**World Trade Center Health Program**

**Nationwide Provider Network**

2021

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Nationwide Provider Network   
RFP: 75D301-21-R-71962

# SECTION 1- BACKGROUND

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) was signed into law on January 2, 2011; the Act was subsequently reauthorized through 2090. Pub. L. 111-347, as amended by Pub. L. 114-113 and Pub. L. 116-59; codified at 42 U.S.C. §§ 300mm – 300mm-61. The Zadroga Act established the World Trade Center (WTC) Health Program within the Department of Health and Human Services’ Centers for Disease Control and Prevention (CDC) to provide medical monitoring, screening, and treatment for responders and survivors of the September 11, 2001, terrorist attacks. Responders include workers or volunteers who provided rescue, recovery, debris cleanup, and related support services on or in the aftermath of the September 11, 2001, terrorist attacks at the World Trade Center, the Pentagon, or the aircraft crash site near Shanksville, PA. Survivors include persons who were present in the New York City (NYC) Disaster Area in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the NYC Disaster Area for a certain period following the September 11, 2001, terrorist attacks. In order to enroll in the Program, survivors and responders must meet certain eligibility criteria described in the Zadroga Act ( <https://www.cdc.gov/wtc/eligiblegroups.html>). The WTC Health Program has promulgated regulations implementing the Zadroga Act that govern the administration of the Program at 42 CFR pt. 88.

The WTC Health Program (the Program) is a limited benefit health program, meaning that treatment is covered for only specified health condition(s) resulting from exposure to airborne toxins, hazards, or other adverse conditions arising from the September 11, 2001, terrorist attacks. A provider affiliated with the WTC Health Program must diagnose a member with a covered health condition and determine that it is related to the member’s 9/11 exposure and the determination must then be certified by the Program for the member to receive treatment. An enrolled member must meet certain exposure, latency, and symptom-onset requirements for their health condition to be certified. Program eligibility and certification decisions are made by the WTC Health Program enrollment and certification specialists, respectively. A range of conditions are covered including mental health, aerodigestive disorders, and cancer; see 42 C.F.R. § 88.15 for the complete List of WTC-Related Health Conditions (List).

The Clinical Centers of Excellence (CCEs) and Nationwide Provider Network (NPN) provide treatment and medical monitoring for over 100,000 Program members, while the WTC Health Program administers Program policy, makes eligibility and certification decisions, and covers the costs associated with treatment and monitoring. The Zadroga Act encompasses myriad Program administration and performance responsibilities including those pertaining to enrollment, initial evaluation, medical monitoring, and care management of covered health conditions for eligible individuals through diagnostic and treatment services. There are currently seven (7) CCEs and one Short-term Survivor Clinic (SSC) in the New York Metropolitan Area, and one NPN that administers benefits to members. As of December 2020, there were a total of 80, 146 responders and 28,394 survivors enrolled in the Program; of these, 22, 122 live outside of the New York Metropolitan Area and are served by the NPN as defined in Section 3313 of the Zadroga Act; 42 U.S.C. § 300mm-5.

## SECTION 1.1 – Definitions

**Business Days**: All days excluding Saturdays, Sundays, and designated federal holidays.

**Calendar Days**: All days including Saturdays, Sundays, and designated federal holidays.

**Certification: WTC Health Program review for purposes of approval of coverage of the determination that a health condition in a particular WTC Health Program member is a WTC-related health condition, as included on the List of WTC-Related Health Conditions in 42 CFR 88.15, or a health condition medically associated with a WTC-related health condition** and the member’s 9/11 exposures are substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition. *See* 42 CFR 88.1, 88.18.

**Certified-eligible survivor**: An individual who has been identified as eligible for medical monitoring and treatment as of January 2, 2011; or a screening-eligible survivor who is eligible for follow-up monitoring and treatment pursuant to § 88.12(b) of the Regulations (<https://www.cdc.gov/wtc/regulations2.html>). *See* 42 CFR 88.1.

**Clinical Center of Excellence (CCE):** A New York metropolitan area (NYMA)-based medical facility that, in accordance with the Zadroga Act and program regulations, operates under an individual contractual relationship with the WTC Health Program to provide medical monitoring, diagnosis, and treatment services for members in the NYMA. Members are assigned a CCE which is responsible for coordinating their care under the WTC Health Program. There are currently seven CCEs contracted with the Program and one Short-term Survivor Clinic: one for the survivor population and six for the responder population. *See* 42 CFR 88.1

**Codebook:** A list of medical codes (i.e., ICD-9 and ICD-10) managed by the Program that determines approved medical treatments covered by the Program, identifies care suites, provides prior authorization requirements, and other applicable coverage guidelines.

**FDNY Responders:** Active and retired FDNY members who performed 9/11-related rescue and recovery efforts in and around New York City.

**Fraud**: Any of the following:

* Knowingly submitting, or causing to be submitted, false claims or making misrepresentations of fact to obtain a Federal health care payment for which no entitlement would otherwise exist;
* Knowingly soliciting, receiving, offering, or paying remuneration (e.g., kickbacks, bribes, or rebates) to induce or reward referrals for items or services reimbursed by Federal health care programs;
* Making prohibited referrals for certain designated health services (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244.pdf).

**General Responders:** Responders identified as eligible for monitoring and treatment based on certain eligibility criteria, generally, onsite workers or volunteers who performed 9/11-related rescue, recovery, debris cleanup, and related support services in and around New York City.Includes certain active and retired NYPD, Port Authority Police, Port Authority Trans-Hudson Corporation Tunnel workers, employees of the NYC Chief Medical Examiner’s Office or other morgue workers, and vehicle-maintenance workers. *See* 42 CFR 88.1, 88.3, 88.4.

**Go-Live Date**: Set date where the NPN is fully operational, independent, and available for use following the implementation period.

**Initial health evaluation:** The assessment of one or more symptoms that may be associated with a WTC-related health condition and includes a medical and exposure history, a physical examination, and additional medical testing as needed to evaluate whether the individual has a WTC-related health condition or health condition medically associated to a certified WTC-related health condition and is eligible for treatment under the WTC Health Program. *See* 42 CFR 88.1.

**Monitoring** means periodic physical and mental health assessment of a WTC responder or certified-eligible survivor in relation to exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks and which includes a medical and exposure history, a physical examination and additional medical testing as needed for surveillance or to evaluate symptom(s) to determine whether the individual has a WTC-related health condition. *See* 42 CFR 88.1.

**Nationwide Provider Network (NPN):** A nationwide network of health care providers throughout the United States administered by a central entity under contract with the Program to provide WTC-related health care, including initial health evaluation, monitoring, and treatment, for Program members who live outside the NY Metropolitan Area. *See* 42 CFR 88.1.

**Outreach and Education:** A service provided by the contractor to ensure prospective members have information they need about the WTC Health Program and how to apply.

**Pentagon/Shanksville Responders:** Active and retired members of fire and police departments (fire or emergency personnel), employees of recovery or cleanup contractors, volunteers who performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site in Arlington, VA, or the crash site near Shanksville, PA. *See* 42 CFR 88.1.

**Personally Identifiable Information (PII):** Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other information that is linked or linkable to a specific individual. Office of Management and Budget Circular No. A-130 (July 27, 2016).

**Prior Authorization (PA)**: PA is required for certain services that required to meet specific eligibility criteria before they are eligible for coverage by the WTC Health Program. The NPN contractor shall maintain multiple, closed treatment plans in their benefit plan system, allowing each separate treatment plan to have unique PA criteria for the same service. Reasons that services or items require a PA are multi-use/certification specific services, high cost, high fraud/waste/abuse potential, or off-label use. PA approval may be granted on a per-service basis for a member after PA criteria are met. See the WTC Health Program codebook and Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) for more information.

