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Report to Congressional Committees

August 2017

WORLD TRADE CENTER HEALTH PROGRAM

Improved Oversight Needed to Ensure Clinics Fully Address Mandated Quality Assurance Elements

GAO-17-676

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GAO Highlights

Highlights of GAO-17-676, a report to congressional committees

Why GAO Did This Study

The WTC Health Program provides health care services to eligible responders and survivors of the September 11, 2001, attacks through eight clinics. NIOSH and clinics share responsibility for several program components. The James Zadroga 9/11 Health and Compensation Reauthorization Act, which extended the program to 2090, included a provision for GAO to examine three of these components—certification of conditions for treatment coverage, actions to ensure appropriate payments, and quality assurance. This report examines (1) the development and implementation of policies, procedures, and guidance for certifying health conditions, (2) actions taken to ensure appropriate payments, and (3) the development and implementation of a quality assurance program, including mandated elements. GAO reviewed relevant legal requirements, policies and procedures, and clinic contracts. GAO also interviewed NIOSH officials, clinics, and responder and survivor committees.

What GAO Recommends

GAO recommends that NIOSH (1) develop and implement procedures for review of clinic quality assurance plans, (2) develop guidance that specifies how mandated elements should be addressed in these plans, and (3) develop required uniform performance measures for mandated elements in quarterly audits. NIOSH agreed with GAO's recommendations.

View GAO-17-676. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Certifying health conditions: The National Institute for Occupational Safety and Health (NIOSH)—an agency within the Department of Health and Human Services that administers the World Trade Center (WTC) Health Program—has developed policies, procedures, and guidance necessary for Health Program clinics and NIOSH to certify enrollees' WTC-related health conditions as being eligible for treatment. These include instructions for submitting certification paperwork, medical guidelines, and thresholds for determining whether a condition is WTC-related, and specific condition-related guidance. Medical directors of the clinics—contracted to provide health services to enrollees—noted that the guidance was clear and helpful in making determinations.

Ensuring appropriate payments: WTC Health Program clinics have implemented procedures for reviewing medical claims to help ensure appropriate payments, and NIOSH has taken steps to ensure accuracy. Each clinic uses a different claims-processing system and reviews different types of claims information, such as a patient's enrollment status. NIOSH officials noted that establishing uniform claims-review standards for the clinics would require expensive technological upgrades or other significant resources. Instead, NIOSH officials say they rely on its claims-adjudication contractor to conduct a standardized review of all claims prior to payment. A 2014 external review found the adjudication contractor's claims-review process to be robust.

Implementing a quality assurance program: NIOSH has not ensured that clinics address mandated quality assurance elements, but indicates that recently allocated funding and a new strategic plan will enhance quality assurance. Clinics are required to develop quality assurance plans that address three elements mandated by law: ensuring adherence to monitoring and treatment protocols, appropriate referrals, and prompt communication of test results. NIOSH has not systematically reviewed the plans. GAO found that some of the clinics did not include all three mandated elements, and the extent to which the plans addressed each element varied. For example, plans for two clinics addressed adherence to either monitoring protocols or treatment protocols, but not both. NIOSH officials told us they recently used allocated funding to increase staff, which will help focus on quality assurance oversight, but they have not developed a systematic process to closely review the plans or provided guidance for clinics to help ensure consistency in their plans. Without this, there is a risk that clinics are not addressing mandated elements that may provide important information about the quality of care and identify any needed improvements.

NIOSH developed a tool for reviewing clinics' quarterly audit reports and shared it with them in 2015. However, the tool does not require clinics to evaluate and report on uniform performance measures for all three mandated elements. GAO reviewed clinics' audit reports for one quarter in fiscal year 2016 and found that most clinics did not report on measures or any other information for all three mandated elements. Until NIOSH develops and requires reporting on uniform clinic performance measures that includes all mandated elements, it will be difficult for the agency to systematically identify any deficiencies and make the necessary improvements.

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Abbreviations

CCE	Clinical Centers of Excellence
CDC	Centers for Disease Control and Prevention
HHS	Department of Health and Human Services
NPN	Nationwide Provider Network
NIOSH	National Institute for Occupational Safety and Health
PHSA	Public Health Service Act
PPM	Policy and Procedures Manual
QA	Quality Assurance
QASP	Quality Assurance Surveillance Plan
WTC	World Trade Center
WTC-3	World Trade Center-3 Certification Request Form
WTC Health Program	World Trade Center Health Program
Zadroga Act	James Zadroga 9/11 Health and Compensation Act of 2010
Zadroga Reauthorization Act	James Zadroga 9/11 Health and Compensation Reauthorization Act

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The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The September 11, 2001 attacks on the World Trade Center (WTC), the Pentagon, and over Shanksville, Pennsylvania caused great loss of life and directly affected the long-term physical and mental health of many exposed to the event. In particular, in the New York City area, the collapse of the WTC and the burning of adjacent buildings produced a dense dust and smoke cloud containing toxic compounds. Responders and survivors exposed to these and other hazards experienced a wide range of physical and emotional trauma following the attacks.[1]

In light of health problems experienced by responders and survivors following each of these September 11 attacks, Congress passed the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) which became law on January 2, 2011.[2] The act established the World Trade Center Health Program (WTC Health Program) to provide approximately $1.6 billion in federal funding for medical monitoring and treatment benefits to responders and survivors enrolled in the program

[1]According to the Zadroga Act, responders include individuals who performed rescue, recovery, or other related services at any of the three disaster sites. Survivors are individuals who are not responders but were affected by the attack on the WTC and meet other criteria related to being in the New York City disaster area, such as being in the dust or dust cloud on September 11, 2001.

[2]Pub. L. No. 111-347, 124 Stat. 3623.

through fiscal year 2016.[3] The WTC Health Program was re-authorized under the James Zadroga 9/11 Health and Compensation Reauthorization Act (Zadroga Reauthorization Act) on December 18, 2015.[4]

The Zadroga Act provides a framework for enrolling responders and survivors in the WTC Health Program, evaluating health conditions, and certifying those conditions as being covered by the program to provide needed treatment.[5] As part of this framework, the act establishes a list of covered conditions for which treatment may be provided to an enrollee if the program determines that the condition is related to exposure to the September 11 attacks. The list includes certain aerodigestive disorders (such as asthma), musculoskeletal disorders, mental health conditions, and certain types of cancer.[6] (See app. I for the complete WTC Health Program list of covered conditions.) Screening, monitoring, and treatment of health conditions for WTC Health Program enrollees who reside in the New York City area are provided through contracts with seven New York metropolitan area clinics determined to meet certain requirements, known as Clinical Centers of Excellence (CCE), and for those who reside outside of the New York area through a contract with a nationwide network of providers, known as the Nationwide Provider Network (NPN).[7] The program is administered by the Centers for Disease Control and

[3]Pub. L. No. 111-347, tit. I, 124 Stat. 3624 (adding Title XXXIII to the Public Health Service Act (PHSA)) (codified at 42 U.S.C. §§ 300mm et seq.). In this report we refer to WTC Health Program responders and survivors collectively as enrollees.

[4]Pub. L. No. 114-113, div. O, tit. III, 129 Stat 2242, 2996.

[5]GAO has done previous work related to the implementation of the WTC Health Program in response to the Zadroga Act. For example, see GAO, *World Trade Center Health Program: Approach Used to Add Cancers to List of Covered Conditions Was Reasonable, but Could Be Improved,* GAO-14-606 (Washington, D.C.: July 23, 2014); and GAO, *World Trade Center Health Program: Potential Effects of Implementation Options*, GAO-11-735R (Washington, D.C.: Aug. 4, 2011).

[6]Since the passage of the Zadroga Act, additional covered conditions have been added, including 60 types of cancer such as esophageal and thyroid cancer. For more information on the addition of cancer coverage, see GAO-14-606.

[7]Throughout this report, unless otherwise noted, we refer to the seven CCEs and the NPN collectively as the eight clinics or, simply, the clinics. As of May 2017, the contracted seven CCEs were 1) Icahn School of Medicine at Mount Sinai, 2) New York University School of Medicine, 3) Northwell Health, 4) State University of New York (Stony Brook), 5) Rutgers University, 6) the Fire Department of New York City, and the 7) New York City Health and Hospitals Corporation. The NPN is operated by Logistics Health, Inc., which subcontracts with health systems, such as United Healthcare.

Prevention (CDC), an agency within the Department of Health and Human Services (HHS); the director of CDC's National Institute for Occupational Safety and Health (NIOSH) also serves as the Administrator of the WTC Health Program and NIOSH has responsibility for program management and oversight.

In addition to providing the framework for medical services, both the Zadroga Act and the clinic contracts outline oversight and administrative responsibilities. As part of the oversight of medical services, the Zadroga Act requires that NIOSH, working with the CCEs, develop and implement a quality assurance (QA) program that includes certain mandated elements, such as ensuring adherence to monitoring and treatment protocols. NIOSH also included the NPN in this required QA program.[8] Additionally, clinic contracts and program policy require that clinics review medical claims for accuracy prior to submission to the program's claims adjudication contractor to determine whether the claims should be paid.

The Zadroga Reauthorization Act effectively created a 75-year health plan for the responders and survivors of the September 11 attacks by extending medical coverage for enrollees through 2090. The Act appropriates a total of $4.7 billion in yearly increments through fiscal year 2025 and then provides an annual baseline appropriation of $570 million—adjusted yearly by the increase in the Consumer Price Index for all urban consumers—through 2090. The act included a provision for us to examine the procedures for certifying health conditions to obtain treatment coverage, benefit coordination, claims payment processes, and the QA program.

In this report, we address the following questions:

1. To what extent has NIOSH developed and implemented policies, procedures, and guidance necessary for certifications of health conditions covered by the WTC Health Program?
2. What actions has NIOSH taken to ensure appropriate payment of WTC Health Program claims, including coordinating benefits with workers' compensation or other health coverage?

