WORLD TRADE CENTER HEALTH PROGRAM: CDC SHOULD STRENGTHEN EFFORTS TO MONITOR AND EVALUATE CLINIC COMPLIANCE WITH CONTRACT TERMS

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Inspector General
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EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention did not monitor and evaluate World Trade Center Health Program clinic compliance with contract terms and conditions as required by Federal regulations.

WHY WE DID THIS REVIEW

The World Trade Center Health Program (WTCHP) was established in January 2011. The WTCHP is administered by the Centers for Disease Control and Prevention (CDC) through its National Institute for Occupational Safety and Health (NIOSH). Under the WTCHP, CDC’s Procurement and Grants Office (PGO) contracted with clinics to provide medical services and pharmacy benefits to eligible responders and survivors with health conditions related to the September 11, 2001, terrorist attacks on the World Trade Center. As of March 31, 2013, WTCHP medical service claims totaled $60,755,311, and pharmacy claims totaled $59,701,656.

PGO contracting officers (COs) are responsible for awarding and administering clinic contracts. NIOSH contracting officer representatives (CORs) serve as the COs’ “eyes and ears” by monitoring and evaluating clinic performance and reporting deviations from contract terms and conditions. The COs are responsible for determining the adequacy of clinic performance.

The objective of this review was to determine whether CDC’s PGO and NIOSH monitored and evaluated clinic compliance with contract terms and conditions, as required by Federal regulations.

BACKGROUND

The Federal Acquisition Regulation (FAR) establishes the basic requirements for contract administration by Federal agencies. The U.S. Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) provides additional requirements for contracts awarded and administered by HHS operating divisions. Contractor monitoring is performed jointly by the CO and the COR. The CO must ensure the contractor’s compliance with all the terms and conditions of the contract (HHSAR subpart 342.70). The COR monitors contractor performance and advises the CO about delivery and acceptance or rejection of deliverables and recommends necessary changes to the schedule of work or period of performance. Agencies must develop quality assurance surveillance plans (QASP) when acquiring services through performance-based service contracts. A QASP identifies contract conditions that require monitoring and describes the method of surveillance. Agencies must prepare interim evaluations of contractor performance for contracts with a period of performance, including options, exceeding 1 year.

In July 2011, CDC awarded WTCHP contracts, with four annual renewal options, to eight clinics in the New York/New Jersey metropolitan area. CDC exercised the first renewal option for all eight contracts in June 2012. WTCHP funds awarded to the clinics as of March 31, 2013, totaled approximately $57 million.
In conjunction with NIOSH, the PGO established the QASP that the CORs are to follow when monitoring WTCHP clinic performance. The QASP contains surveillance methods, including random monitoring and either periodic or 100-percent inspections, and requires the CORs to document all surveillance.

According to the clinics’ contracts, quarterly evaluations are to be completed jointly by the CORs and COs. The CORs are to enter the evaluations in the Contractor Performance Assessment Reporting System (CPARS), an online database for tracking Federal contractor performance. The finalized evaluations are made available to other Federal Government agency COs through the Past Performance Information Retrieval System (PPIRS) (FAR § 42.1503).

WHAT WE FOUND

The PGO and NIOSH did not monitor and evaluate clinic compliance with contract terms and conditions as required by Federal regulations. Specifically, the COs did not ensure that the CORs used the surveillance methodology established in the QASP to monitor clinic contract performance. In addition, neither the CORs nor the COs took timely or appropriate action when they learned of three instances of clinic contract noncompliance. Furthermore, the CORs’ and COs’ evaluations of contractor performance were not completed as required and were not always entered into the CPARS and the PPIRS.

These inadequacies occurred because the PGO and NIOSH did not (1) consider the QASP surveillance methodology to be mandatory or the QASP performance standards to be realistic or attainable for the clinics and (2) have standard operating procedures to ensure that required performance evaluations were conducted in a timely manner.

The PGO COs and other agency COs rely on monitoring and evaluation of contractors’ performance to make informed business decisions when awarding and renewing Federal contracts. Meaningful past-performance evaluations are critical to ensuring that the Federal Government does business with contractors that deliver quality goods and services on time and within budget.