**Protected Health Information (PHI):** Individually identifiable health information (health information, including demographic information, collected from an individual and created or received by a health care provider, health plan, employer, or health care clearinghouse that relates to the individual’s past, present, or future mental or physical health condition, provision of health care, or payment for care and which identifies the individual or is reasonably believed to make the individual identifiable) that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes individually identifiable health information in certain education records, certain student medical records, employment records held by a covered entity in its role as employer, and records regarding a person who has been deceased for more than 50 years. 45 CFR 160.103.

**Responder:** Certain workers or volunteers who provided rescue, recovery, debris cleanup, or related support services on or in the aftermath of the September 11, 2001, terrorist attacks for specified amounts of time between September 11, 2001 and July 31, 2002. There are three groups of responders in the WTC Health Program: FDNY Responders (and surviving FDNY family members); WTC General Responders (including NYPD); and Pentagon and Shanksville, PA Responders. *See* 42 CFR 88.1.

**Retention: A service provided by the contractor to maintain contact and promote continued participation with current NPN members and encourage inactive members to participate in the Program.**

**Screening-eligible survivor:** An individual who is not a WTC responder, claims symptoms of a WTC-related health condition, and meets the eligibility criteria for a survivor specified in § 88.8 of the Regulations (<https://www.cdc.gov/wtc/regulations2.html>). *See* 42 CFR 88.1.

**Survivors:** Certain persons who claim symptoms and who were in the dust or dust cloud on 9/11; lived, worked, or attended school, childcare, or adult daycare in the New York City Disaster Area during specified timeframes;; performed non-responder 9/11 cleanup or maintenance work; were eligible for a Lower Manhattan Development Corporation Residential Grant; or whose employers were eligible for certain incentive grants. *See* 42 CFR 88.1, 88.7, 88.8, 88.10.

**Technical Guidance Document (TGD):** A technical guidance document (TGD) is an official communication from the WTC Health Program Contracting Officer Representative (COR) and the WTC Health Program. TGDs are included as part of the WTC Health Program Procedures and will be provided upon award, if not in the Administrative Manual (https://www.cdc.gov/wtc/handbook.html) or in the online policies and procedures.

**Utilization Management (UM)[[1]](#footnote-2)[[2]](#footnote-3):** The evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan.

**Utilization Management -- Concurrent Review (CCR):** a method of reviewing patient care and services during a hospital stay to validate the necessity of care and to explore alternatives to inpatient care. It is also a form of utilization review that tracks the consumption of resources and the progress of patients while being treated. CCR involves review of necessity decisions made while the patient is currently in an acute or post-acute setting (CCR may also be referred to as “Urgent Concurrent”[[3]](#footnote-4)).

**Utilization Management -- Continued Stay Review (CSR):** type of review used to determine that each day of the hospital stay is necessary, and that care is being rendered at the appropriate level. It takes place during a patient’s hospitalization for care. CSR is conducted concurrently (as is CCR); however, it applies to non-Diagnosis Related Grouping (DRG) facilities in which the status of each day of a hospital stay is addressed separately. DRG facilities may only require an initial review in which the determination would apply to the entire hospital stay.

**Utilization Management -- Prospective Review:** The review of medical necessity for the performance of services or scheduled procedures before admission.

**Utilization Management -- Retrospective Review:** Medical necessity review after treatment is provided.

**Waste**: Failure to control costs or regulated payment associated with federal program funding that results in taxpayers not receiving reasonable value for their money in connection with any government-funded activities due to an inappropriate act or omission by payers with control over or access to government resources. Importantly, waste relates primarily to mismanagement, inappropriate actions, or inadequate oversight (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244.pdf).

**WTC Health Program**: The program established by Title XXXIII of the Public Health Service Act, as amended, 42 U.S.C. 300mm to 300mm-61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 , Pub. L. 111-347, as amended by Pub. L. 114-113 and Pub. L. 116-59), to provide medical monitoring and treatment benefits for eligible responders to the September 11, 2001, terrorist attacks and initial health evaluation, monitoring, and treatment benefits for residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks. *See* 42 CFR 88.1.

**WTC Health Program member**: Any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program. *See* 42 CFR 88.1.

**WTC-related health condition**: An illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with expertise in treating or diagnosing the health conditions in the List of WTC-Related Health Conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, including a mental health condition. Only those conditions on the List of WTC-Related Health Conditions codified in 42 CFR 88.15 may be considered WTC-related health conditions. *See* 42 CFR 88.1.

## SECTION 1.2 – Selected Roles and Business Associates

The following is a non-exclusive list of other WTC Health Program contractors and business associates with which the NPN may be expected to engage while carrying out Program services and functions.

**Clinical Center of Excellence (CCE):** A NYMA-based medical facility that, in accordance with the Zadroga Act, operates under an individual contractual relationship with the WTC Health Program to provide medical monitoring, diagnosis, and treatment services for members in the NY metropolitan area. Members residing in NYMA or otherwise electing care through a CCE are assigned a CCE which is responsible for coordinating their care under the WTC Health Program. There are currently eight CCEs contracted with the Program: one for the survivor population and six for the responder population. There is also a Short-term Survivor Clinic in the NYMA.

**Comprehensive Cost Avoidance, Coordination of Benefits, and Recovery (CCA):** A vendor who implements a comprehensive cost avoidance, coordination of benefits, and recovery platform from pre- to post-payment processes to facilitate the ability of the WTC Health Program to improve efficiency and control health care costs without compromising quality of care.

**Data Center (DC)**: One of several centers under contract with the WTC Health Program to support various functions, including receiving data from the CCEs and NPN; developing examination, monitoring, and treatment protocols; establishing provider credentialing criteria; and coordinating outreach activities. *See* 42 CFR 88.1.

**Health Program Support (HPS):** A vendor under contract to support various Program functions, including processing member enrollment and certification applications, managing the customer-service call center, managing the provider network, administering benefit plans, processing medical claims, maintaining the member database, and coordinating member communications.

**Health Program Evaluation (HPE):** A vendor providing consulting services for data analytics to support strategic planning and program evaluation.

**Pharmacy Benefits Manager (PBM):** A vendor who disseminates the Program’s formulary updates and works closely with the NPN contractor on pharmacy claims adjudication.

**Outreach Partner:** Vendor who supports needs of recruitment for responders and survivors through culturally and linguistically appropriate educational materials during various outreach efforts.

# SECTION 2 - PURPOSE

The purpose of this contract is to serve members living outside of the New York metropolitan area (NYMA) by administering and managing the Nationwide Provider Network (NPN).

The solicitation is intended for a single contract to provide limited health care delivery services that include:

* Contract management
* Member services
* Program Communications
* Establish and maintain Nationwide Provider Network
* Administer monitoring and treatment
* Conduct physician determinations and request certifications
* Administer end-to-end medical benefits claim and billing program
* Coordination of benefits with private health insurance for survivors
* Quality Assurance Controls to prevent unauthorized services
* Case management and care coordination

In supporting the Program, the NPN contractor shall work closely with the WTC Health Program administering agency and its contractors as listed in SECTION 1.2., and other federal and non-federal stakeholders as directed.

The WTC Health Program is a federally funded, limited health benefit program and, therefore, must comply with all federal regulations and requirements, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191; 42 U.S.C. § 1320d), as modified, and the corresponding implementing regulations, including the Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164).

# SECTION 3 – SCOPE OF WORK

The scope of work for a NPN is defined by SECTION 3313 of the Zadroga Act and incorporates requirements from other parts including SECTIONs 3301, 3304, 3305, and 3331 and listed in SECTION 4 of this Performance Work Statement (PWS). The NPN contractor shall operationalize a nationwide provider network to ensure eligible members receive monitoring and treatment only for appropriately certified condition(s). The NPN contractor is responsible for an up-to-date understanding of and compliance with the Zadroga Act and the Program’s implementing regulation, including any amendments, as well as the Program’s policies, standard operating procedures, technical and medical guidance documents, and WTC Health Program Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) The NPN contractor shall manage the NPN using advanced and continually improved industry standards. The NPN contractor shall provide these services with the goals of minimizing costs to the WTC Health Program, improving member health, and providing superior member services. The NPN contractor shall manage the contract to ensure that subcontracts, staffing, reporting, security, deliverables, repositories, and Quality Assurance (QA) experts and services meet the requirements of the contract.