[8]See Pub. L. No. 111-347, 124 Stat. 3625 (adding PHSA § 3301(e)) (codified at 42 U.S.C. § 300mm(e)).

3. To what extent has NIOSH developed and implemented a QA program for the WTC Health Program, including the mandated QA program elements?

To determine the extent to which NIOSH has developed and implemented policies, procedures, and guidance for certification of health conditions for the WTC Health Program, we collected and reviewed certification policies, procedures, and medical guidelines developed and implemented by NIOSH and the eight clinics (the seven CCEs and the NPN). We examined these policies, procedures and guidance to understand how WTC-related conditions (those on the WTC Health Program's list of covered conditions) and medically associated conditions (which are covered conditions caused by the progression or treatment of underlying WTC-related conditions but are not on the list) are certified. We interviewed NIOSH medical officers and the eight clinic medical directors, with a specific focus on the development and implementation of certification guidance and procedures. We discussed the certification process with officials from CSRA—the program's claims adjudication contractor responsible for conducting preliminary reviews of the certification paperwork and adjudicating claims to determine whether they should be paid.[9] We also discussed the process with officials from the WTC Responders and Survivors Steering Committees and a 9/11 advocacy organization to understand the implementation of the certification process.[10] We compared this collected information to the Zadroga Act requirements for certification as well as sections on certification in the WTC Health Program Policy and Procedures Manual

[9]CSRA Inc.—formed when the public sector businesses of Computer Sciences Corporation (the WTC Health Program's former contractor) and SRA International merged—provides IT solutions and professional services to U.S. government agencies and programs. For example, CSRA processes benefit claims and payments for veterans' health care and the Medicaid program.

[10]The WTC Responders Steering Committee and the WTC Survivors Steering Committee were created to play a consultation role on the administration of the WTC Health Program and to represent and provide input from program stakeholders. The Zadroga Act requires that the Administrator of the WTC Health Program consult with these committees to receive input from affected stakeholders, and facilitate the coordination of monitoring, initial health evaluations, and treatment programs for responders and eligible survivors. See Pub. L. No. 111-347, 124 Stat. 3627 (adding PHSA § 3302) (pertinent provision codified at 42 U.S.C. § 300mm-1(b)).

We interviewed an official from 9/11 Health Watch, an advocacy organization the mission of which includes tracking the implementation of the Zadroga Act, monitoring the health services provided by clinics, and advocating for Zadroga Act re-authorization.

(PPM) used and maintained by NIOSH to establish policies for all aspects of the program.

To identify actions that the WTC Health Program has taken to ensure appropriate payment of claims, including coordinating benefits, we collected and reviewed policies, procedures, and guidelines developed and implemented for the coordination of health service coverage, and submission and payment of claims. We interviewed officials from NIOSH, the clinics, the WTC Responders and Survivors Steering Committees, and the 9/11 advocacy organization to understand how the program relays benefit information to its participants and what challenges, if any, exist for the participants related to this process. We interviewed the same organizations, as well as CSRA, to identify the amount in claims paid by sources of coverage (such as private health insurance), as well as to understand the claims process and any controls in place for this process to ensure appropriate payment. To help identify such controls, we reviewed an HHS Office of Inspector General report on WTC Health Program claims controls, as well as an external report funded by NIOSH that addressed the safeguards in place to prevent fraud, waste, and abuse.[11] We compared all of this information to requirements on payment in the Zadroga Act, the PPM, and the contracts between NIOSH and the clinics.

To determine the extent to which NIOSH has developed and implemented a WTC Health Program QA program, we collected and reviewed QA plans developed by the eight clinics under the 2011-2017 CCE contracts and the 2010-2016 NPN contract. We also reviewed NIOSH's instructions and internal tools related to the clinics' contractually required quarterly audits and analyzed the results of these audits for one reporting quarter. Our review of the clinics' QA plans and quarterly audit reports focused on

[11]The HHS Office of Inspector General report examined whether CDC's internal controls were effective in ensuring that claims for WTC Health Program pharmacy benefits and medical services were paid in accordance with federal requirements. See Department of Health and Human Services, Office of Inspector General, *Not All Internal Controls Implemented by CDC Were Effective in Ensuring That World Trade Center Health Program Pharmacy and Medical Claims Were Paid According to Federal Requirements*, A-02-14-02008 (Washington, D.C.: Sept. 2016). The external report was based on a review conducted under a NIOSH task order to examine the program's efforts to detect and prevent fraud, waste, and abuse and to recommend technologies to improve such detection; see Data Networks Corporation, *NIOSH World Trade Center Health Program (WTC Health Program) Fraud, Waste, and Abuse Support*, (Reston, Va.: Aug. 20, 2014), 19-20.

whether they addressed the mandated Zadroga Act QA elements.[12] We interviewed officials from NIOSH and the clinics, the WTC Responders and Survivors Steering Committees, and the same 9/11 advocacy organization as previously indicated. We compared the information collected about the development and implementation of the WTC Health Program's QA program to the QA elements mandated by the Zadroga Act, clinic contracts, the WTC Health Program PPM, and standards for internal controls in the federal government.[13]

We conducted this performance audit from September 2016 to August 2017 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.

Background

The Zadroga Act established the WTC Health Program to provide benefits for medical monitoring and treatment services through contracted clinics to responders and survivors of the September 11 attacks. As of December 2016, there were 77,006 enrollees, including responders from the WTC, Pentagon, and Shanksville, Pennsylvania, disaster sites; and survivors from the WTC disaster site.[14]

[12]Additional contractual QA elements (not explicitly required in the act, and, thus, not in the scope of our review) include measuring, monitoring, and increasing patient satisfaction; continuous process improvement; and providing benefits counseling, among other things.

[13]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014). GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: Nov. 1, 1999). Internal control is a process affected by an entity's management, oversight body, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

[14]Under the Zadroga Act, responders include individuals who performed rescue, recovery, demolition, debris cleanup, law enforcement, or other related services at any of the three disaster sites. Survivors include individuals who are not responders, but who were, for example, (1) present on September 11, 2001, in the New York City disaster area in the dust or dust cloud, or (2) who worked, resided, or attended school, child care, or adult day care in the New York City disaster area for at least 4 days during the 4-month period after the attacks, or at least 30 days during the 11-month period after the attacks. The New York City disaster area is the area of Manhattan south of Houston Street, including the WTC attack site, and any block in Brooklyn within a 1.5 mile radius of the WTC attack site.

WTC Health Program Structure

The initial performance period of the CCE contracts was from July 2011 to June 2016, with an extension through December 2016, and, according to NIOSH officials, a transition period that ran through March 2017. NIOSH recently awarded CCE contracts under a new solicitation that took effect in April 2017 and will run through 2022. The NPN was funded under contract from September 2010 through September 2015 and NIOSH officials noted that they used a 6-month extension and a 3-month transition of services clause to carry the original contract through June 30, 2016. A second contract was awarded to the same institution and went into effect in July 2016 under a new solicitation and will run through 2020. NIOSH contracts with CSRA to assist with the certification process and adjudicate claims to determine whether they should be paid. CSRA's current contract started in December 2016 and runs through May 2017, with options to extend the contract until May 2021.[15] Finally, NIOSH officials noted that they have an interagency agreement with the Centers for Medicare and Medicaid Services to process payments for WTC Health Program claims.

Enrollment Process

Responders and survivors are eligible to enroll in the WTC Health Program based on one of three requirements: that they (1) were previously enrolled for monitoring and treatment services that were in place as of January 2, 2011, prior to the establishment of the WTC Health Program; (2) meet Zadroga Act enrollment eligibility requirements which, for responders, are based on performing certain activities at specified sites within specified date ranges, and, for survivors, are based on being in the New York City disaster area dust cloud on September 11, 2001, or on time spent living, working, or other activities in the New York City disaster area within a specified date range; or (3) meet modified eligibility

[15]According to NIOSH, CSRA held the contract for the WTC Health Program until November 30, 2016. On December 1, 2016, the new Health Program Support Contract went into effect with Karna LLC as the prime contractor with options to extend the contract until May 31, 2021. CSRA is subcontracted by Karna to continue providing services to the program.

criteria as determined by the program.[16] Further, survivors need to have symptoms of a WTC-related condition to be eligible for enrollment, but this requirement does not apply to responders. Once enrolled, responders are eligible for ongoing medical monitoring regardless of whether they have any symptoms of a WTC-related condition.

Certification of Health Conditions for Treatment

All responders and survivors must have their conditions certified by NIOSH to obtain treatment coverage. An enrolled responder is automatically eligible to receive medical monitoring from a WTC Health Program clinic, and if through one of these monitoring exams a physician determines that the responder has a WTC-related condition or medically associated condition (a condition that results from the progression or treatment of a covered health condition and may itself be eligible to be certified for treatment coverage), the physician can apply to have that condition certified to receive treatment coverage.[17]

Survivors who are enrolled in the program are not, however, automatically eligible for monitoring. An enrolled survivor may receive a one-time initial health evaluation related to a WTC-related condition for which they have symptoms. If a physician determines that the survivor has a WTC-related condition, the physician can then apply to have that condition certified for treatment. Only if certified can the survivor receive both treatment and monitoring from the program.

Under the Zadroga Act, certain criteria must be met to be eligible for certification, regardless of whether an enrollee is a responder or survivor.

[16]Prior to the WTC Health Program, Congress passed appropriations to provide limited health screening and treatment services to persons involved in rescue, recovery, and cleanup operations around the former site of the WTC. This program was known as the WTC Medical Monitoring and Treatment Program. For more information, see Congressional Research Service, *Comparison of the World Trade Center Medical Monitoring and Treatment Program and the World Trade Center Health Program Created by Title I of P.L. 111-347, the James Zadroga 9/11 Health and Compensation Act of 2010*, R41292 (Washington D.C.: Jan. 25, 2011). Additionally, NIOSH officials noted that survivors were also covered prior to the WTC Health Program through the WTC Environmental Health Center Community Program.