WHAT WE RECOMMEND

We recommend that CDC:

- monitor clinics’ performance in accordance with contract terms,
- address clinics’ noncompliance with contract terms as required by HHSAR subpart 342.70, and
- follow FAR section 42.1503 by developing and implementing standard operating procedures for evaluating contract performance.
CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In written comments on our draft report, CDC concurred with our recommendations and described the actions that it has taken to address our recommendations. CDC also provided technical comments under separate cover. We addressed those comments as appropriate.
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INTRODUCTION

WHY WE DID THIS REVIEW

The World Trade Center Health Program (WTCHP) was established in January 2011 under the James Zadroga 9/11 Health and Compensation Act of 2010, P.L. No. 111-347 (Zadroga Act). The WTCHP is administered by the Centers for Disease Control and Prevention (CDC) through its National Institute for Occupational Safety and Health (NIOSH). Under the WTCHP, CDC’s Procurement and Grants Office (PGO) contracted with clinics to provide medical services and pharmacy benefits to eligible responders and survivors with health conditions related to the September 11, 2001, terrorist attacks on the WTC.

PGO contracting officers (COs) are responsible for awarding and administering clinic contracts. NIOSH contracting officer representatives (CORs) serve as the COs’ “eyes and ears” by monitoring and evaluating clinic performance and reporting deviations from contract terms and conditions. The COs are responsible for determining the adequacy of clinic performance. Our review focused on CDC’s efforts to monitor and evaluate clinic compliance with WTCHP contract terms and conditions.

OBJECTIVE

Our objective was to determine whether CDC’s PGO and NIOSH monitored and evaluated clinic compliance with contract terms and conditions, as required by Federal regulations.

BACKGROUND

Federal Contracting Requirements

The Federal Acquisition Regulation (FAR) establishes the basic requirements for contract administration by Federal agencies. The U.S. Department of Health and Human Services (HHS)

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1 Medical services are limited to initial health evaluations, monitoring, and treatment of World Trade Center (WTC)-related health conditions, including aerodigestive and musculoskeletal disorders as well as mental health conditions.

2 Responders are individuals who performed rescue, recovery, demolition, debris cleanup, or related services.

3 Survivors are individuals who lived, worked, or attended school, childcare, or adult daycare in the New York City WTC disaster area following the terrorist attacks of September 11, 2001. The Zadroga Act defines this area of Manhattan as being south of Houston Street and any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former WTC site.

4 Three COs were responsible for the clinic contracts during our audit period. The PGO appointed one NIOSH employee to act as the COR for the first year of the contracts and two other NIOSH employees to act as CORs for the second year of the contracts.

5 Section 3301(d) of the Zadroga Act requires that we review WTCHP expenditures to detect inappropriate billing and payment for services, as well as unreasonable administrative costs. However, when we began our fieldwork, insufficient medical services claims data were available to perform a thorough review because clinics had only recently begun generating claims. We are planning further work regarding section 3301(d) of the Zadroga Act.
Acquisition Regulation (HHSAR) provides additional requirements for contracts awarded and administered by HHS operating divisions. Selected requirements are summarized below.

Contract Monitoring

Contractor monitoring is an essential element of contract administration that is performed jointly by the CO and the COR (HHSAR § 342.7000). The CO must ensure the contractor’s compliance with all the terms and conditions of the contract and use program personnel for assistance and advice in monitoring the contractor’s performance. The CO must also ensure that monitoring conducted by the CORs conforms to the terms of the contract (HHSAR subpart 342.70). When a contractor fails to meet the terms of the contract, the CO must issue a written notice requiring the contractor to either correct the instance of noncompliance or provide an explanation within 10 days (HHSAR § 342.7002).

The COR is responsible for providing technical monitoring during contract performance and advising the CO on the delivery and acceptance or rejection of deliverables in accordance with contract terms, assessing contractor performance, and recommending necessary changes to the schedule of work and period of performance to accomplish the contract’s objectives (HHSAR § 342.7001).