The NPN contractor shall make every effort to ensure the accuracy, quality, and timeliness of all written communications and deliverables prior to providing the information to the Contracting Officer (CO), Contracting Officer’s Technical Representative (COR), WTC Health Program Units, and other stakeholders.

# SECTION 4 – TASKS TO BE PERFORMED

The NPN contractor must possess the knowledge, capability, and resources to effectively provide services to manage the NPN in accordance with all federal, state, and any other applicable laws; regulations; policies; procedures; and WTC Health Program requirements.

The NPN contractor awarded the contract under the associated request for proposals (RFP) shall be responsible for cooperating with the WTC Health Program and the incumbent NPN contractor during an estimated (4) four month transition period to become the NPN contractor responsible for completing all required services.

The NPN contractor shall provide competent and qualified staff to work on the scope of services under the contract. The NPN contractor is responsible for ensuring the accuracy, timeliness, and completion of all tasks assigned under the resulting contract.

At a summary level, these tasks include:

1. Implementation Services
2. Administrative Requirements
3. Member Services
4. Maintain Nationwide Provider Network
5. Administer Health Benefits and Claims

## SECTION 4.1 – Implementation

All required services must be successfully implemented for the incoming contractor to begin performance of the contract on the agreed upon contract ”Go-Live” date. The NPN contractor shall develop an Implementation Plan. Once the plan has been approved, any material changes to the plan must be documented and presented in conjunction with the monthly progress report. (See SECTION 8). The plan shall include:

1. Assignment of dedicated NPN key personnel to lead and manage transition and implementation efforts;
2. Defined project management plans for implementing all tasks and deliverables in accordance with this PWS;
3. Establishment of the staff utilized under the contract, including subcontractors, with clearly defined roles and responsibilities to include the proposed labor mix of personnel who will be responsible for implementing this requirement, including the identification of key personnel and the percentage of their time devoted to the contract; and
4. Transition activities, including testing of system integration and customer service capabilities.

The NPN implementation team shall collaborate with the WTC Health Program, COR, and the incumbent NPN contractor to facilitate the implementation and transfer of all aspects of the NPN and provide the Program the following standard implementation services:

### SECTION 4.1.1 - Meeting participation

The NPN contractor shall participate in a kick-off meeting either virtually or in-person with WTC Health Program personnel within seven (7) days of award. The NPN contractor must coordinate with the COR and CO to establish dates, location, and agenda for the kickoff meeting. The contractor must take meeting minutes, which must be provided to WTC Health Program five (5) days post kickoff. The NPN contractor shall conduct project implementation status meetings with appropriate WTC Health Program staff thereafter on an agreed-upon schedule (e.g., weekly).

### SECTION 4.1.2 – Pre-transition audit

The NPN contractor shall complete an audit to evaluate all process and system readiness in order to operationalize the network and services at least 15 calendar days prior to the “Go-Live” date. Pre-transition audit results shall be shared with the Program as part of the Weekly Service Log and Agenda (SECTION 8).

### SECTION 4.1.3 - Training

The NPN contractor shall provide onsite and/or virtual training for new operational processes and systems to the NPN staff and/or WTC Health Program staff if applicable, in accordance with the training section in this document (See SECTION 4.2.3).

### SECTION 4.1.4 - Data/File transfers

Implement system programming for data/file transfers including data collection, data mapping, and data from systems listed in SECTION 4.2.6, and file transfers to and from the WTC Health Program and the Program’s contractors. The contractor shall develop and maintain data and file mapping to support its operations and provide meaningful data analytics and reports to demonstrate its status and performance of requirements implementation with capability to transfer the data and files to the Government when requested and at the end of the contract. Data may include service/item claims, eligibility files, prior approval (PA) review files, and member information. All file transfer processes must be tested for accuracy and HIPAA compliance and be in place 30 days before the “Go-Live" date. Data formatting shall be indicated by the Program and mutually acceptable by the NPN contractor.

## SECTION 4.2 – Administrative and Contractual Requirements

The NPN contractor shall develop and maintain an Operations Manual that is transferrable to the government and contains a complete set of written standard operating procedures and plans with descriptions of all contract-related services, processes, and activities of this PWS. The Operations Manual shall be used to meet the objectives outlined in this PWS and provide the requisite security and process support for the WTC Health Program’s NPN. The Operations Manual shall be aligned with the WTC Health Program policies and procedures and Administrative Manual which can be found at <https://www.cdc.gov/wtc/ppm.html>. The Operations Manual is due to the WTC Health Program within 60 days of award (See SECTION 8). Unless otherwise specified, all plans are maintained in the Operations Manual and have the same deliverable dates. A Staffing Plan shall be submitted within 30 days of award and provide staffing status report quarterly including dedicated hours for the functions listed in Section 4.2.1.

### SECTION 4.2.1 – Key Administrative Functions

Key Personnel:

The NPN contractor shall notify the Program if there is a change in “Key Personnel.” If it becomes necessary to replace someone holding a position listed as “Key Personnel,” the NPN shall provide the Program the resume of another staff person of equal or greater experience for review and approval. The NPN shall provide, at a minimum, the following key personnel:

1. Senior Account Manager: a dedicated senior account manager assigned to the WTC Health Program account who:
2. Qualifications
   1. Has a minimum of five years of experience in a Government account management role.
   2. Holds a minimum bachelor’s degree in business, Health Administration, or related field
3. Roles & Responsibilites
   1. Returns all WTC Health Program staff inquiries on the same or next business day
   2. Attends all weekly, monthly, and semi-annual scheduled client and implementation meetings
   3. Facilitates and coordinates all requirements related to the account.
4. Medical Director: a dedicated medical director that is assigned to the WTC Health Program account who:
   1. Qualifications
      1. Possesses the necessary education and experience as a physician, preferably specializing in occupational health
      2. Has a minimum of five years of relevant clinical experience that enables them to make independent clinical decisions and recommendations for the WTC Health Program and member population
   2. Roles and Responsibilities
      1. Returns all WTC Health Program inquiries on the same or next business day
      2. Attends all weekly, monthly, and semi-annual scheduled client meetings in which clinical based updates or decisions are required. Attendance at the weekly Medical Forum Call, monthly Responder Steering Committee, and quarterly Pharmacy and Therapeutics (P&T) meeting is required
5. Program Manager:
6. Qualifications
   1. Has a minimum of ten years of experience in a Government program management role
   2. Holds a minimum bachelor’s degree in business, Health Administration, or related field or equivalent formal training with relevant credential
7. Roles and Responsibilities
   1. Returns all WTC Health Program staff inquiries on the same or next business day
   2. Attends all weekly, monthly, and semi-annual scheduled client and implementation meetings
   3. Facilitates and coordinates all requirements related to the contract
8. Business Analysts (2 individuals)- Dedicated business analysts assigned to the WTC Health Program account who:
   1. Qualifications
      1. Each have a minimum of three years of experience in a healthcare business analyst role
   2. Roles and Responsibilities
      1. Provide all regular client reporting within required timeframes
      2. Support program management and operations (i.e., QA, claims issues, program performance)
      3. Respond to inquiries for ad-hoc reporting on the same or next business day with estimates of the time requirement for the response and associated cost (if any).
9. Case Management Lead: a dedicated nurse case manager that is assigned to the WTC Health Program account who:
   1. Qualifications
      1. Possesses the necessary education, credentials and experience to make and oversee case management decisions
   2. Roles and Responsibilities
      1. Returns all WTC Health Program inquiries on the same or next business day
      2. Attendance at the case management forums meeting is required
10. Care Coordinator/Social Service Lead:
    1. Qualifications
       1. Possesses the necessary education, credential and experience to make and oversee care coordination decisions
    2. Roles and Responsibilities
       1. Returns all WTC Health Program inquiries on the same or next business day
       2. Attendance at the case management forums meeting is required
11. Member Services Lead:
    1. Qualifications
       1. Has at least five years of experience working with public, customers, clients or similar experience
    2. Roles and Responsibilities
       1. Oversees issues, changes, and quality around all member services functions. Works directly with the WTC Health Program Health Plan Operations Deputy and Member Services and Enrollment Unit Chief and staff

The NPN shall carry out the following key functions to administer the NPN.