[17]For example, a medically associated condition might be: a responder who is receiving treatment for lung disease experiences significant weight gain as a side effect of the lung medication. The weight gain has resulted in a diagnosis of diabetes and depression. Since the responder had no previous history of diabetes or depression prior to the lung disease diagnosis and certification, these two new health conditions may be eligible for certification as medically associated conditions caused by the treatment of the original lung disease.

Specifically, a WTC Health Program physician must determine that (1) the condition for which the enrollee seeks coverage is on a list of covered conditions; and (2) exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11 attacks is "substantially likely to be a significant factor in aggravating, contributing to, or causing" the condition.[18] NIOSH is responsible for reviewing a physician's determination to provide a certification that allows for the program to cover treatment for the enrollee's condition.

Payment for Services Provided to Enrollees

The WTC Health Program covers enrollees' initial health evaluations, monitoring visits, and treatment services without any deductibles, copayments, or other costs to enrollees. Although the Zadroga Act generally provides that the WTC Health Program is to be the primary payer for these health services, the act establishes the program as a secondary payer in certain circumstances. The WTC Health Program is a secondary payer when an enrollee has (1) a covered condition that is work related and the enrollee has filed an applicable workers' compensation claim or (2) a covered condition that is not work related and the enrollee is covered by a public or private health insurance plan.[19] In addition, the Zadroga Act specifies that as part of the process for payment or reimbursement, NIOSH must review claims to determine if treatment is medically necessary and in accordance with the program's treatment protocols.

According to NIOSH and CSRA, the vast majority of claims are ultimately paid by the WTC Health Program. CSRA reported that, in fiscal year 2016, for example, the program paid approximately $182 million in claims; of this amount, $6.1 million was recouped from workers' compensation, $1.8 million was covered by private insurance, and approximately $0.4 million was covered by public insurance.

[18]Pub. L. No. 111-347, 124 Stat. 3639, 3652 (adding PHSA §§ 3312 and 3322) (codified at 42 U.S.C. §§ 300mm-22 and 300mm-32). In this report we refer to exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11 attacks as "September 11 exposure."

[19]Pub. L. No. 111-347, 124 Stat. 3653 (adding PHSA § 3331) (codified to 42 U.S.C. § 300mm-41). The worker's compensation exception does not apply when responders are covered under a workers' compensation plan administered by New York City.

Quality Assurance

The Zadroga Act mandates that NIOSH and clinics work together to develop a QA program for health services that includes three specific elements:

- ensuring adherence to monitoring and treatment protocols;
- ensuring appropriate diagnostic and treatment referrals for participants; and
- verifying prompt communication of test results to participants.[20]

Through its contracts, NIOSH requires that the clinics implement certain QA activities. Specifically, each clinic is required to develop and document a "QA plan" that includes the procedures it will use to monitor and improve certain services and must submit the plan to NIOSH for approval. Importantly, a clinic's QA plan must also include how it will address the three elements mandated in the Zadroga Act. The PPM specifies that NIOSH must review and approve these plans to ensure both consistency among them and alignment with program goals and objectives.

Another QA activity required by the contracts is an internal QA audit that each clinic must conduct at a minimum of every quarter, the results of which must be provided to NIOSH. The contracts require these quarterly audits to include specific components, such as a medical management review to ensure medical practice guidelines are being followed by the clinics, and a medical records review to determine whether appropriate procedures are being followed for collecting and maintaining medical records.[21]

[20]See Pub. L. No. 111-347, 124 Stat. 3625 (adding PHSA § 3301(e)) (codified at 42 U.S.C. § 300mm(e)).

[21]In addition to medical management reviews and medical records review components, the clinics are required to address the following components in their quarterly audits: "targeted health care compliance" to evaluate the adequacy of the clinics' procedures for ensuring that only approved health services are provided by the program; "claims history" to identify any irregularities in claims; and "personnel training" to ensure proper training.

NIOSH Has Developed Policies, Procedures, and Guidance Necessary for Certification of WTC Health Conditions

NIOSH has developed the policies, procedures, and guidance necessary for implementing the certification process across the clinics. The Zadroga Act outlines a framework for the certification process, which begins when a WTC Health Program physician examines an enrollee and makes a determination regarding whether the enrollee has a health condition covered by the program and that the enrollee's September 11 exposure is related to the enrollee's health condition. NIOSH has implemented a number of policies, procedures, and guidance to help physicians and program officials make determination and certification decisions, such as standardized forms, required medical information, and condition-specific medical guidance. Clinic, steering committee, and advocacy group officials have pointed to some potential certification challenges in the future, and NIOSH has taken steps to address many of them.

NIOSH policies and procedures for certification. NIOSH has built on the framework for certification established by the Zadroga Act by developing detailed policies and procedures necessary for certifying conditions as described in the PPM. For example, NIOSH has required the use of the World Trade Center-3 (WTC-3) form as the standard document to be completed by the WTC Health Program physician when requesting certification. (See app. II for the WTC-3 form). The form must contain a medical narrative that links exposure from the September 11 attacks to the health condition, diagnostic codes for the condition for which the physician is requesting certification, and identifying information for the enrollee and examining physician.

NIOSH also outlines in the PPM some of the information that should be included in the medical narrative of the WTC-3 form, including information about exposure on September 11, time-linked emergence of health symptoms, and any relevant data that are available from monitoring or screening exams. All WTC-3 forms must include a signed affirmative statement from the physician that the enrollee's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11 terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition or mental health condition. If the physician is unable to make an affirmative finding, then certification cannot be submitted or considered by NIOSH.

Additionally, NIOSH also has documented in the PPM the certification procedures for medically associated conditions—those conditions that result from the treatment or progression of a WTC-related health

condition. While the WTC-3 form is still used, NIOSH may require additional information for certification, including the use of published peer-reviewed literature to establish that the medically-associated health condition is the direct result of treatment or progression of a certified WTC-related health condition.

NIOSH medical guidance for certification. To help WTC Health Program physicians submit the proper paperwork, NIOSH has developed and distributed guidance for completing the WTC-3 form. This guidance includes instructions for completing the WTC-3 form; reasonable practice examples, such as medical narrative examples for various conditions; and optional assessment forms (e.g. an exposure form for psychological conditions that describes what the enrollee witnessed during the September 11 attacks, among other things, which can assist with determining a mental health diagnosis). Additionally, NIOSH has developed and distributed separate medical guidance to assist physicians and NIOSH officials with decisions about whether an enrollee has a condition that is eligible for certification. For example:

- **Exposure duration minimums for specific sites:** These requirements use location, intensity, duration and "exposure tiers" to help determine whether exposure was a significant factor in causing the health condition. For example, a "Tier 1" exposure rating would require a participant to be conducting search and rescue at the World Trade Center site from September 11 to September 14, 2001 for a minimum of 4 hours.
- **Time intervals for new onset of symptoms:** These requirements are used to provide the maximum amount of time between exposure and the onset of new aerodigestive disorders. For example, asthma has a 5-year limit for the new onset of symptoms, which is measured from the last date of exposure to the September 11 attacks. Consequently, if an enrollee's symptoms appear after 5 years from the last day of exposure, the enrollee is not eligible for certification for that condition.
- **Minimum latency requirements for covered cancers:** NIOSH has developed minimum latency requirements that must be met before a cancer condition can be certified. Thyroid cancer, for example, has a latency period of 2.5 years. Therefore, the earliest acceptable date for a WTC Health Program thyroid cancer certification is March 11, 2004 (assuming an exposure date of September 11, 2001).
- **Condition-specific guidance:** NIOSH has also developed guidance for specific categories of conditions to help determine whether the

condition is eligible for certification. For example, for musculoskeletal disorders, physicians and NIOSH officials must determine, among other things, that the condition (1) is chronic and recurrent; (2) was caused by heavy lifting or repetitive strain; (3) was treated on or before September 11, 2003; and (4) occurred during rescue and recovery in the New York City disaster area in the aftermath of the September 11 terrorist attacks.

All eight clinic medical directors we interviewed noted that the guidance from NIOSH to assist with the implementation of the certification process has been clear, useful, and specific. One clinic medical director said that NIOSH has done a good job of structuring its guidance, especially for cancer certification, and the guidance the clinic has received has been clear. Another clinic medical director commented that NIOSH has been very communicative and has obtained feedback from the clinics as it developed the certification process and guidance. Additionally, an official from the WTC Responders Steering Committee noted that, while it took some time to implement a formal certification process, the process is working very well. The clinic medical directors we interviewed also noted that they interact with NIOSH on a regular basis, including through weekly calls and discussions with NIOSH medical officers regarding certification issues and questions. One clinic staff member noted that the clinic has open access to NIOSH officials, and that any issues that may arise regarding the certification process are resolved quickly.