Quality Assurance Surveillance Plans

Agencies must develop quality assurance surveillance plans (QASPs) when acquiring services through performance-based service contracts (FAR §§ 37.604, 46.103(a) and 46.401(a)). QASPs identify contract conditions that require monitoring and describe the methods of surveillance (FAR subpart 46.4).

Contractor Performance Evaluations

Agencies must prepare interim evaluations of contractor performance for contracts with a period of performance, including options, exceeding 1 year (FAR § 42.1502(a)). The evaluations must be submitted to an online database known as the Past Performance Information Retrieval System (PPIRS) in accordance with agency procedures (FAR § 42.1503).

World Trade Center Health Program

When the WTC buildings collapsed on September 11, 2001, nearly 3,000 people died, and an estimated 250,000 to 400,000 people who were visiting, living, working, and attending school nearby or responding to the attack were exposed to a mixture of dust, debris, smoke, and various chemicals. In the months that followed, thousands of people who returned to the area to live and work, as well as responders who were involved in site cleanup, were also exposed.

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6 A new rule, effective September 3, 2013, establishes contract evaluation criteria to be used by all Government agencies, as well as required elements of agency procedures for implementing contractor past-performance evaluations. See 78 Fed. Reg. 46783.
From fiscal years 2002 through 2010, Congress provided funding for health evaluations and diagnostic and treatment services to affected individuals through grants and cooperative agreements under the World Trade Center Medical Monitoring and Treatment Program (MMTP) and the World Trade Center Environmental Health Center Community Program (EHCCP). However, data collection for these programs did not provide sufficient detailed information to help identify ways to improve program effectiveness and oversight or reliably estimate future program costs.7

Congress passed the Zadroga Act to establish, among other things, greater accountability for administering the WTCHP. In response to the Zadroga Act’s requirement to provide for the uniform collection of claims data, CDC implemented a fee-for-service medical claims reimbursement process. The Zadroga Act funded the WTCHP for a 5-year period beginning July 1, 2011, with Federal funding capped at approximately $1.6 billion. As of March 31, 2013, approximately 64,000 individuals were enrolled in the WTCHP.

**World Trade Center Health Program Clinics**

In July 2011, CDC awarded WTCHP contracts, with four annual renewal options, to eight clinics in the New York/New Jersey metropolitan area.8 From July 1, 2011, to March 31, 2013, the eight clinics were awarded a total of $56,601,281 in WTCHP contract funds.

Under the contracts, the clinics were reimbursed for contract deliverables related to member services (e.g., conducting outreach activities and providing benefits counseling) and administrative services (e.g., reviewing medical service claims data for appropriateness and collecting and reporting monitoring and treatment data). CDC exercised the first renewal option for all eight contracts in June 2012.

**World Trade Center Health Program Claim Reimbursement Process**

At WTCHP clinics, physicians provide medical services and prescribe medication to eligible WTCHP responders and survivors. After clinic review and approval, the claims are submitted to Computer Sciences Corporation (CSC), a claims-processing intermediary under contract to CDC. After adjudication by CSC, claims are (1) denied, (2) held pending receipt of additional information, or (3) forwarded to National Governmental Services (NGS) for payment. NGS processes reimbursement of medical service and pharmacy claims using WTCHP funds disbursed by HHS’s Centers for Medicare & Medicaid Services (CMS).9 As of March 31, 2013, NGS paid WTCHP medical service claims totaling $60,755,311 and pharmacy claims totaling $59,701,656.

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7 MMTP and EHCCP data did not include information regarding responders’ health, specific services that responders received, and the cost of providing services to responders.

8 Some of the clinics offer services at more than one location in the New York/New Jersey metropolitan area.

9 Section 3306(14)(B) of the Zadroga Act prohibits CDC from paying WTCHP medical service claims.
World Trade Center Health Program Clinic Contract Monitoring

Quality Assurance Surveillance Plan

In conjunction with NIOSH, the PGO established the QASP that the CORs are to follow when monitoring WTCHP clinic performance. The QASP contains performance standards for 15 contract deliverables that require surveillance. Eight of the standards relate to administrative activities (e.g., checking providers’ licensing, handling member complaints, and conducting quality assurance audits). Five of the standards relate to medical service quality control activities (e.g., reviewing and approving medical service and pharmaceutical claims and ensuring that only WTCHP-related conditions are claimed). The remaining two standards relate to member service activities (i.e., updating member contact information and updating a program information Web site).