1. Training Coordination: (SECTION 4.2.3)
   1. Coordinates and tracks all training provided to NPN contractor staff and Network Provider staff and support staff
2. Pharmacy Support: (SECTION 4.6.6)
   1. Establishes pharmacy program processes, quality assurance, and troubleshoots pharmacy related issues; authorizes medications based on WTC Health Program policy and Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>).
   2. Attends all quarterly P&T meetings, mandatory trainings, and other meetings that are related to the pharmacy benefits.
3. Quality Management: (SECTION 4.9)
   1. Troubleshoots issues, implements new quality initiatives.
   2. Works continuously to improve quality across NPN contractor services as well as collaborates with the Program and Network Providers to improve quality care.
4. Communications Support: (SECTION 4.4)
   1. Develops a website and web presence, develops and disseminates communication materials in plain language to members, develops and disseminates outreach materials for potential members, and collaborates with the Communication Unit chief to ensure communication needs are met.
5. Technical Support: (All Sections)
   1. Possess the skills to troubleshoot technical issues and work directly with the Program technical staff and business associates
6. Medical Claims/Billing Support: (SECTION 4.7)
   1. Possesses expertise in claims administration and adjudication aligned with managing a limited health care benefit plan.
7. Medical Coding Support: (SECTION 4.7)
   1. Possesses medical expertise in medical coding for the purposes of billing and determining coverage and the ability to audit and support network providers in understanding authorized treatment and associated coding.
8. Certification Coordination: (SECTION 4.6.3)
   1. Possesses the medical and technical expertise to assist the Medical Director and Case Management Lead in creating WTC-3 requests for members, submitting them to the program, and in troubleshooting any quality or technical issue associated with WTC-3 requests.
9. HIPAA/Privacy Oversight: (SECTION 10)
   1. Possess the knowledge and skills to oversee all HIPAA security incidents and works closely with the Program HIPAA Privacy Officer
10. Provider Network Management: (SECTION 4.5)
    1. Manages provider compliance WTC Health Program specific with terms and conditions, provider education, enrollment and disenrollment of providers, and dissemination of benefits updates to providers

The Staffing Plan is due as part of the proposal and a staffing list is due quarterly (See SECTION 8).

SECTION 4.2.2 – Participation in meetings

The NPN contractor shall participate in meetings as requested to ensure collaboration with the WTC Health Program, the CCEs, the DCs, the PBM, and other contractors to the WTC Health Program. The NPN contractor shall require the key personnel, including Medical Director, Program Manager, and staff responsible for key functions (See SECTION 4.2.1), to participate in the Responder Steering Committee Meetings, Survivor Steering Committee Meetings, Medical Forum call, Data Center outreach calls, Pharmacy and Therapeutics forum and other forums/meetings as requested.

The NPN contractor shall select qualified staff to participate in WTC Health Program meetings. Travel will be required for meetings listed below and staff must be available to travel for ad-hoc meetings as determined by the program. Required meetings include:

* Monthly outreach calls organized by the General Responder Data Center
* Weekly Medical Forum Calls
* Responder and Survivor Steering Committee Meetings
* Semi-annual or annual report meetings
* Meeting series established by CO, COR, or the Program

### SECTION 4.2.3 – Training

The NPN contractor shall establish a training plan to provide comprehensive virtual or in-person training to all appropriate NPN contract staff to ensure cohesive and quality benefits and ensure understanding of the limited-health benefit plan. Training shall be tracked and reported as required in SECTION 8.

1. The NPN contractor shall develop and provide training to all network provider staff on a regular basis, as determined by the NPN contractor Operations Manual. The NPN contractor must implement a security awareness and training program for all members of its workforce at least annually, and must provide HIPAA training to all members of its workforce at least annually and to new members of the workforce within a reasonable time after joining the NPN contractor. The NPN contractor shall work with the Program to review provider education materials for accuracy.
2. The NPN contractor shall require contractor to attend (virtually; in person or by recorded video) the WTC Health Program Administrative Overview Training within the following timeframes:
   1. All NPN contractor key personnel within 3 months of award
   2. NPN contractor staff identified as holding key functions within 3 months award
   3. All NPN contractor clinical staff, call center and other support staff within 6 months of contract award
   4. All new hires within 30 days of onboarding.
3. All NPN contractor and subcontractor staff shall attend WTC Health Program and Program contractor (PBM etc.,) hosted trainings aligned to their roles and responsibilities.
4. NPN contractor key staff and clinical staff shall remain up to date on research findings and best practices funded by the Program by attending meetings as listed in section 4.2.2.
5. The NPN must deliver NPN established “provider specific” training and resources for enrolled providers (See SECTION 4.5) to ensure they are familiar with the WTC Health Program’s billing and coverage policies and procedures, through:
   1. Orientation training for newly enrolled providers when possible
   2. Annual trainings for all enrolled providers
   3. Ad hoc trainings when requested or is otherwise determined to be necessary
   4. Established training and criteria specific to the “preferred provider group or site”
   5. Remediation training as needed
   6. Report number and types of training conducted on monthly report.
6. The NPN contractor shall train staff to respond in an emergency, or difficult situation when a conflict or violent event occurs, to ensure the health and safety of staff and members. The NPN contractor shall follow any WTC Health Program policy (to be provided upon award) that deals with such situations.
7. The NPN contractor shall provide HIPAA training to all staff that have access to personally identifiable information (PII) including personally identifiable health information (PHI).

### SECTION 4.2.4 – Risk Management

The NPN contractor shall prepare a Risk Management Plan as part of the Operations Manual. Once approved, the NPN contractor shall perform all required services in accordance with their established Risk Management Plan, document their activities, and include reports in the monthly, mid-year, and annual reports, as appropriate (See SECTION 8). The Plan shall include any potential administrative and operational program integrity risks and proposed strategies to reduce/mitigate these risks. The Plan shall be continuously assessed and updated to ensure relevant risks are mitigated appropriately.

### SECTION 4.2.5 – Change Request and Control Process

The NPN Contractor shall manage the contract to ensure the required services are being performed and the required contract deliverables are being submitted. As part of this requirement, the NPN contractor shall maintain a WTC Health Program-approved change control process to identify, record, assess, and secure approval for changes to the project. The NPN contractor and the WTC Health Program shall follow this process to classify, prioritize, approve, or reject changes, so that implementation does not negatively impact core mission applications, functions, or live production environments. The Change Request Log shall always address any variance from the baseline plan.

Change requests need to be described clearly, including their cost and schedule implications, to allow the WTC Health Program to make appropriate decisions. The NPN contractor shall require authorization by the WTC Health Program before starting any work on changes. The Program requires seven (7) business days to review and provide prior written approval for any change requests submitted by the NPN contractor. Change requests shall be tracked in a Change Request Log (see SECTION 8).

### SECTION 4.2.6 – Systems

The NPN contractor shall maintain its operating systems and ensure they are running optimally and in accordance with the HIPAA Privacy, Security, and Breach Notification Rules at 45 CFR pts. 160, 162, and 164, as well as the Federal Information Security Modernization Act of 2014 (Pub. L. 113-283). The NPN contractor must perform comprehensive systems testing and QA audits, with results reported to the WTC Health Program at least 30 calendar days prior to the “Go-Live” date. The systems may be integrated with each other to centralize and streamline access and control for secured data exchanges. These systems shall include:

1. Call center system (see SECTION 4.3.5)
2. Member portal/web-based system (See SECTION 4.3.1)
3. Provider portal/web-based system (See SECTION 4.5.5)
4. Claims adjudication system (See SECTION 4.7)
5. Electronic member record system: System must be able to store in real time Member records such as demographic information, other health insurance (OHI) information, enrollment and certification information, medical records when appropriate, prior authorization records. It must also track appointments/services rendered, document Member interactions, and hold important documents related to the Members care and Program affiliation. The system must be able to generate data reports including individual member reports as well as data reports for the entire cohort (ex: all survivor members).