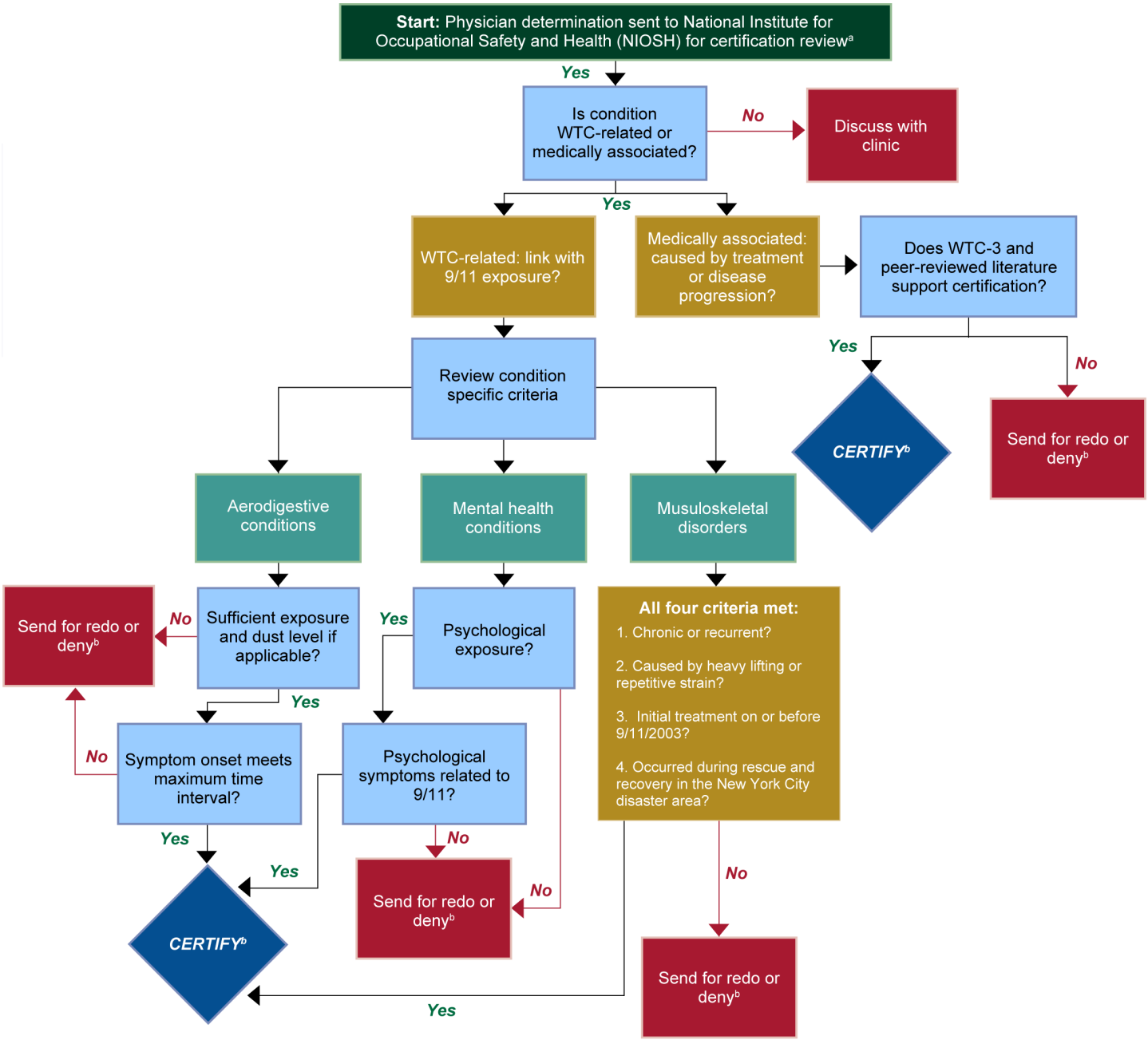
NIOSH procedures for reviewing certification of requests. NIOSH has developed procedures for the review of certification requests made using the policies, procedures, and medical guidance provided to the clinics. Physicians who determine that an enrollee has a covered condition make a request for certification by submitting the WTC-3 paperwork to CSRA. CSRA reviews the physician's paperwork for completeness, including ensuring that the individual is properly enrolled in the program, the medical narrative is present, and the physician has signed the WTC-3 form. If the paperwork is complete, CSRA then forwards it to NIOSH. CSRA forwards all certification paperwork once a week.

Once NIOSH receives the certification paperwork, it evaluates the request based on the WTC-3 information, program policies in the PPM, and program medical guidance to certify that the condition is on the WTC Health Program's list of covered conditions or is a medically associated condition and that the enrollee's exposure was substantially likely to be a significant factor in aggravating, contributing to, or causing the condition. After this review, NIOSH can make one of three decisions for each health

condition covered by the request: (1) the health condition is certified, enabling the enrollee to receive treatment for the condition; (2) the health condition is denied certification, which gives the enrollee the right to request an appeal of the denial decision; or (3) the request is suspended and categorized by NIOSH as a “re-do” pending receipt of additional information about the request from the physician submitting the request.[22] (See fig. 1 for an overview of the certification review process.)

[22]The WTC Health Program allows physicians to request treatment pending completion of the certification review. This must be specifically requested by a clinic physician to support the timely institution of therapy and continuity of care while a certification request is being reviewed.

Figure 1: Process for World Trade Center (WTC) Health Program Reviews of Non-Cancer Certification Requests for Treatment Coverage



Source: GAO graphic based on NIOSH document. | GAO-17-676

Note: NIOSH administers the WTC Health Program.

[a]A physician who determines that an enrollee has a covered condition makes a request for certification by submitting the paperwork to CSRA (the program's adjudication contractor). Before CSRA forwards the paperwork to NIOSH for certification review, CSRA reviews the physician's paperwork for completeness by, for example, ensuring that the individual is properly enrolled in the program, the medical narrative is present, and the physician has signed the paperwork.

[b]NIOSH sends its decision to CSRA. CSRA then forwards that decision to the clinic and the enrollee.

In some instances, NIOSH uses medical expertise to make certification decisions on a case-by-case basis. For example, NIOSH officials noted that certifications related to mental health conditions are complicated because they are often linked to other WTC-related health conditions. NIOSH officials stated that it would be challenging to write a comprehensive policy to address every mental health case, so certification decisions related to mental health are often made on a consensus basis by NIOSH's medical officers. Additionally, certain medically associated conditions are evaluated and certified on a case-by-case basis, especially if they are conditions that the program has not previously approved.[23]

Although NIOSH has the ability to deny certification requests, such denials are not common. According to NIOSH officials, from July 2011 through mid-October 2016, there were 281 WTC-related condition denials and 27 medically associated condition denials. For comparison, in the 12 month period from January 1, 2016 to December 31, 2016, more than 20,000 enrollees had a medical exam to determine and certify a health condition. Some of the denial reasons cited by NIOSH officials include (1) the condition was not covered by the program; (2) the enrollee had insufficient exposure to claim treatment for the condition; and (3) the condition does not meet latency requirements, such as those for cancer. NIOSH officials attributed the low denial rate to the medical guidance that the program has implemented, as well as the communication between NIOSH and the clinics on certification issues.

Future certification challenges. Clinic medical directors, steering committee officials, and an official from the 9/11 advocacy organization we interviewed noted that the program may face certification challenges

[23]The WTC Health Program developed a codebook that contains all of the diagnosis and procedure codes that are available to enrollees. The codebook aligns with all of the WTC-related conditions that are listed in the Zadroga Act, and the diagnosis and procedures included in the codebook limit what treatments can be provided to enrollees based on their certification. The program has a process for requesting and approving additions to the codebook and these requests are reviewed by NIOSH for medical appropriateness and consistency with medical evidence, among other things.

in the future as enrollees (including children) continue to age; the program moves further in time from the September 11 attacks; non-covered conditions, such as auto-immune diseases, become more prevalent; and mental health conditions continue to affect enrollees. NIOSH officials noted they are taking steps to begin preparing for these future challenges. They commented that they have discussed the aging participant population with WTC Responders and Survivors Steering Committees, clinics, and program scientific and technical advisors. They have also recently created a Scientific Forum to assess areas of emerging health concerns within the program's aging population. Further, since 2014, the agency has convened a monthly mental health forum to discuss challenges related to mental health conditions. NIOSH reiterated that most mental health cases, not just cases related to affected children who are now being treated as adults, require the expert, clinical judgement of a physician or psychiatric specialist to determine if such a condition is related to WTC exposure. According to the agency, other challenges are addressed through current program policies and procedures such as the process by which interested parties may petition for the addition of health conditions to the list of WTC-related health conditions.[24] For example, the program has received six petitions to add various autoimmune diseases to the list of covered conditions and in each case determined that insufficient evidence existed to add these health conditions to the list at this time.

To Help Ensure Appropriate Payments, NIOSH Has Taken Steps to Coordinate Benefits and Review the Accuracy of Claims

NIOSH has taken steps to coordinate benefits by requiring that clinics help enrollees determine their eligibility and apply for different sources of coverage. NIOSH is also in the process of developing additional tools to assist with the coordination of benefits. To help ensure appropriate payments for health services, NIOSH requires that the clinics review claims for medical necessity. Moreover, the program's adjudication contractor also has implemented procedures to help ensure appropriate payments, such as procedures for reviewing the accuracy of all claims.

[24]See Pub. L. No. 111-347, 124 Stat. 3642 (adding PHSA § 3312(a)(6)(B)) (codified at 42 U.S.C. § 300mm-22(a)(6)(B)).

Clinics Have Procedures for Coordinating Benefits by Helping Enrollees Determine and Apply for Sources of Coverage and NIOSH Is Developing Additional Tools to Assist with These Efforts

The Zadroga Act requires that NIOSH enter into contracts with the clinics to, among other things, coordinate and assist enrollees with applications for workers' compensation and other programs that may provide additional benefits. Specifically, NIOSH is required to (1) provide counseling for benefits for WTC-related health conditions that may be available under workers' compensation or other benefit programs for work related injuries or illnesses, health insurance, disability insurance, or other insurance plans or through public or private social service agencies; and (2) assist eligible individuals in applying for such benefits.[25] Staff from the seven CCEs told us that various staff assist enrollees with health benefits or coverage during a variety of patient encounters, such as during pre-exam telephone interviews and initial exams.

All of the clinics have documented their benefit coordination procedures in their operations manuals. These cover who is responsible for providing benefits counseling, when counseling occurs, what topics are covered as part of this counseling, and whether clinics must help enrollees apply for certain sources of coverage. For example,

- one clinic requires that a social worker discuss workers' compensation, health insurance, and social service assistance prior to and at an enrollee's first monitoring visit, as well as during all of the enrollee's subsequent treatment-related appointments.
- all eight clinics require that benefits counselors or case managers coordinate or provide benefits counseling.
- at three of the clinics, physicians, nurses, or other health provider staff may also provide counseling.
- all of the clinics also require that benefits counseling staff discuss or help enrollees apply for workers' compensation, if applicable.