For each of the 15 standards, the QASP contains surveillance methods to be followed, including random monitoring and either periodic or 100-percent inspections. The QASP also contains a surveillance report template for use in documenting performance of surveillance and results. The CORs are required to document all surveillance, and if a clinic’s performance was unacceptable, the CORs are required to inform the CO and document the discussion.

Contractor Performance Evaluations

The clinic contracts specify that evaluations would be completed jointly by the CORs and the COs quarterly. The CORs are to enter the evaluations in the Contractor Performance Assessment Reporting System (CPARS), an online database for tracking Federal contractor performance. The COs are to review and approve the evaluations and then forward them to the clinics for comment. Final evaluations and clinic comments are made available to other Federal Government contracting officers through the PPIRS. PGO officials informed us that before deciding whether to renew a contract, a CO can review completed evaluations on the contractor in the PPIRS, including those completed by other Federal agencies.

HOW WE CONDUCTED THIS REVIEW

We reviewed CDC’s efforts to monitor and evaluate clinic contract performance during the period July 1, 2011, through March 31, 2013. Specifically, we visited clinics and interviewed clinic officials to identify any contract compliance issues. We also visited and interviewed PGO and NIOSH officials to determine the extent of CDC’s contract monitoring efforts. In addition, we reviewed the QASP developed by both the PGO and NIOSH, as well as clinic performance evaluations prepared by NIOSH.

In June 2013, NIOSH and PGO revised the QASP with the exercise of the second renewal option of the clinic contracts.

The PPIRS is a Web-enabled application that provides timely and pertinent contractor past-performance information to the Federal acquisition community for use in making source-selection decisions. The PPIRS assists acquisition officials by serving as the Federal Government’s single source for contractor past-performance data.
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.

The details of our audit scope and methodology are contained in Appendix A.

**FINDINGS**

The PGO and NIOSH did not monitor and evaluate clinic compliance with contract terms and conditions as required by Federal regulations. Specifically, the COs did not ensure that the CORs used the surveillance methodology established in the QASP to monitor clinic contract performance. In addition, neither the CORs nor the COs took timely or appropriate action when they learned of three instances of clinic contract noncompliance. Furthermore, the CORs’ and COs’ evaluations of contractor performance were not completed as required and were not always entered into the CPARS and the PPIRS.

These inadequacies occurred because the PGO and NIOSH did not (1) consider the QASP surveillance methodology to be mandatory or the QASP performance standards to be realistic or attainable for the clinics and (2) have standard operating procedures to ensure that required performance evaluations were conducted in a timely manner.

The PGO COs and other agency COs rely on monitoring and evaluation of contractors’ performance to make informed business decisions when awarding and renewing Federal contracts. Meaningful past-performance evaluations are critical to ensuring that the Federal Government does business with contractors that deliver quality goods and services on time and within budget.

**CONTRACTING OFFICERS AND CONTRACTING OFFICER REPRESENTATIVES DID NOT MONITOR THE CLINICS’ PERFORMANCE IN ACCORDANCE WITH CONTRACT TERMS**

Federal regulations require that contractor performance be monitored to ensure compliance with contract terms and conditions (HHSAR subpart 342.70). The COs are responsible for ensuring that the monitoring conforms to the terms of the contracts (HHSAR § 342.7001). The contracts outline a QASP containing performance standards for 15 contract deliverables that are to be surveyed through random monitoring and either periodic or 100-percent inspections. The CORs are responsible for monitoring clinic contract performance by using the QASP and documenting surveillance actions (HHSAR § 342.7001 and FAR § 46.401).