## SECTION 4.3 - Member Services

The NPN contractor shall establish a comprehensive Member Services program with dedicated representatives to provide support for all aspects of WTC Health Program Member engagement including scheduling appointments, answering member and designated representative questions, benefits counseling, assistance selecting a provider, language services, and retention and outreach services. *See* Sections 3303 and 3313(b) of the Zadroga Act; 42 U.S.C. §§ 300mm-2, 300mm-23(b).

### SECTION 4.3.1 – Member Portal

The NPN contractor shall establish a web-based self-service portal (See 4.2.6) for members to:

1. schedule provider and case management appointments
2. reach out to the NPN contractor directly for questions and concerns (e.g., chat feature, feedback mechanism, receive a callback)
3. access certification records
4. access benefit information, including prior authorizations, referrals, scheduling, and care plans, and Explanation of Benefits (EOB).
5. find network providers
6. review claims related to their care.

### SECTION 4.3.2 – Transfers

The NPN Contractor shall process all transfers in accordance with the WTC Health Program Member Transfer Policy (to be provided upon award).

### SECTION 4.3.3 – Member Disenrollment

If the WTC Health Program determines that a member should be disenrolled from Program, the NPN contractor shall follow the procedures indicated by the Program and outlined in the WTC Health Program member handbook (https://www.cdc.gov/wtc/handbook.html) to assist in communicating and transitioning the member’s care to a provider(s) outside of the Program. If the NPN becomes aware of a member whose exposure may require further review or seems inconsistent with Program enrollment policies, the NPN shall notify the Program for further review.

### SECTION 4.3.4 – Member Retention

Member retention activities are those performed to maintain contact with members and encourage inactive members to participate in the Program. The NPN shall establish a Member Retention Plan as part of the Implementation Plan and Operations Manual and implement retention activities that align with the retention benchmarks and Program priorities as described in the WTC Health Program Member Retention Standard Operating Procedures (to be provided upon award).

The previously reported retention rate should not decline:

1. More than 2.0%, in absolute terms, in six (6) months, or
2. More than 0.5%, in absolute terms, in twelve (12) months.

An acceptable retention rate is when at least 65% of eligible members have received a monitoring exam in the previous eighteen (18) months. All records of completed exams during the lookback period must be added to the database before the calculations are made. This rate shall exclude members who:

* + - 1. Are deceased,
      2. Have stated they do not want to participate in any aspect of the Program and do not want to be contacted again, or
      3. Have no valid contact information on file and therefore cannot be reached.

### SECTION 4.3.5 – Member Call Center

The NPN contractor shall provide a service center (call center/helpdesk/support) with knowledgeable and accessible representatives that are well trained in the specifics of the WTC Health Program. The call center must provide accurate and timely information to members, prescribers, pharmacies, CCE/NPN staff (when applicable), and the WTC Health Program staff and be able to resolve issues quickly, which is vital to the success of the Program. The NPN shall provide the following call center system and operational features:

1. Furnish a dedicated toll-free number exclusive to WTC Health Program for incoming service calls, including telephone technology for the hearing impaired and multi-lingual support.
2. Ensure call center staff have access to Member records and consent forms (e.g., HIPAA, Designated Representative forms, etc.)
3. Interactive Voice Response (IVR) system messaging that is exclusive to WTC Health Program member services.
4. Service shall be available in multiple time zones and multiple languages (See SECTION 4.3.8 and SECTION 4.3.7).
5. Management of call scripting/messaging; regularly update call scripts that have been reviewed and approved by the Program for accuracy.
6. Service call centers located in more than one geographic region to permit continuous operations in the event of a local disaster or business disruption.
7. On-call emergency messaging for returned calls within 8 hours.
8. Warm transfer call routing capability for members so they do not have to disconnect from the original call to call separate services such as Case Managers, WTC Health Program Main Call Center, Victim’s Compensation Fund Call center etc.
9. Average Speed of Call Answer within 20 seconds or fewer.
10. Call Abandonment rate of fewer than 2% of calls.
11. First Call Resolution Rate of 98%.
12. Written member inquiries shall be answered within ten business days of receipt.
13. Provide service support for claims.
14. Provide translation services for Spanish, Polish, Chinese, and other languages (e.g., Russian).

The NPN contractor shall maintain and make available to the government for audit materials including call logs, call records, notes, documentation, quality controls, and reporting. A call activity and quality control summary shall be provided no less than quarterly to provide trend analysis and outliers. In addition, the NPN contractor shall coordinate quarterly calls with the WTC Health Program to perform a call audit where calls are listened to for quality assurance. The audit shall review for quality, accuracy, and courtesy. Coaching opportunities for Call Center staff shall be identified as well as improvements in language and processes. Upon request, NPN contractor shall provide digital recordings of phone calls within two (2) business days of request. The NPN contractor shall save all call recordings for a minimum of 90 days and store the recordings in an environment secured to the level of their system and data types being saved, in accordance with the security requirements in Section 11. The NPN shall notify the Program when the call center lines are unavailable, assess and mitigate the impact of the call center’s unavailability, and inform the Program when the issue is resolved.

The NPN contractor call center shall be able to handle, the following matters:

1. Answering general questions about Program processes (such as eligibility or condition coverage)
2. Serving as a reference for questions about the medical review process
3. Serving as a liaison between programs to direct points of contact to the right entity (for example, participating in three-way calls between Program and members for complaint resolution)
4. Scheduling monitoring exam and treatment appointments for Program members assigned to the NPN
5. Explaining the member’s rights and responsibilities as a member of the WTC Health Program’s NPN
6. Answering questions regarding the research consent form. The consent form is only needed one time to record the member’s agreement to allow their past and future information to be used for research purposes, and the consent is optional. If a consent form is not signed, the information may still be used for internal analyses for purposes of the WTC Health Program.
7. Explaining the benefits and covered services offered under the WTC Health Program’s NPN, including covered conditions and limitations
8. Providing Program information updates to members and providers (such as newsletters, letters, brochures, emails)
9. Explaining the process for obtaining WTC Health Program NPN services (e.g., eligibility)
10. Providing information on the NPN providers from whom members may obtain services
11. Fielding and responding to member questions and complaints regarding NPN benefits and/or services (i.e., captured from member satisfaction survey, the resource line, or Case Managers)
12. Advising members of the applicable complaint and appeals procedures, and the member’s rights to a fair review as outlined in the Member Handbook (https://www.cdc.gov/wtc/handbook.html) and WTC Health Program Administrative Manual (https://www.cdc.gov/wtc/ppm.html)
13. Assisting with obtaining medical records, including processing member requests to release protected information
14. Assisting in outreach efforts to locate enrolled members who have been inactive or lost to the Program
15. Assisting in member transfers (See SECTION 4.3.2).

Call Center Staff Training

The Call Center staff supporting the NPN contractor’s Call Center shall provide the specific training hours for all call center staff (See also SECTION 4.2.3):

1. A minimum of 40 hours provided by the NPN contractor of training prior to taking live calls; including WTC Health Program Administrative Overview (See SECTION 4.2.3).
2. Receive a minimum of two hours of initial training or re-training per year in the specifics of the WTC Health Program.
3. Receive annual HIPAA training for all workforce members and receive HIPAA training for new members of the workforce within a reasonable time of their joining the NPN contractor.
4. Receive training on an ad-hoc basis as major Program changes are made. WTC Health Program Culture Training shall be a standard component of the NPN’s operations to orient new team members and serve as a refresher training for existing team members.