NIOSH is developing a number of support tools to help clinics with the benefits counseling process in particular by creating a uniform set of questions and documents to use with enrollees. An official from the WTC Responders Steering Committee told us that these tools will improve benefits counseling across the clinics. The tools have been presented to

[25]Pub. L. No. 111-347, 124 Stat. 3630 (adding PHSA § 3305(a)(1)(D)) (codified at 42 U.S.C. § 300mm-4(a)(1)(D))

the CCEs and the WTC Responders and Survivors Steering Committees for feedback. The tools include

- a benefits eligibility assessment screening tool designed to create a customized benefits counseling plan for each enrollee, which, according to NIOSH officials, has been finalized;
- a benefits counseling handbook that supplements the screening tool and includes a training manual, which, according to NIOSH officials, is expected to be finalized in July 2017; and
- benefits fact sheets developed for enrollees to educate them about benefits and counseling services as well as provide information on how to get help, which, according to NIOSH officials, will continue to be developed as needed.

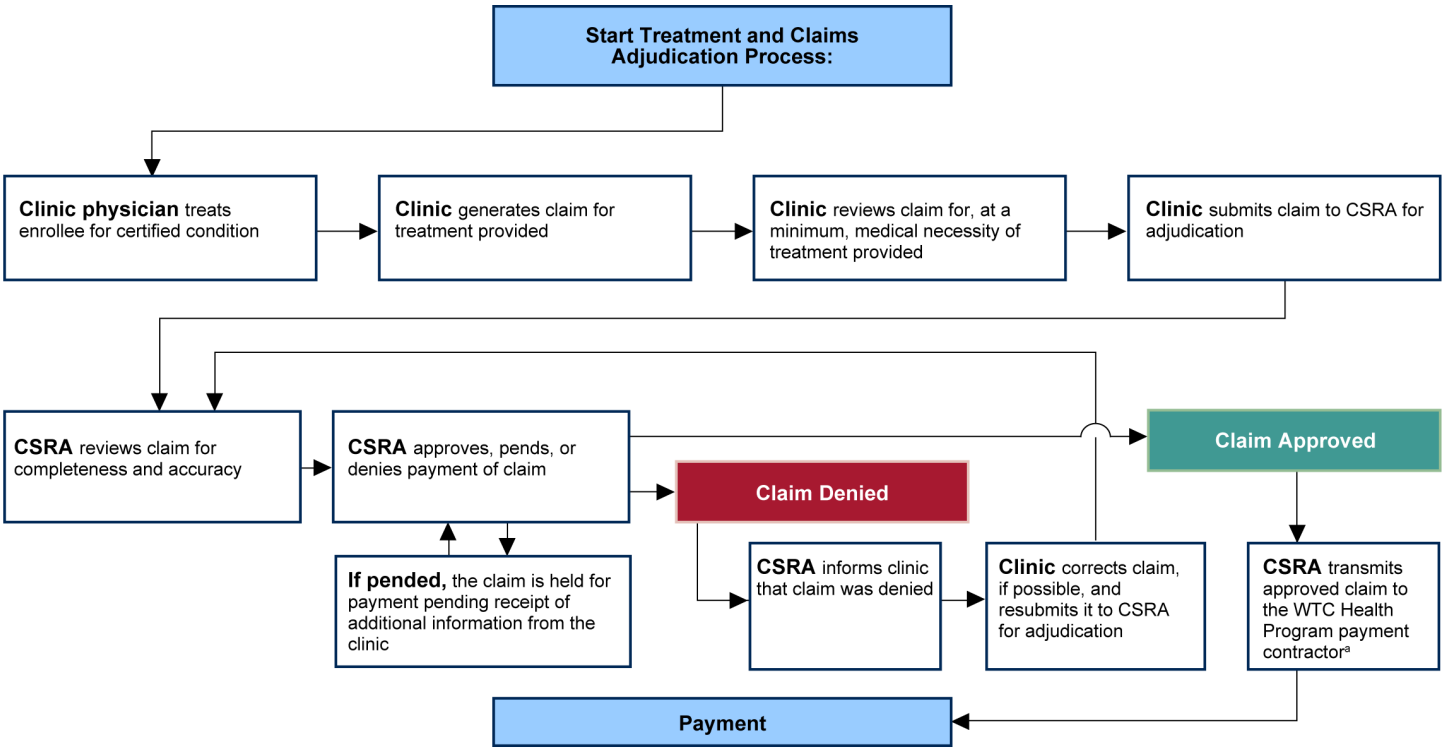
Officials from the WTC Responders and Survivors Steering Committees told us that clinics have generally done a good job explaining health benefits or coverage to enrollees, even though it can be a complicated program for some enrollees to understand. For example, an official from the Survivors Steering Committee explained that some survivors are still under the impression that the WTC Health Program will cover their health care services when, in fact, private health insurance is the primary payer for most. The Survivors Steering Committee official added, however, that the survivor clinic has done everything possible to provide accurate and comprehensive benefits counseling.[26]

Clinics Have Varied Procedures for Reviewing Claims, and the Program's Adjudication Contractor Also Has Implemented Procedures to Help Ensure Appropriate Payments

The PPM requires that clinics review and approve all claims for accuracy, and under their contracts with NIOSH, the clinics must also ensure that claims are submitted and paid only for approved health services for WTC-related conditions and medically associated conditions. The clinics have documented claims-review procedures in their operations manuals to help ensure appropriate payment of claims, but each clinic is reviewing different types of information. (See fig. 2 for more information about the claims adjudication process.)

[26]Survivors receive health services through one of two clinics: (1) for those survivors living in the New York metropolitan area, there is a CCE dedicated to serving survivors, or (2) for those survivors who reside outside of New York, the NPN.

Figure 2: Overview of World Trade Center (WTC) Health Program Process for Adjudicating Claims for Payment



Source: GAO analysis based on National Institute for Occupational Safety and Health (NIOSH) and CSRA documents and interviews. | GAO-17-676

Note: Clinics are the contracted Clinical Centers of Excellence and the Nationwide Provider Network that provide benefits for medical monitoring and treatment services to responders and survivors. CSRA is the WTC Health Program's claims-adjudication contractor.

[a]According to National Institute for Occupational Safety and Health officials, the WTC Health Program has an interagency agreement with the Centers for Medicare and Medicaid Services to process payments for WTC Health Program claims.

NIOSH officials told us that all clinics must review claims information related to medical necessity to ensure that treatment, monitoring, and screening services adhere to established requirements and medical guidelines; clinics may choose, but are not required, to review other information as well, according to NIOSH. As such, we found variation in the types of information clinics are reviewing related to enrollee and provider enrollment, duplicative claims, and fraudulent claims, among

other information.[27] A 2014 external review of the WTC Health Program completed under a NIOSH task order also found that NIOSH had not prescribed what types of claims information the clinics must review, which, according to the review, has resulted in "non-uniform standards" for claims review.[28]

NIOSH officials explained that clinics perform electronic reviews of claims using different electronic claims systems and, therefore, each clinic is not necessarily able to review the same types of information. NIOSH officials stated that implementing a standardized review of claims information at the clinic level would require that each clinic use the same system, and this would be costly and burdensome to implement.[29] NIOSH officials indicated that clinics would be able to look at the same types of information if they performed a manual review of claims, but this would also be resource intensive and burdensome.

Risks associated with the clinics reviewing different types of claims information may be mitigated by procedures of the program's adjudication contractor, CSRA. After the clinics' review, all claims are subject to a standardized second check by CSRA prior to payment. CSRA has several claims checks, or edits, in place as part of the adjudication process and consistently reviews the same types of non-medical information across all claims.[30] According to NIOSH officials, CSRA is checking some of the same information as the clinics but in a more uniform and consistent manner. For example, CSRA checks whether a claim is for an enrolled member, the health service was provided by an enrolled provider, the enrollee has been certified for coverage of the

[27]Each CCE must manage an internal and external provider network to ensure enrollees have access to the necessary expertise required to diagnose and treat their certified covered conditions. CCEs are responsible for enrolling these providers as participating providers in the WTC Health Program.

[28]Data Networks Corporation, *(WTC Health Program) Fraud, Waste, and Abuse Support*, 19.

[29]Clinic contracts were awarded to health care institutions that provide services to the general population, or the employees of the Fire Department of New York City, not just WTC Health Program enrollees. Thus, the electronic claims system that a clinic uses is not exclusively for the WTC Health Program.

[30]While CSRA reviews all claims, it only performs a manual medical review of certain claims, such as claims above a certain dollar amount; claims for services rendered to enrollees who were not certified for the diagnosis included on the claim; claims for certain medical services, including emergency room and dental claims; and claims with contradicting codes.

condition for which health services were rendered, and whether the claim is a duplicate, among other checks. These checks are documented in the WTC Health Program Claims Processing Workflow manual. NIOSH officials noted that each month the clinics receive copies of their denied claims, which are then reviewed at monthly meetings between the clinics and NIOSH to ensure that problems are addressed. CSRA officials told us that they also follow three industry-standard measures related to the accuracy of claims:

- payment accuracy, which looks at the number of claims processed and compares the number that were paid correctly to the number that included some kind of anomaly;
- financial accuracy, which looks at the dollar amount of each claim and compares total dollars paid to total dollars that should have been paid; and
- non-financial statistical accuracy, which looks at whether or not claims' data fields that do not affect payment or financial accuracy were filled out correctly.

Claims Review by World Trade Center Health Program Adjudication Contractor

All health service claims are adjudicated by CSRA, the program's contractor, prior to payment. As part of this process, CSRA conducts a series of checks using claim and member eligibility data to ensure the proper pricing and payment of bills. Specifically, CSRA reviews (among other things):

- whether the individual is enrolled in the program;
- whether the provider is enrolled in the program;
- whether the enrollee was certified for coverage of the condition on or before the date(s) that health services were rendered;
- whether the billing code being claimed matches the health service provided;
- claims for certain medical services, such as emergency room and dental claims;
- claims above $400,000; and
- whether there are duplicate claims.

Based on the results of the review of this information, claims are denied, approved for payment, or pended—that is, held for payment pending receipt of additional information.