The COs did not ensure that the CORs used the surveillance methodology established in the QASP to monitor clinic contract performance. Rather than inspecting or randomly monitoring the 15 contract deliverables as required by the QASP, the CORs conducted frequent status meetings with clinic officials—either in-person or by telephone—and reviewed the clinics’ monthly progress reports on their activities and accomplishments. Although the CORs
maintained limited documentation related to these activities, they did not document that the monitoring performed addressed the deliverables outlined in the QASP.

PGO and NIOSH officials stated that they did not use the QASP because they did not consider the use of the QASP surveillance methodology to be mandatory. Additionally, the officials considered the QASP performance standards outlined in the contract to be unrealistic or unattainable for the clinics because the WTCHP was a new and evolving program.

**CONTRACTING OFFICERS AND CONTRACTING OFFICER REPRESENTATIVES DID NOT ADEQUATELY ADDRESS THE CLINICS’ NONCOMPLIANCE WITH CONTRACT TERMS**

The CO must ensure that contractor performance complies with contract terms and conditions (HHSAR § 342.7001(d)). Federal regulation requires that, when a clinic fails to meet the terms of its contract, the CO must issue a written notice requiring the clinic to either correct the instance of noncompliance or provide an explanation within 10 days (HHSAR § 342.7002). The COR is responsible for providing technical monitoring and recommending necessary changes to the contract to accomplish the contract objectives (HHSAR § 342.7001(c)).

We identified three instances of clinic contract noncompliance. The COs and the CORs had been holding ongoing meetings with the noncompliant clinics and learned of the instances of noncompliance; however, the COs did not issue written notices to the clinics directing them to take corrective action. Moreover, the CORs did not recommend changes to accomplish the contracts’ objectives. Consequently, clinics were noncompliant with key contract terms throughout our audit period and CDC did not receive all of the services for which it had contracted.

**Four Clinics Did Not Submit Medical Service Claims Within Required Timeframe**

Clinics are contractually required to submit claims data to CSC within 2 weeks of receipt from physicians. Four of the clinics did not comply with the 2-week requirement. Officials from the four clinics stated that before claims could be submitted, they had to review charges for accuracy and appropriateness, which they considered time consuming. Additionally, one clinic was required to seek reimbursement from WTCHP members’ other health insurers before billing the WTCHP.

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12 CDC stated that PGO and NIOSH recognized that the QASP was a tool used to conduct surveillance of clinics’ performance. However, CDC determined that the initial QASP inaccurately reflected the best approach for monitoring the clinics’ performance during the startup period of the contracts because of unanticipated challenges of starting up the WTCHP.

13 The clinic contracts were renewed in June 2013, and some of the contract terms were modified. We did not review the renewed contracts because they were renewed after our audit period.

14 The CO orally gave the clinic, which did not ensure that only WTC-related conditions were claimed, 30 days to submit a corrective action plan in September 2012.
One Clinic Did Not Ensure Only World Trade Center-Related Conditions Were Claimed

Clinics are contractually required to ensure that only WTC-related conditions are claimed for reimbursement under the WTCHP. One clinic did not submit any medical service claims for reimbursement until February 2012, when the clinic began submitting all claims for its members, whether WTC-related or not. The clinic continued to submit all claims through February 2013 and relied on CSC to identify and deny non-WTC-related claims. The clinic began to manually review and identify WTC-related clinic member claims on a monthly basis in March 2013. Only then did it identify and submit claims for WTC-related health conditions to CSC for reimbursement. Clinic officials stated that the clinic’s financial systems could not identify and segregate claims for WTC-related conditions, but they planned to manually review and resubmit claims for the period before March 2013.

Seven Clinics Did Not Review Pharmacy Claims

Section 3312(b)(4)(B) of the Zadroga Act allows for the coverage of medically necessary prescription drugs. Under the WTCHP, clinic physicians prescribe medications for members’ WTC-related health conditions. WTCHP members take these prescriptions to the pharmacies of their choice to be filled. Clinics are contractually required to review and approve all WTCHP prescriptions before the pharmacy fills them. The contract does not specify or require the Government to furnish a system or method by which prescriptions would be reviewed and approved. The contract does require the review to include matching the prescription to the WTC-related health condition for which the medication was prescribed. Pharmacy claims are adjudicated and submitted to NGS for payment by the WTCHP pharmacy benefits manager, Emdeon. As of March 31, 2013, paid pharmacy claims totaled $59,701,656.