### SECTION 4.3.6 – Benefits Counseling

The NPN contractor shall provide benefits counseling through implementing the Benefits Counseling Eligibility Assessment and Screening Tool (BEAST), an electronic tool that generates a customized benefits-counseling plan for an individual member based on the member’s responses to the BEAST questions (to be provided upon award). Benefits counseling includes all Program benefits, changes to benefits, and information on workers’ compensation, other health insurance, health insurance under the Affordable Care Act, and social services, to facilitate the members’ efforts to acquire those benefits.

The BEAST shall be administered in conjunction with each annual monitoring visit, with additional administrations upon request or as appropriate based on changes to member status that may affect benefit eligibility (e.g., certification). The NPN contractor shall monitor and report on BEAST implementation to ensure that each active member is administered the initial or updated BEAST in the semi-annual and annual report. Documentation of BEAST assessment shall be part of member records.

### SECTION 4.3.7 – Translation Services

The NPN contractor shall provide or have access to over-the-phone interpretation (OPI) service. These services commonly provide a minimum of 100 languages and dialects including  Spanish, Mandarin, Cantonese, Polish, Russian, Italian, and Portuguese. The NPN contractor shall also provide written translational services to include Spanish, Chinese, and Polish while ensuring consistency in translated materials by implementing the translation guide that will be provided by the Program and assess the member needs and report on utilization for translation and interpretive services semi-annually.

### SECTION 4.3.8 – Availability of Member Services

Member services including, the call center, scheduling, and case management shall be accessible during business hours for all geographic time zones in the U.S. mainland including Eastern Time (ET), Central Time (CT), Mountain Time (MT), and Pacific Time (PT). The NPN shall identify when members reside in the U.S. territories and accommodate partial business hours (e.g., 2 hours per week) for Alaskan Time (AKT), Hawaii-Aleutian Time (HT), Samoa Time (UTC-11) and Chamorro Time (UTC+10).

### SECTION 4.3.9 – Disruptive Members

The NPN contractor shall establish and train NPN staff on procedures to address disruptive members. The NPN contractor shall work with the WTC Health Program Member Services Unit to align the procedures with Program policy. The NPN contractor shall report to the Program within 10 days on the Disruptive Member Incident Report of the situations deemed by the NPN contractor as “disruptive” to coordinate further communication.

## ­SECTION 4.4 – Communication

The WTC Health Program is responsible for content of all public facing materials. The NPN must utilize available WTC Health Program materials when communicating with members about the Program. Generally, the Program’s Communications Unit produces communication products that are applicable to the entire WTC Health Program cohort.

The NPN is responsible for creating NPN-specific communications to NPN members and the public. For example, communications related to the NPN’s specific policies and procedures, decisions, and operations. The WTC Health Program Communications Unit must approve all NPN developed communication materials using the process described in the Administrative Manual (https://www.cdc.gov/wtc/ppm.html). All communications shall be developed by NPN contractor staff with communications, marketing, or similar experience. NPN contractor communications staff must collaborate with the WTC Health Program Communications Unit to ensure topics deemed important by the Program are disseminated to NPN members in a timely manner. The NPN contractor shall follow the WTC Health Program co-branding guide (to be provided upon award) and seek approval anytime it is using the WTC Health Program logo.

### SECTION 4.4.1 – Communication Products

The NPN shall be responsible for developing a Communication Plan outlining communication products and activities each year. This plan must be developed following the applicable to WTC Health Program policy and shall be submitted with the Operations Manual. (Technical Guidance and related policy documents will be provided upon award).

All communication products must be translated into Spanish, Chinese (traditional and simplified), and Polish and be made available to members who select that language preference. The WTC Health Program translation guide must be used to ensure accurate and consistent messaging in translated materials. The translation guide will be provided at the time of award by the Communications Unit.

The NPN contractor must have the ability to develop and mail letters, welcome packets, and other communication materials as appropriate. The NPN shall track bounce rates, open rates, and returned mail to ensure Program messages are meeting the needs of the audience. After mass mailings or large email blasts, the NPN shall report these findings to the Communications Unit in the monthly reports, when applicable. This shall be used to guide future communication products.

Communication products include:

1. Welcome packets - The NPN contractor shall provide new members welcome packets that includes guidance on next steps, program materials, and answers to frequently asked questions. The welcome packet must be reviewed and approved by the Program’s Communications Unit prior to implementation and reviewed annually.
2. Website - The NPN contractor shall develop a website with information about the NPN for members and potential NPN members. The contractor must have all content approved by the Program to ensure the website has accurate information and uses appropriate branding and link strategy.
3. Digital Communication - The NPN contractor should also propose other methods of digital communication for interacting with members such as social media, email, newsletters, etc. to establish a regular cadence of communication with NPN members.
4. When requested by the Program, NPN shall provide Members with written notice when changes occur that may affect their medical or pharmacy benefits.

### SECTION 4.4.2 – Retention activities for current members

The NPN contractor must perform retention activities for current members. The NPN contractor must coordinate with the Program to review and approve materials and activities prior to implementation. All retention activities must be included in the Communication Plan in adherence to WTC Health Program policy. Retention activities should be aimed at maintaining contact with members and encourage inactive members to participate in the Program. These communication products and activities should include education to members about WTC Health Program medical and pharmacy benefits and encourage members in the NPN to utilize available benefits. These activities should help the NPN meet the established retention metrics (See SECTION 4.3.4).

### SECTION 4.4.3 – Outreach and Education for current and prospective members

The NPN contractor must provide outreach and education to potential members. The NPN contractor must coordinate with the Program to review and approve materials and activities prior to implementation. All retention activities must be included in the Communication Plan in adherence to WTC Health Program policy. Retention activities should be aimed at maintaining contact with members and encourage inactive members to participate in the Program. These communication products and activities should provide information about enrollment in the NPN and ensure all members enrolled with the NPNare informed about the ability to receive care in the NPN.

## SECTION 4.5 –Nationwide Provider Network Management

The NPN contractor shall establish and deliver a nationwide provider network for the WTC Health Program with access to quality services using a comprehensive network of health systems and providers to adequately and efficiently serve members who live in all U.S. states and territories outside of the NYMA as defined in Section 3313 of the Zadroga Act; 42 U.S.C. § 300mm-5. The NPN contractor shall submit a Network Management Plan as part of the Implementation Plan that covers the contractor’s approach to network development and maintenance as well as monitoring network adequacy and quality. The NPN contractor’s provider network shall be in place at the start of healthcare delivery.

### SECTION 4.5.1 – Network Composition

The network shall include experienced providers currently practicing in occupational, internal, or family medicine, and board-certified specialists, all with no active disciplinary actions. The providers must be easily accessible by car, train, or bus in convenient locations within the mileage standards of member (see Administrative Manual, <https://www.cdc.gov/wtc/ppm.html>) residence. The NPN may also enroll providers who are already enrolled in the WTC Health Program provider network.

The network shall include enrolling:

1. Hospitals
2. Post-acute care facilities
3. Rehabilitation facilities
4. Outpatient surgery centers
5. Urgent care facilities
6. Specialty clinics
7. Trauma centers
8. Specialists
9. Primary care physicians
10. Durable medical equipment providers
11. Home health care providers
12. Hospice Providers
13. Dental providers

When enrolling providers, the NPN contractor shall collect the following provider information including the provider’s National Provider Identifier (NPI), tax ID, Drug Enforcement Administration (DEA) number, license number, credentialing information and all information to be included in the contractor system. The contractor shall be responsible for the accuracy and completeness of provider enrollment data. The contractor shall establish and maintain the provider directories that capture the following information for each network provider:

1. Provider Name
2. Provider Gender
3. Provider place of practice address
4. Provider appointment telephone number
5. Provider Type
6. Provider Specialty
7. Provider Subspecialty
8. Provider quality indicator(s)
9. Provider website (if available)
10. Telehealth availability
11. National Provider Identifier (NPI)
12. Tax Identification Number (TIN)
13. Drug Enforcement Administration (DEA) Number

### SECTION 4.5.2 – Network Development and Agreement

The NPN contractor shall be responsible for identifying, contacting, negotiating, and contracting with hospitals, physicians, and other healthcare professionals and practitioners to serve members who reside outside of the NYMA. If the NPN contractor chooses to leverage existing provider networks or relationships, they must develop an approach to systematically update provider agreements to ensure compliance with this contract. The network providers must agree to the terms and conditions of the Program approved network agreement. The agreement must include terms that specify a provider fee ceiling set at rates paid under the Federal Employees’ Compensation Act (FECA), administered by the U.S. Department of Labor (DOL). For treatment not covered under FECA, the fee ceiling is pursuant to the applicable Medicare fee for service rate. The agreement shall also include requirements for coordination of benefits, training and communication requirements, compliance with Program and/or NPN contractor led audits that require submission of member medical records, a prohibition on balance billing members, and compliance with utilization management standards.