Source: GAO analysis of documents from the National Institute for Occupational Safety and Health and the Department of Health and Human Services and Department of Health and Human Services' Office of the Inspector General reports. | GAO-17-676

The 2014 external review also found that the system edits that have been put in place were "robust and consistent with other claims processing systems." The review noted that the auto adjudication system was "able to identify duplicate billings and high-dollar claim payment limits." According to the external review, by implementing these controls, the program is able to "limit the number of fraudulent claims."[31]

NIOSH stated that there was a significant amount of interaction with CSRA when the claims adjudication system was being developed. The agency and CSRA took into consideration several unique aspects of the program when developing this system. For example, NIOSH officials grouped diagnostic and procedure codes specific to a particular WTC-related health condition into "care suites." These care suites have been integrated into the claims processing system. The 2014 external review found that the system automatically denies non-cancer related claims that are submitted with diagnostic and procedure codes that don't match a patient's condition, helping to prevent erroneous payment of claims.[32]

[31]Data Networks Corporation, *(WTC Health Program) Fraud, Waste, and Abuse Support*, 18.

[32]Data Networks Corporation, *(WTC Health Program) Fraud, Waste, and Abuse Support*, 18.

NIOSH Has Not Ensured That Clinics Address Mandated QA Elements, but Indicates Recently Allocated Funding and a New Strategic Plan Will Enhance Its QA Efforts

NIOSH has not systematically reviewed clinics' QA plans or developed guidance for the clinics to ensure plans consistently address the three mandated QA elements. In addition, NIOSH has not developed or required uniform performance measures for clinics to ensure quarterly audits consistently address mandated elements. Funding has recently been allocated to the QA program and NIOSH is now developing a QA strategic plan.

NIOSH Has Not Systematically Reviewed QA Plans or Developed Guidance for the Clinics to Ensure Plans Consistently Address Mandated Elements

NIOSH officials told us they reviewed and approved the clinics' required QA plans when the plans were submitted to the agency in 2011. However, NIOSH had not developed and documented a systematic approach to reviewing the plans at that time. Further, the agency did not provide guidance to the clinics for the development of their plans, including how they should address the mandated elements. According to NIOSH officials, establishing and overseeing the delivery of health care services and the program's payment structure were initially their main priorities. Consequently, they did not focus on the clinics' QA plans to ensure they addressed all three mandated QA elements. Officials told us that this was because the program had few staff when it was first established in 2011.

In addition, NIOSH has not conducted reviews of the plans over time. NIOSH officials also told us that in the years following the program's authorization they focused on ensuring that the clinics had implemented required changes in health care services-related policies rather than verifying that related changes were also made to the QA plans. For example, NIOSH officials noted that they assessed the clinics' implementation of policy changes for practices related to pharmaceutical distribution during a NIOSH field audit of the clinics, but they did not verify that each clinic had updated how they addressed this in their QA plans. NIOSH officials added that they do not keep in-house copies of the current clinic operations manuals, which in most cases include the clinics' QA plans, making it difficult to conduct reviews even if NIOSH opted to do so.

According to the WTC Health Program PPM, NIOSH must review and approve these plans to ensure both consistency among them and alignment with program goals and objectives. In addition, federal internal control standards call for agencies to document responsibilities through policies and to define objectives in terms that are understood at all levels. These standards also call for agencies to perform ongoing monitoring and remediate identified deficiencies on a timely basis.[33]

The lack of systematic review of and guidance for the clinics' QA plans may have contributed to inconsistencies. We found that as of December 2016, three of the eight clinics had QA plans that did not include all three of the mandated QA elements. Specifically, two clinics had a QA plan that did not include the elements about ensuring adherence to monitoring and treatment protocols, and ensuring appropriate diagnostic and treatment referrals. Another clinic had a QA plan that did not include the latter of these two elements.

Further, we found that the QA plans were inconsistent in three additional ways:

- First, although five of the eight clinics' plans included all three mandated QA elements, the extent to which they addressed each element varied (for example, by addressing adherence to monitoring protocols or treatment protocols instead of both, as mandated by the Zadroga Act). (See box below.)
- Second, the clinics' QA plans also addressed how they would monitor the three mandated QA elements in different ways, such as by identifying broad QA-related goals or describing specific procedures to address the same element. For example, one clinic addressed the element related to ensuring appropriate diagnostic and treatment referrals by identifying the goal of "ensuring appropriate diagnostic and treatment referrals" and not identifying specific procedures for achieving this (such as reviewing medical records, as noted in another clinic's plan).
- Third, we found that as of March 2017, one clinic had a QA plan that was out-of-date.[34] Another clinic had a QA plan that was first developed in 2011 and still had several sections marked as "under

[33]GAO-14-704G

[34]The QA plan that NIOSH provided to us as the clinic's most recent, completed version was dated "2011-2012."

development." NIOSH officials stated that they were aware that many of these plans had not been updated since they were originally provided to NIOSH.

Variation in the Extent to Which World Trade Center (WTC) Health Program Clinics Addressed the Three Mandated Quality Assurance (QA) Elements in Their QA Plans

While most of the clinics' QA plans included all three of the mandated QA elements, the extent to which they addressed each varied. Specifically,

- ***Adherence to monitoring and treatment protocols.*** Two of the eight clinics addressed either adherence to monitoring protocols or treatment protocols, but not both.
- ***Ensuring appropriate diagnostic and treatment referrals for participants.*** One of the eight clinics addressed referrals for non WTC-related conditions and WTC-related pulmonary function issues rather than referrals for all conditions.
- ***Verifying prompt communication of test results to participants.*** Four of the eight clinics addressed monitoring exam results only rather than all test results that could be sent to enrollees, such as treatment related test results.

Source: GAO analysis of WTC Health Program clinic QA plans received in December 2016 and January 2017. | GAO-17-676

The lack of a systematic review of the clinic QA plans by NIOSH and guidance for the clinics pose a potential risk that the clinics will continue to inconsistently address the mandated elements. These mandated elements may provide important information and insights into the quality of care provided by the clinics, as well as help to identify any needed improvements. NIOSH officials stated that they have identified important lessons that will inform their review of clinic QA plans moving forward. These officials specifically acknowledged the need for having staff to thoroughly review plans, utilizing program staff from across the program to leverage expertise when conducting reviews, and having a more systematic review process, including a process for capturing changes made by the clinics to their QA plans. Officials stated that they have hired additional staff since 2011 and are using a new approach for the review and approval of the clinic contracts, including QA plans, for the new performance period. Officials added that they also would like to have a dialogue with the clinics regarding the type and quality of the information NIOSH expects to see included in their QA plans. However, as of June 2017, NIOSH had not documented procedures or guidance for reviewing QA plans and setting expectations for the plans' content.

NIOSH Has Not Developed or Required Uniform Performance Measures for Clinics to Ensure Their Quarterly Audits Consistently Address the Mandated Elements

Although NIOSH recently began focusing on systematic reviews of the quarterly internal audits clinics are required to conduct, it has neither developed nor required the use of uniform performance measures for the clinics to use to ensure these audits cover all three of the mandated QA elements. Specifically, in 2015, NIOSH developed and began using a tool to review the seven CCEs' audit reports, which it shared with the CCEs to indicate the kinds of information that NIOSH would expect to see in the reports. However, NIOSH has not developed a similar tool to review the NPN's quarterly audits.[35] The tool that NIOSH shared with the CCEs includes a performance measure related to one of the mandated elements (verifying prompt communication of test results to enrollees)—specifically, evaluating 100 percent of letters on a monthly basis and finding that no more than one letter being sent later than 30 days. However, according to NIOSH officials, CCEs' use of the tool is not mandatory; therefore, CCEs are not required to report on this measure. In addition, the tool does not include uniform performance measures for each of the other two mandated elements.

NIOSH officials stated that for the first 4 years, the program was not adequately staffed, which made it difficult to focus on the quarterly audits. Instead, staff focused on other aspects of program development, such as establishing the program's health care services and payment structure. NIOSH officials noted that they recently reached a staffing level that will allow them to be more strategic in how they conduct QA activities, including those related to the clinic audits.

The clinic's quarterly audits are contractually-required QA activities, for which results must be provided to NIOSH. Although NIOSH is not required to develop uniform performance measures for the clinics to use to audit the three mandated QA elements, we have previously reported that such measures are important to evaluate program performance.[36] Federal internal control standards call for agencies to define objectives in specific and measurable terms so that performance towards achieving those objectives can be assessed, establish appropriate performance

[35]Officials stated that they are developing a checklist for this purpose that they expect will be completed in July 2017.

[36]See, for example, GAO, *Military Personnel: Performance Measures Needed to Determine How Well DOD's Credentialing Program Helps Service Members*, GAO-17-133 (Washington, D.C.: Oct. 17, 2016), 9.

measures for the defined objectives, and conduct ongoing monitoring.[37] An official from the WTC Survivors Steering Committee, as well as an official from the 9/11 advocacy organization we spoke with, added that NIOSH should take the lead in developing QA standards and metrics, with the latter stating that it is important for all of the CCEs to be held to the same QA standards. We have previously reported that agencies can better assess their progress towards achieving goals by establishing a performance baseline for programs.[38]

The absence of uniform performance measures required for all mandated elements may have contributed to inconsistencies among the clinics' audit reports. Specifically, in reviewing the clinics' quarterly audit reports for one quarter in fiscal year 2016, we found that five of the eight clinics did not report on measures or any other information for all of the mandated QA elements. In some cases, clinics reported on a mandated element using their own performance measures, resulting in variation. For example, one clinic audited the element related to adherence to monitoring and treatment protocols by measuring the percentage of charts with documentation that "standards of care" practices were followed for monitoring exams. In contrast, another clinic did not report on monitoring exams at all, instead focusing on reviewing claims to ensure that pharmaceutical treatments were medically necessary or related to a condition on the WTC list. Finally, some clinics reported information related to the performance measure that NIOSH included (but did not require) in its tool in ways that did not fully align with the measure. For example, two clinics reviewed samples rather than 100 percent of letters sent to enrollees to communicate monitoring exam test results.