Only one clinic developed a method to enable it to review and approve member prescriptions before they were filled by pharmacies during our audit period. The remaining seven clinics did not review and approve their members’ WTCHP prescriptions before they were filled. Officials from the seven clinics stated that they were unable to comply with this contract requirement for various reasons, including: (1) reviewing prescriptions would be time consuming; (2) other controls, such as a limited formulary, were in place; and (3) neither NIOSH nor the pharmacy benefits manager provided a method that would allow review and approval of prescriptions before their being filled.

CONTRACTING OFFICERS AND CONTRACTING OFFICER REPRESENTATIVES DID NOT COMPLETE EVALUATIONS OF CLINICS’ PAST PERFORMANCE AS REQUIRED

Past-performance evaluations demonstrate whether the contractor conformed to contract requirements, forecasted and controlled costs, adhered to the contract schedule, was reasonable and cooperative, had a record of good business ethics, and had a business-like concern for the interest of the customer.

Agencies must prepare interim evaluations of contractor performance for contracts with a period of performance, including options, exceeding 1 year (FAR § 42.1502(a)). According to the
clinic contracts, quarterly evaluations are to be completed jointly by the COs and the CORs. The evaluations must be completed in the CPARS and submitted to the PPIRS in accordance with agency procedures (FAR § 42.1503). PGO officials informed us that before deciding whether to renew a contract, a CO can review completed evaluations on the contractor in the PPIRS, including those completed by other agencies. Final evaluations and clinic comments are made available to other Government agency contracting officers through the PPIRS as records of contractor performance.

The COs and CORs did not complete clinic evaluations quarterly as required. As of March 31, 2013, each clinic should have had six performance evaluations. However, only two evaluations had been completed for each of the eight clinics covering varying performance periods. Fourteen of the 16 completed evaluations were entered into the CPARS; however, only 1 of the 16 was finalized and submitted to the PPIRS. Further, the completed evaluations included only the instance of noncompliance concerning one clinic’s inability to submit appropriate claims data and did not include the other two instances of contract noncompliance described above. The COs and the CORs stated that they did not include two of the instances of contract noncompliance in evaluations because they did not consider them significant enough to affect the contractors’ performance ratings. Nevertheless, CDC renewed the contracts without modifying them to address the clinics’ contract noncompliance.

During our audit period, CDC did not have any standard operating procedures for contractor performance evaluations. Additionally, the PGO did not grant the CORs access\textsuperscript{15} to clinic contracts in the CPARS at the start of the CORs’ appointments.

Without current contract performance evaluations, CDC did not have the information necessary to make adequate contracting decisions. Meaningful past-performance evaluations are critical to ensuring that the Federal Government does business with companies that deliver quality goods and services on time and within budget.

**RECOMMENDATIONS**

We recommend that CDC:

- monitor clinics’ performance in accordance with contract terms,
- address clinics’ noncompliance with contract terms as required by HHSAR subpart 342.70, and
- follow FAR section 42.1503 by developing and implementing standard operating procedures for evaluating contractor performance.

\textsuperscript{15} One COR was never granted access to his contracts in the CPARS, another COR’s access was delayed 10 months, and the third COR’s access was delayed 5 months.
CDC COMMENTS

In written comments on our draft report, CDC concurred with our recommendations and described the actions that it has taken to address our recommendations. CDC also provided technical comments under separate cover. We addressed those comments as appropriate.

CDC’s comments, except for technical comments, appear as Appendix B.
APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed PGO and NIOSH procedures for monitoring and evaluating clinics’ contract performance, as well as clinics’ compliance with the contract terms and conditions, during the period July 1, 2011, through March 31, 2013. We did not perform an overall assessment of the internal control structures of the PGO, NIOSH, or the clinics. Rather, we reviewed only the internal controls related to our objective.