The NPN is responsible for preventing and resolving any incidences of balance billing from providers. The NPN is responsible for collaborating with providers to ameliorate any claims denial trends and provide support to members impacted by inappropriate billing.

### SECTION 4.5.3 – Network Adequacy and Evaluation

The contractor shall perform a comprehensive assessment aligned with the Quality Assurance Plan (QAP) (SECTION 4.9), requirements and adjust provider networks as needed. Network adjustments may result from changes in the number of members in each region, providers leaving the network, or other unexpected changes in the needs of the network. This comprehensive assessment shall include a review of the network to identify gaps in specialty providers and mitigation strategies.

### SECTION 4.5.4 – Network Quality of Care

In compliance with the NPN requirements and approved Quality Assurance Plan (SECTION 4.9), the NPN contractor shall ensure all network providers are appropriately licensed, credentialed, and have an approved network enrollment agreement in place. The contractor’s provider verification services shall include a provider screening solution which continuously monitors all actively enrolled providers and related parties, generates alerts based on changes in risk factors, and automates the end-to-end provider screening process during all enrollment and re-enrollment periods.

The contractor shall maintain accreditation of its healthcare network by a national accrediting organization (National Committee for Quality Assurance (NCQA) or Utilization Review Accreditation Commission (URAC)) throughout the contract or otherwise demonstrate that they meet equivalent standards. In cases where the standards of the NPN contractor and those of the accrediting body conflict, the higher standard shall apply. The contractor shall ensure that all providers in the provider network are properly licensed under applicable state laws and/or regulations and are properly insured. The contractor shall review licensing and insurance documentation on a semi-annual basis.

The contractor shall ensure that all providers are trained in accordance with the Operations Manual and PWS training requirements (See SECTION 4.2.3). Training should, at a minimum, ensure that providers are educated regarding the limited care nature of this program, service authorization requirements, program specific diagnosis codes, fee limitations, and billing and dispute pathways. Training shall occur at provider enrollment and on an ongoing basis as needed.

The contractor shall establish mechanisms to evaluate network providers by performance, quality metrics tied to outcomes, patient experience, patient safety measures, operational efficiency, and access (See SECTION 4.9).

SECTION 3305 of the Zadroga Act gives the Data Centers (DCs) responsibility “for establishing criteria for the credentialing of medical providers participating in the nationwide network under SECTION 3313.” If NPN credentialing is changed based on the input of the DCs, the WTC Health Program Administrator will work with the NPN contractor and the DCs to align the credentialing criteria and modify the NPN contract accordingly.

### SECTION 4.5.5 – Provider Portal

The NPN shall provide a comprehensive online self-service provider portal. The provider portal may be integrated with the claims portal and/or member portal to centralize and streamline access and control for secured data exchanges. The provider portal should include providing access to:

1. claims submission
2. monitoring of claims status
3. monitoring of payment status
4. review of claims appeal or correction
5. access to the current fee schedules
6. access to approved member benefit plans
7. inquiry of member eligibility
8. inquiry of member prior authorization and referrals

## SECTION 4.6 – Administer Healthcare Benefits

The NPN contractor shall administer health care benefits and member services to both responder and survivor members of the WTC Health Program living outside of the NYMA unless otherwise approved by the WTC Health Program. All Program benefits provided through the NPN must be medically necessary and administered only to qualified enrolled members, and must comply with all the Program’s policies and procedures and the WTC Health Program Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) (Sections 3313, 3321, 3322, and 3323 of the Zadroga Act; 42 U.S.C. §§ 300mm-23, 300mm-31, 300mm-32, and 300mm-33). The NPN contractor’s Medical (or Clinical) Director shall provide clinical and administrative oversight for adherence to monitoring protocols and medical necessity of rendered treatment.

### SECTION 4.6.1 – Initial Health Evaluations and Annual Monitoring Exams

Initial Health Evaluation

The NPN shall provide one Initial Health Evaluation (IHEs) to screening-eligible survivors and responders. The examinations shall be conducted by qualified and credentialed providers, preferably ones specializing in Occupational Medicine (see SECTION 4.5.1).

IHE is a baseline (initial) exam that includes a Medical History Questionnaire (MHQ) (to be provided upon award), which consists of an occupational history, clinical history, and review of symptoms; an exposure assessment; vital signs assessment; EKG (if appropriate); spirometry testing; blood and urine analyses; a chest x-ray (as needed); and a physical examination (TGD 011 to be provided upon award). The MHQ may be conducted via mail, online platform, or telephone. Scheduling this evaluation shall be completed within 12 months of eligibility into the Program or assignment to the NPN.

Annual Monitoring Exam

The Annual Monitoring Exam (AME) is a follow-up monitoring examination for all responders and certified-eligible survivors that includes the same components of the IHE except for the exposure assessment.

These exams are intended to:

1. provide physical and mental health assessments designed to identify acute and latent health effects related to a member’s exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks
2. serve as an avenue for clinical data collection, analysis, and reporting to ensure that all services provided adhere to appropriate protocols
3. inform the diagnosis of WTC-related or medically associated conditions that could lead to certification and a treatment referral
4. Inform the member an illness is determined not to be WTC-related and coordinate referrals to provider outside of the NPN
5. Inform the member that no illness is detected/diagnosed
6. If a screening-eligible survivor is found to have no WTC-related conditions, the member will be counseled regarding conditions that may develop in the future and self-pay requirements for subsequent exams.

The NPN contractor shall provide exam results for both AME and IHE to the member within 15 business days after completion of the exam(s).

### SECTION 4.6.2 – Diagnostic Services

Diagnostic services are available for survivors during the diagnostic process during the IHE period and for responders during their first Annual Monitoring Evaluation (AME) and during all periods of annual monitoring. Both responders and survivors may continue diagnostic services when test results require continued testing for conclusive diagnosis that may result in a WTC-related certification. Diagnostic services during the certification process may continue. The NPN contractor shall provide continued appropriate and necessary diagnostic testing until a determination is made by either the NPN contractor Medical Director to move the certification request forward to the Program, or until the Program has made a determination. These diagnostic services may include specialty consultation and/or temporary treatment to enable differential determination of a covered condition, or to determine the condition is not WTC-related or medically associated with a WTC-related condition. Upon determination that the condition is not due to 9/11 exposure, the NPN contractor shall refer the member to an appropriate provider using non-WTC benefits. Diagnostic services shall not be continued after the date of denial.

### SECTION 4.6.3 – Certifications

When an enrolled member’s AME, IHE, or other diagnostic evaluation detects an illness or health condition on the list of WTC-related health conditions, and the network provider determines it is likely related to the member’s exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks, then this determination shall be submitted to the NPN contractor’s Medical Director for determination as indicated by the Program’s Administrative Manual (https://www.cdc.gov/wtc/ppm.html).