Despite the lack of uniform performance measures required by NIOSH for the clinics' quarterly audits, NIOSH officials told us that they were confident that information on each element was collected on an annual basis. They said this information could be addressed by the combined results of the clinics' quarterly audits and two other reporting mechanisms—clinic monthly reports and periodic Quality Assurance

[37]GAO-14-704G

[38]See, for example, GAO, *Defense Health Care Reform: Additional Implementation Details Would Increase Transparency of DOD's Plans and Enhance Accountability*, GAO-14-49 (Washington, D.C.: Nov. 6, 2013), 17 as cited in GAO, *Military Personnel: Performance Measures Needed to Determine How Well DOD's Credentialing Program Helps Service members*, GAO-17-133 (Washington, D.C.: Oct. 17, 2016), 10.

Surveillance Plan (QASP) objective assessments.[39] However, NIOSH noted that it does not have a system in place for tracking the evaluation and reporting of the mandated QA elements over time. Additionally, only one of the mandated QA elements—verifying prompt communication of test results—is required to be evaluated using a uniform performance measure through any one of these two other reporting mechanisms, specifically the QASP assessment.[40] Notably, this is the same element that has a corresponding quarterly audit measure. The lack of uniform performance measures that must be used each quarter poses a potential risk that the clinics are not auditing and reporting on the three QA elements mandated in the Zadroga Act in a consistent or timely manner that allows for comparisons across the program. Until the clinics are consistently measuring and reporting on their mandated QA elements, NIOSH may not be able to identify both unique and similar deficiencies across clinics, and therefore is unable to systematically address any problems and make necessary improvements.

Funding Allocated to the WTC Health Program QA Program Has Increased and NIOSH Is Now Developing a QA Strategic Plan

Funding for the WTC Health Program QA program has recently increased, and NIOSH is now in the process of developing a QA strategic plan. When the Zadroga Act established the WTC Health Program in January 2011, it did not make funds specifically available for the WTC Health Program's QA program and generally available funds were not allocated for that purpose. According to NIOSH officials, early steps towards developing and implementing a QA program were performed by a minimal number of staff as an additional responsibility. Starting in fiscal year 2016, the Zadroga Reauthorization Act made funds specifically

[39]The Federal Acquisition Regulation requires that agencies develop a Quality Assurance Surveillance Plan, or QASP, for all services acquired under performance-based contracts (48 C.F.R. subpts. 37.6 and 46.4 (2016)). A QASP identifies contract work that requires surveillance by the agency and the surveillance method for monitoring each condition (48 C.F.R. § 46.401 (2016)). QASP performance objectives, performance thresholds, and surveillance methods are written into each WTC Health Program clinic contract in addition to their QA program-related requirement. According to NIOSH officials, the first QASP assessment was conducted in 2014, and they expect to do a QASP assessment during the new 5-year clinic contract performance period.

[40]This QASP objective requires that the CCEs provide a letter to enrollees informing them of exam results within 2 weeks of the completion of the exam 95 percent of the time and within 4 weeks of completion of the exam 100 percent of the time. The NPN must provide such a letter to enrollees within 10 business days of completion of the exam 95 percent of the time and within 15 business days 100 percent of the time.

available for the development and implementation of a QA program.[41] NIOSH officials stated that they have allocated and are beginning to use funding to assign additional staff to further develop and implement the QA program. According to these officials, the additional staff will work to achieve the following goals: (1) promote excellence in health care, efficiency in program operations, protections against risk that would impact the program's reputation, and financial integrity or compliance with requirements; (2) identify opportunities for improving health care through analysis of relevant information; and (3) foster detection of fraud, waste and abuse.

NIOSH officials told us that the agency is undertaking activities to meet these goals, such as: building an inventory of what has been done thus far; and reporting information, certification, claims, and treatment in a consistent and timely manner. NIOSH staff is also considering defining minimum best practices and standards that they have identified across the clinics. A clinic medical director agreed that NIOSH should make comparisons across the seven CCEs and determine which are performing the best. According to this medical director, the CCEs could use this information to learn from each other's best practices, leading to overall improvements in the health care services provided through the program. Additionally, officials stated that they are coordinating QA processes across NIOSH staff working on the WTC Health Program to prevent duplication or cross-purpose work. Finally, another activity underway is NIOSH's development of a strategic plan that outlines many of the clinics' QA activities and the QASP assessment, among other activities, as well as NIOSH's oversight role. The March 2017 draft we reviewed includes an overview of the types and frequency of reviews, analyses, and audits that are conducted across the program and how these should be implemented and monitored. According to NIOSH officials, the draft was expected to be finalized in June 2017.

Conclusions

For responders and survivors who suffer serious health problems as a result of exposures related to the September 11 attacks, WTC Health Program benefits may be an important source for needed health care services. Among other factors, eligibility for these benefits is contingent on an individual having a covered health condition related to exposure to

[41]Pub. L. No. 114-113, § 302(a)(2), 129 Stat. 2997 (amending PHSA § 3351(b)(1)) (codified at 42 U.S.C. § 300mm-61(b)(1)).

the September 11 attacks. Consequently, ensuring the integrity of the program, including a robust certification process, appropriate claims adjudication, and the quality of the health care services provided are paramount.

The Zadroga Act requires that the WTC Health Program develop a QA program that includes specific elements that should be addressed to help ensure the quality of the health care services provided. While NIOSH has taken some steps toward developing a QA program, the lack of a systematic, documented review process with specific guidance for the clinics' QA plans has introduced risk that the clinics' activities are not adequately addressing mandated QA elements. Furthermore, a lack of uniform performance measures required by NIOSH relative to the clinics' quarterly audits has exacerbated this risk. NIOSH has focused on other priorities, primarily the implementation of health care services, but with the program's re-authorization extending funding for and provision of services until 2090, there is a heightened need to develop and document the policies, procedures, and guidance necessary to ensure that the QA elements mandated by the Zadroga Act are being addressed. Having such documentation in place will enhance the activities of the QA program, help ensure that responders and survivors are receiving the highest quality care, and allow for the identification of common problems and implementation of clinic and program-wide health care service improvements.

Recommendations for Executive Action

To help ensure that the WTC Health Program QA program addresses required QA elements, including the three elements mandated in the Zadroga Act, we recommend that the Director of NIOSH take the following actions:

• develop and implement procedures for conducting systematic reviews of each clinic's QA plan (recommendation 1);

• develop and disseminate guidance that clearly specifies how the clinics should address mandated elements in their QA plans (recommendation 2); and

• develop uniform performance measures that clinics are required to use to consistently evaluate mandated elements through their audits every quarter (recommendation 3).

Agency Comments

We provided a draft of this report to HHS for comment. In its written comments, which are reproduced in Appendix III, HHS concurred with our recommendations. HHS agreed that the recommendations would further strengthen the program's existing QA efforts and it is establishing a workgroup to address them. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, and appropriate congressional committees. In addition, the report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

Appendix I: World Trade Center (WTC) Health Program List of Covered Conditions

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) established the WTC Health Program and included a list of World Trade Center (WTC)-related health conditions. Responders and survivors of the September 11 attacks who are enrolled in the WTC Health Program may receive treatment for these conditions. According to the act, the list may be amended by the Administrator of the WTC Health Program—the director of the National Institute for Occupational Safety and Health (NIOSH)—to include other conditions as more information is learned about the relationship of September 11 site exposures and those conditions. The following conditions were on the list as of June 2017.[1]

Acute traumatic injuries:

- Burn
- Complex sprain
- Eye injury
- Fracture
- Head trauma
- Tendon tear
- Other similar acute traumatic injuries

Aerodigestive disorders (or airways and digestive disorders):

- Asthma
- Chronic cough syndrome
- Chronic laryngitis
- Chronic nasopharyngitis
- Chronic respiratory disorder—fumes/vapors
- Chronic rhinosinusitis
- Gastroesophageal reflux disorder
- Interstitial lung diseases
- Reactive airways dysfunction syndrome
- Sleep apnea exacerbated by or related to another condition described in the list of aerodigestive disorders

[1]To review information about the WTC Health Program list of covered conditions, see https://www.cdc.gov/wtc/faq.html (accessed June 14, 2017).

- Upper airway hyperreactivity
- WTC-exacerbated and new-onset chronic obstructive pulmonary disease

Cancers that fall into the following categories:[2]

- Childhood cancers (any type of cancer diagnosed in a person less than 20 years of age)
- Malignant Neoplasms
  - Blood & lymphoid tissue
  - Digestive system
  - Eye & orbit
  - Female breast
  - Female reproductive organs
  - Head & neck
  - Respiratory system
  - Skin (Melanoma/non-Melanoma)
  - Soft tissue
  - Thyroid
  - Urinary system
- Mesothelioma
- Rare cancers

Mental health conditions:

- Acute stress disorder
- Adjustment disorder
- Anxiety disorder (not otherwise specified)
- Depression (not otherwise specified)
- Dysthymic disorder
- Generalized anxiety disorder
- Major depressive disorder

[2]For a detailed list of cancers in each category, see https://www.cdc.gov/wtc/coveredcancers.html (accessed June 14, 2017).