We conducted fieldwork at PGO and NIOSH administrative offices in Pittsburgh, Pennsylvania, and Atlanta, Georgia, and at the eight clinics located throughout the New York/New Jersey metropolitan area during the period September 2011 through June 2013.

METHODOLOGY

To accomplish our objective, we:

- reviewed relevant Federal requirements;
- reviewed WTCHP contracts awarded to the clinics;
- held discussions with PGO officials to gain an understanding of the PGO’s role in awarding and renewing WTCHP contracts, as well as ensuring contractor compliance;
- held discussions with NIOSH officials and reviewed the QASP and COR clinic files to gain an understanding of NIOSH’s procedures for monitoring and evaluating clinics’ contract performance;
- interviewed officials at all eight clinics and reviewed the clinics’ written procedures to identify any contract compliance issues;
- reviewed NIOSH’s clinic performance evaluations to determine whether the contract compliance issues we identified were included; and
- discussed the results of our review with CDC 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: CDC COMMENTS

TO: Inspector General, U.S. Department of Health and Human Services
FROM: Director, Centers for Disease Control and Prevention
DATE: November 27, 2013

The Centers for Disease Control and Prevention (CDC) appreciates the opportunity to review and comment on the Office of Inspector General’s (OIG) draft report, “World Trade Center Health Program: CDC Should Strengthen Efforts to Monitor and Evaluate Clinic Compliance With Contract Terms.” Thank you for your review of this important program.

As stated in the draft report, the objective of this review was to determine whether CDC’s Procurement and Grants Office (PGO) and National Institute for Occupational Safety and Health (NIOSH) monitored and evaluated World Trade Center Health Program (WTCHP) clinic compliance with contract terms and conditions, as required by federal regulations. The draft report identified three findings regarding the improper monitoring and evaluation of clinic compliance and provided the following recommendations to address these findings:

OIG Recommendation: OIG recommends that CDC monitor clinics’ performance in accordance with contract terms.

CDC Response: CDC concurs with this recommendation and understands contractor monitoring is an essential element of contract administration that is performed jointly by the Contracting Officer (CO) and the Contracting Officer’s Representative (COR)—HHSAR 342.7000. PGO is aware of the requirement for a Quality Assurance Surveillance Plan (QASP) when acquiring services through performance-based service contracts and established a QASP for monitoring the WTCHP clinic performance.

The initial QASP measures were created as performance standards to be achieved by the contractors. However, due to early challenges of starting the new WTCHP and new requirements developed under the Zadroga Act, CDC realized that the initial contract QASP did not reflect the best approach for monitoring clinics’ performance during the early start-up period of the contracts. Priority was given to maintaining continuity of health care, as required by the Zadroga Act.
As a result of the Zadroga Act, NIOSH was required to solicit, contract, and stand up an entire health care system in an extremely short period of time (over a period of a few months). To comply with new requirements in the Zadroga Act, CDC awarded competitive cost plus fixed fee contracts to the clinical centers in support of the WTCHP. The clinical centers were unfamiliar with federal contracts and had to develop new institutional channels to process fee-for-service bills and administrative tracking systems to enable them to authorize services by a network of external providers rendering diagnostic and treatment services to program members. These issues created a significant learning curve for the clinical centers.

In addition, the Zadroga Act required clinical centers to adhere to uniform standards and submit uniform claims. After the work commenced, CDC realized that making the existing systems of the Clinical Center contractors conform to uniform standards was going to require more effort than anticipated. CDC held monthly status meetings between the CO, the COR, and the contractors to monitor the clinics' performance and address issues. NIOSH also held weekly clinical director and administration telephone meetings with the Clinical Center of Excellence (CCE), during which the COR addressed issues and worked with each CCE to resolve any perceived non-compliance issues. During this time, and in consideration of unanticipated start-up issues and challenges, it was determined that the QASP needed to be modified to better suit the requirements and capture changes to the measures and methods of surveillance. The CO and COR determined that the Clinical Center contractors should have been given a start-up period of one year before QASP measures were applied to give the Clinical Centers and the government time to become fully operational. Therefore, monitoring of contract performance focused on the contractors' efforts to modify their systems to achieve the uniform standards during the start-up period.

