusion sites. Furthermore, he stated that DoD and HHS officials met weekly to review the work performed, costs incurred, and payments made. In addition, the AOR stated that the Army Contracting Command Headquarters approved the payments that KPMG invoiced monthly based on costs incurred. ACC-APG JCRD officials stated that KPMG was meeting agreed-upon schedule, delivery, and cost metrics.[8]

[7] An undefinitized prototype agreement means the contract terms, specifications, or price are not agreed upon before the contractor begins performance under the agreement. Definitization means the Government and the contractor agreed on or determined agreement terms, specifications, and price, which converts the undefinitized agreement to a definitive agreement.

[8] We were unable to review the AOR file to determine the oversight performed and if there was documentation of KPMG meeting agreed-upon schedule, delivery, and cost metrics. The AOR did not have access to his files because they were maintained by HHS and he was only assigned to HHS for this effort.

Program Termination

On November 10, 2021, the ASPR sent a letter to the OUSD(A&S) requesting that the DoD immediately terminate the OT agreement. The letter explained that the increased demand for mAb therapeutics had created a shortage for the public and that the ASPR determined in September 2021 that the distribution of therapeutics had to return to a state and territory-coordinated distribution system. The ASPR letter stated that the Food and Drug Administration had authorized a new antiviral drug, and the HHS anticipated the Food and Drug Administration authorization of an oral COVID-19 antiviral soon. The new antiviral drugs would not require intravenous administration and, therefore, would not require an infusion infrastructure. The letter also stated KPMG's infusions represented a small portion of the overall Government effort for accelerating access to mAb treatments for COVID-19 but represented a significant cost investment.[9]

ACC-APG JCRD officials stated that the DoD reviewed the termination request and met with HHS officials to discuss it. Subsequently, the ACC-APG JCRD issued the stop work order to KPMG on November 30, 2021, to stop all work no later than December 14, 2021. On January 4, 2022, the ACC-APG JCRD issued the notice of termination to KPMG with an effective date of February 4, 2022.

After KPMG received the termination notice, the HHS, ACC-APG JCRD, and KPMG agreed that KPMG would submit its settlement proposal by March 30, 2022. ACC-APG Orlando officials terminated the agreement by issuing an agreement modification dated June 14, 2022, documenting that the total cost of the OT agreement was $44.7 million at the time of termination.

Summary

We confirmed that offices within the DoD and HHS partnered to solicit bids and award the OT agreement to KPMG. Specifically, the HHS and its offices, ASPR and BARDA, initiated the program to create an infusion center model for mAb therapeutics infusions for COVID-19, provided funding, and later decided to terminate the program. In addition, ASPR and BARDA partnered with DoD offices, JPEO-CBRND, ACC-APG JCRD, and ACC-APG Orlando, to define program requirements, solicit white papers, evaluate bids, make the award, and monitor contractor performance. KPMG performed the work under the OT agreement for about 9 months until the ASPR requested termination and the ACC-APG JCRD directed KPMG to stop work by December 14, 2021. The ACC-APG JCRD then officially terminated the OT agreement, effective February 4, 2022.

[9] The termination letter stated that as of October 11, 2021, KPMG-supported sites had completed 24,703 mAb infusions; however, it is unclear how many were directly related to KPMG efforts. The 24,703 infusions represented about 1.6 percent of all infusions supported by ASPR's Allocation, Distribution, and Administration, which counted 1,540,000 infusions as of October 13, 2021.

We also noted that neither the ACC-APRG JCRD nor the DoD OT agreement file had documentation to support that the HHS conducted market research or that, during the market research, it identified three prospective contractors for white paper requests. Therefore, without the necessary documentation, we were unable to determine whether the OT agreement complied with 10 U.S.C. § 2371b and the OUSD(A&S) OT Guide, which requires the DoD to use competitive procedures to the maximum extent practicable and to document the rational for making Government investment decisions.

We have made recommendations in a recent report to address the lack of retaining documentation for the OT program. In DoD OIG Report No. DoDIG-2021-077, "Audit of Other Transactions Awarded Through Consortiums," April 21, 2021, there were two recommendations to the Principal Director of Defense Pricing and Contracting (DPC) related to ensuring competition to the maximum extent practicable and maintaining documentation of major decisions made to support an OT award. While we made these recommendations specifically for OTs awarded through a consortium, the responses we cite below will apply to all OT awards. Specifically, we recommended the DPC Principal Director:

1.c. Reinforce guidelines or implement additional best practices to ensure Other Transactions awarded through consortiums use competition to the maximum extent practicable as required. The DPC Principal Director agreed with the recommendation and stated that the DPC will update the OT Guide to reinforce the use of competition through an assessment of the competitive requirements used in OT consortiums to determine whether competition is encouraged to the maximum extent practicable.

1.d. Implement additional guidance or best practices that ensure contracting personnel maintain documentation for major decisions made to support the award of an Other Transaction agreement in the Other Transaction agreement file. The DPC Principal Director agreed with the recommendation and stated that the DPC will update the OT Guide to ensure guidance adequately addresses requirements. Furthermore, the director stated that the DPC will ensure that the OT Guide requires that OT files contain sufficient documentation and rationale to explain major OT award decisions.

As of the date of this letter, the DPC had not implemented the above recommendations. In July 2023, the DPC updated the OUSD (A&S) OT Guide and was in the process of taking corrective action to reinforce the use of competition and ensuring that OT files contain sufficient documentation and rational to support OT award decisions. Once implemented, internal controls over OT awards related to the lack of documentation to support market research and documentation to support the rationale for major Government investment decisions should be improved. Therefore, we are not performing additional work or making additional recommendations at this time.

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