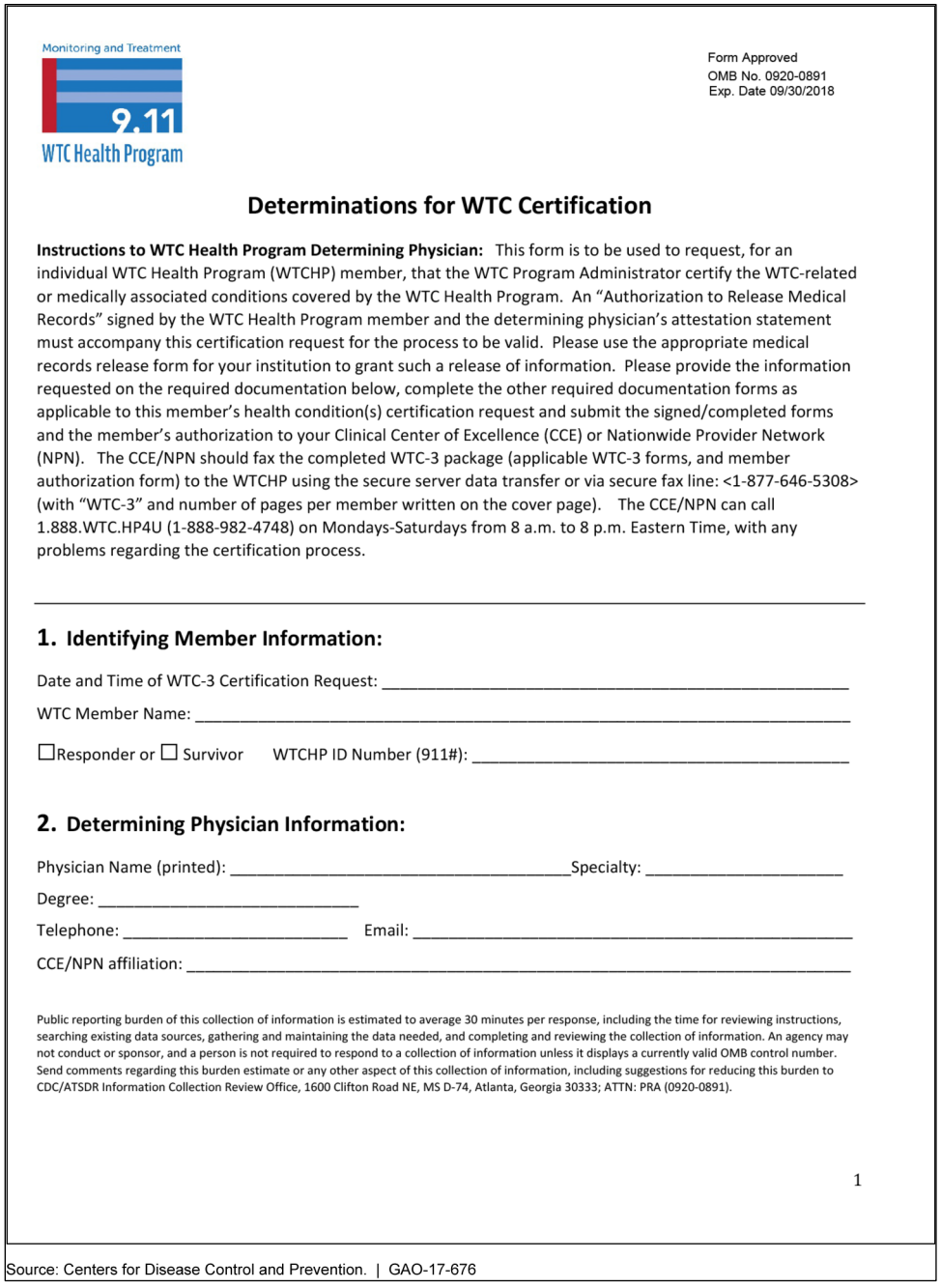
- Panic disorder
- Posttraumatic stress disorder
- Substance abuse

Musculoskeletal disorders:
Limited to responders who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, and meaning chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks.

- Carpal tunnel syndrome (CTS)
- Low back pain
- Other musculoskeletal disorders.

Other:
Other health conditions determined to result from the treatment or progression of an underlying certified WTC-related health condition may be certified as health conditions medically associated with a WTC-related health condition.

Appendix II: World Trade Center-3 (WTC-3) Certification Request Form



Monitoring and Treatment
9.11
WTC Health Program

Form Approved
OMB No. 0920-0891
Exp. Date 09/30/2018

Determinations for WTC Certification

Instructions to WTC Health Program Determining Physician: This form is to be used to request, for an individual WTC Health Program (WTCHP) member, that the WTC Program Administrator certify the WTC-related or medically associated conditions covered by the WTC Health Program. An "Authorization to Release Medical Records" signed by the WTC Health Program member and the determining physician's attestation statement must accompany this certification request for the process to be valid. Please use the appropriate medical records release form for your institution to grant such a release of information. Please provide the information requested on the required documentation below, complete the other required documentation forms as applicable to this member's health condition(s) certification request and submit the signed/completed forms and the member's authorization to your Clinical Center of Excellence (CCE) or Nationwide Provider Network (NPN). The CCE/NPN should fax the completed WTC-3 package (applicable WTC-3 forms, and member authorization form) to the WTCHP using the secure server data transfer or via secure fax line: <1-877-646-5308> (with "WTC-3" and number of pages per member written on the cover page). The CCE/NPN can call 1.888.WTC.HP4U (1-888-982-4748) on Mondays-Saturdays from 8 a.m. to 8 p.m. Eastern Time, with any problems regarding the certification process.

1. Identifying Member Information:

Date and Time of WTC-3 Certification Request: _____

WTC Member Name: _____

☐Responder or ☐ Survivor WTCHP ID Number (911#): _____

2. Determining Physician Information:

Physician Name (printed): _____Specialty: _____

Degree: _____

Telephone: _____ Email: _____

CCE/NPN affiliation: _____

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0891).

1

Source: Centers for Disease Control and Prevention. | GAO-17-676

3. WTC-Related Condition

This section is only necessary if requesting consideration for a WTC-related condition. Provide the WTC-Related Health Condition and the current respective International Classification of Disease [ICD] code - current for the program year (e.g., 2015 ICD-10-CM). Qualifying WTC-related health condition(s):

WTC-Related Condition Name	ICD Code	Listed Condition Mapping	Requesting authorization for time-limited treatment? Y/N

Justification of WTC-Related Health Condition

Using narrative or suggested templates document that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks were determined substantially likely to be a significant factor in aggravating, contributing to, or causing the condition(s). Justification should contain pertinent information about 9/11 exposure and time-linked emergence of symptoms. Please refer to the "WTCHP *Policy and Procedure Manual" at http://www.cdc.gov/wtc/ppm.html and Policy, Procedure Notices at http://www.cdc.gov/wtc/policies.html and the WTC Health Program Codebook* and the *James Zadroga 9/11 Health and Compensation Act of 2010*. Specific written (typed) justification is required to meet this criterion, and shall be appended to this form for submission. The extra page(s) should have the member's name, WTCHP ID, and date. The expected length is less than 1 typewritten page; but not to exceed 2 pages.

4. Medically Associated Condition

This section is only necessary if requesting consideration of a medically associated condition. Complete the information about the medically associated condition under consideration, using both the name of the condition, the ICD code and the WTC-related health condition with which it is being associated. Establish that the medically associated condition "results from" treatment or progression of the underlying WTC-related condition. The underlying WTC-related health condition must first be certified by the WTC Program Administrator before any conditions may be certified as medically associated with the underlying condition.

Medically Associated Condition Name	ICD Code	WTC-Related Condition Name	ICD Code	Requesting authorization for time-limited treatment? Y/N

2

Source: Centers for Disease Control and Prevention. | GAO-17-676

a) Is the underlying WTC-related condition already certified?

☐ Yes

☐ No, but included in this request

b) Is the associated health condition under consideration a direct ***result of the medical treatment*** of the WTC-related health condition?

☐ Yes. If yes, demonstrate in the narrative (including medical records when appropriate) that the health condition "results from" **medical treatment** of the underlying certified WTC-related health condition without the influence of an intermediary health condition or event.

☐ No

c) Is the medically associated health condition under consideration a ***result of disease progression*** of the WTC-related health condition?

☐ Yes. If yes, demonstrate in the narrative (including medical records when appropriate) that that the health condition "results from" **progression** of the underlying certified WTC-related health condition without the influence of an intermediary health condition or event.

☐ No

Medically Associated Condition Narrative

_____
_____
_____

5. Physician Professional Determination and Attestation:

(a) With the patient's approval, the medical file is incorporated by reference and available to support the information on the form. By signing below, I certify that the information I have provided on this form is true and accurate. I understand that any false statements or concealment of material facts may subject me to criminal penalties under 18 U.S.C. § 1001 and 18 U.S.C. § 1035.

(b) In regard to the request for WTC-related certification(s) on this WTC-3, I have determined that the member's exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001 terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing this condition(s).

Physician Signature_____ Date_____

3

Source: Centers for Disease Control and Prevention. | GAO-17-676

Appendix III: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUL 2 1 2017

Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*World Trade Center Health Program: Improved Oversight Needed to Ensure Clinics Fully Address Mandated Quality Assurance Elements*" (GAO-17-676).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT - WORLD TRADE CENTER HEALTH PROGRAM: IMPROVED OVERSIGHT NEEDED TO ENSURE CLINICS FULLY ADDRESS MANDATED QUALITY ASSURANCE ELEMENTS (GAO-17-676)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation

To help ensure that the World Trade Center (WTC) Health Program Quality Assurance (QA) program addresses required QA elements, including the three elements mandated in the Zadroga Act, we recommend that the Secretary of HHS direct the National Institute for Occupational Safety and Health (NIOSH) to take the following actions:

- develop and implement procedures for conducting systematic reviews of each clinic's QA plan;
- develop and disseminate guidance that clearly specifies how the clinics should address mandated elements in their QA plans; and
- develop uniform performance measures that clinics are required to use to consistently evaluate mandated elements through their audits every quarter.

HHS Response

HHS concurs with GAO's three recommendations and believes that implementing the recommendations will further strengthen the existing QA efforts of the WTC Health Program and its participating contractors. The WTC Health Program will establish a workgroup to develop and operationalize the systematic reviews, guidance, and performance measures addressed in GAO's recommendations.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Hernán Bozzolo (Assistant Director), Daniel Klabunde (Analyst-in-Charge), Karen Belli, Jennie F. Apter, and George Bogart made key contributions to this report.

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