The CO worked with the CORs and the contractors to update the QASP, and the updated QASP was incorporated into the contract through a contract modification in April 2013. The CORs have conducted various site visits with each clinic for QASP reviews in November/December 2012, April 2013, and October/November 2013. The CO conducted field observation during the COR's site visits and confirmed that the QASP was being properly utilized for quality assurance. More robust documentation is now required for site visits. The CORs document and review the performance objectives that comprise the QASP requirements. The CORs, along with technical assistance from pharmacy and technical benefit experts and member services, review the performance measures and work with PGO to determine possible remedies, as needed. If any deficiencies are found, corrective action plans will be obtained from the contractors; these will be included in the file and monitored to ensure corrective action is taken.

**OIG Recommendation:** OIG recommends that CDC address clinics' non-compliance with contract terms, as required by the U.S. Department of Health and Human Services Acquisition Regulation subpart 342.70.

**CDC Response:** CDC concurs with this recommendation. OIG identified three instances of clinic contract non-compliance: (1) four clinics did not submit medical service claims within the required timeframe; (2) one clinic did not ensure that only World Trade Center-related conditions were claimed; and (3) seven clinics did not review pharmacy claims.
In each instance, PGO acted to ensure the correction of non-compliance issues. The COs and the CORs have been holding regular progress meetings with the clinics to discuss contract issues.

As a new, highly complex requirement, PGO and NIOSH faced many challenges during the start-up period of the contracts that required a full review of the contract statement of work and QASP. The full contract review identified issues with both the statement of work and the QASP. PGO and NIOSH worked to identify and address all critical issues before formally issuing contract modifications to revise the statement of work and QASP. Through a modification in April 2013, the QASP was revised to fit the different nuances of each clinic and incorporated into the contracts. A contract modification was also issued in June 2013 to revise the statement of work to adjust contract requirements to reflect needed changes that were identified during the start-up period. The three areas of non-compliance identified in the OIG report were addressed in these modifications.

**OIG Recommendation:** OIG recommends that CDC follow Federal Acquisition Regulation (FAR) 42.1503 by developing and implementing a standard operating procedure (SOP) for evaluating contract performance.

**CDC Response:** CDC concurs with this recommendation and has addressed this finding in an appropriate manner. Prior to receiving the draft report on October 24, 2013, PGO proactively developed an SOP, entitled “Contractor Performance Assessment Reporting,” to improve evaluation of contractor performance and ensure compliance with FAR 42.15. The SOP was issued on April 9, 2013, and all PGO acquisition staff received training on the SOP on April 9, 2013.

PGO's SOP codifies our policy to utilize the Contractor Performance Assessment Reporting System (CPARS) to electronically record evaluations of contractor performance and to submit past performance information into the Past Performance Information Retrieval System. The SOP also provides guidance regarding when interim and final CPARS reports should be completed.

All CDC contracts that require reporting of contractor performance information will be registered in CPARS within 14 days of award, and CPARS reports will be completed within 90 days of the end of the period of performance that is being evaluated. Contracts that were awarded prior to the issuance of the SOP, and not registered in CPARS at the time of award, will be registered within 14 days of exercising options or contract expiration.

The SOP includes a clause and provision to be included in all applicable contracts and solicitations. The clause and provision serve as notice to contractors of CDC's intent to use CPARS for recording and maintaining contractor performance evaluations. Contractors are also notified that information contained in the performance evaluations may be used by the U.S. Government for future source selections when past performance is an evaluation factor. This clause has been incorporated into the WTCHP contracts by contract modification.

CDC's Contracting Officer's Representative Appointment Letter was also revised to notify CORs of their duty to use CPARS to complete interim and final past performance assessments of contractor's performance, when required by FAR 42.15, as one of the terms and conditions of their appointment.
We appreciate your consideration of the comments contained in this memo as you develop the final report. We are happy to discuss any of these issues with you. Please direct any questions regarding these comments to Dr. Janean Lomax, OIG, CDC Liaison, at (404) 639-2809 or iggao@cdc.gov.

Thomas R. Frieden, MD, MPH