If the NPN contractor’s Medical Director concurs with the provider’s assessment, the Medical Director shall attest that the member’s exposure is substantially likely to be a significant factor in aggravating, contributing to, or causing the health condition, and shall request certification for the health condition from the Program. The Medical Director may request additional medical testing to confirm a diagnosis of a newly detected WTC-related health condition and/or a health condition medically associated with a given certified WTC-related health condition. Based upon the attestation, the WTC Health Program Administrator will review the request and determine if the certification should be approved or denied. Certification requests must meet all the requirements in the Program Policies and Procedures and Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) prior to submission to the Program.

### SECTION 4.6.4 – Cancer Screening

The NPN contractor shall develop, document as part of the operations manual, and implement procedures to provide screenings for lung, colon, breast, and cervical cancers following the U.S. Preventive Services Task Force (USPSTF) recommendations. The Program’s [Administrative Manual](https://www.cdc.gov/wtc/ppm.html) (https://www.cdc.gov/wtc/ppm.html) indicates which members are eligible for screening and the extent of testing included as part of the cancer screenings within the Program’s limited-care benefits.

### SECTION 4.6.5 – Treatment for Certified Conditions

Under section 3312 of the Zadroga Act (42 U.S.C. § 300mm-31), all treatment services must comply with an established standard for medical necessity and the Program’s treatment guidelines contained in the Program’s [Administrative Manual](https://www.cdc.gov/wtc/ppm.html) (<https://www.cdc.gov/wtc/ppm.html>). The NPN contractor’s Medical Director shall ensure that all medical benefits and treatment are reasonable and appropriate types and levels of care based on medical necessity principles and the medical treatment protocols approved by the WTC Health Program Administrator. The Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) and Program Codebook describe authorized services, service limitations, and services that require prior authorization for reimbursement.

### SECTION 4.6.6 – Pharmacy Services

The WTC Health Program contracts with a Prescription Benefits Manager (PBM) to provide comprehensive pharmacy benefits to Members including customer service, claims adjudication, pharmacy network management, and formulary management. The WTC Health Program makes all decisions related to the pharmacy formularies which are continuously developed and updated. The Program reserves the right to put restrictions on medications when necessary to ensure medication use complies with program policy.

The NPN contractors role in pharmacy services is to provide oversight of members utilization of pharmacy benefits as described in the Program Administrative Manual (https://www.cdc.gov/wtc/ppm.html) . The NPN contractor must develop processes and protocols to manage pharmacy services and document these in the Operations Manual (SECTION 8). Any changes made to processes should be updated within 30 business days in the Operations Manual. This should include:

1. Ensuring there are dedicated NPN staff with adequate experience and training to manage and troubleshoot pharmacy related issues.
2. Providing sufficient education and training to NPN staff regarding the web-based systems used by the PBM or Program, processes required to manage a member’s pharmacy benefits and pharmacy benefits rules, limitations, processes, and procedures. This includes requiring applicable staff to attend trainings provided by the Program or PBM.
3. Educating members about their pharmacy benefits.
4. Educating NPN enrolled providers on the Program pharmacy benefits, limitations, processes, and procedures, and web-based systems when applicable.
5. Encouraging providers enrolled with the NPN to utilize an e-scribing software program that is compatible with the WTC Health Programs PBM e-scribing software system. This will allow the provider to confirm member eligibility and formulary requirements for a prescription prior to sending the prescription to the network pharmacy (e.g., Surescripts).
6. Requiring at least 70% of providers enrolled with the NPN to utilize an e-scribing software program that is compatible with the WTC Health Programs PBM e-scribing software system.
7. Ensuring that the NPN and/or the enrolled providers follow the Program’s requirements for submitting prior authorization or medical necessity documentation for prescription authorizations when applicable.
8. Optimizing Member benefits and cost effectiveness by ensuring medications are prescribed in accordance with the Programs formulary requirements.
9. Documenting medical necessity for prescriptions.
10. Implementing processes and other safeguards to ensure that all prior authorization submissions or decisions are made by a practicing clinician with appropriate knowledge of the medication being prescribed, the Member’s certified condition, and their treatment plan.

Pharmacy Benefits Quality Assurance and Reporting

Prescription data will be available to the NPN for quality management purposes. The NPN shall implement quality assurance for prescriptions including:

1. Performing prescriptions audits
2. Reviewing pharmacy claims data to identify anomalies, outliers, utilization, and prescribing trends.

In addition, the Program will provide reports to the NPN with analysis of prescription activities. This information shall be used to determine cost savings opportunities, inappropriate prescribing trends, compliance with benchmarks set by the Program, and to provide relevant conclusions on their population health status and outcomes. Such reports may include:

1. Annual Pharmacy Evaluations
2. Pharmacy Outlier Reports
3. Monthly pharmacy claims audits
4. Semi- annual reports

### SECTION 4.6.7 – Case Management

The NPN contractor shall provide a comprehensive, regionally appropriate, case management (CM) Plan, including clinical and non-clinical care services that facilitates effective resource coordination throughout the continuum of care. The NPN contractor shall know and understand the clinical, social, and administrative needs of its member population and how they relate to the Program’s limited-care model. The NPN shall assess active members for case-management service needs as clinically indicated through member outreach and medical monitoring. Case Managers shall address the unique health care needs of individual members and improve client satisfaction with the Program.

The NPN contractor shall provide their CM Plan as part of the Operations Manual. It should include details of their team structure and align with the WTC Health Program’s Case Management/Utilization Management Standard Operating Procedure. Staffing shall include both clinical (Registered Nurse Case Managers and Social Workers) and non-clinical staff (such as Care Coordinators).

The NPN must include case management reporting requirements in the semi-annual and annual reports as described in TGD-003 (to be provided upon award) and the Administrative Manual (https://www.cdc.gov/wtc/ppm.html) .

Regional Case Management

In addition to establishing a CM Plan aligned with the WTC Health Program Case Management Operating Procedures, the NPN shall provide a regionally based coverage model to meet the unique locality needs of the NPN members. The regional plan should also include:

1. Registered Nurse (RN)/Social Worker (SW) caseloads assigned by regional location
2. RNs shall hold licensures based on their regional areas of coverage according to the Case Management Society of America standards of practice (cmsa.org)
3. Regional Case Management teams must make it a priority to ensure close coordination with their members for prior authorization of medical services and collaboration with Utilization Management to ensure medical service necessity and appropriate discharge planning where applicable
4. Case Management services shall be accessible during business hours for all geographic time zones in the United States, including Alaska and Hawaii (SECTION 4.3.8).

### SECTION 4.6.8 – Utilization Management

For detailed information on the NPN Utilization Management program requirements, refer to the Case Management/Utilization Management Standard Operating Procedure and applicable TGD’s (to be provided upon award).

The NPN contractor shall establish a formal utilization management process with secure documentation platform, nationally recognized evidence-based guidelines, and timeline for initiation and expansion of the UM process. These plans must be included in the Operations Manual. Utilization Management program must follow regional availability requirements as described in Section 4.3.8. The contractor shall develop a plan to implement Concurrent Review (CCR) and Continued Stay Review (CSR) (See DEFINITIONS SECTION).

The NPN shall provide a UM plan as part of the Operations Manual to include the following elements:

1. Review of authorizations for medical necessity (prior authorization/prospective reviews and retrospective authorizations) as related to member’s WTC certified condition(s)
2. Notification process for members admitted for inpatient (IP) hospitalizations, as well as all other levels of care including:
   1. Rehabilitation
   2. Skilled nursing facilities
   3. Home health care
   4. Any post-acute care facility or service
3. Concurrent (medical necessity) review (CCR) and Continued Stay Review (CSR) processes for IP hospitalizations
4. Medical necessity review of outpatient procedures and services
5. Discharge planning
6. Post-discharge outreach in coordination with case management

The NPN must include utilization management reporting requirements in the semi-annual and annual reports as described in TGD-003 (to be provided upon award) and the Program’s Administrative Manual (https://www.cdc.gov/wtc/ppm.html).

## SECTION 4.7 – Medical Claims Processing and Pricing

The NPN contractor is responsible for processing WTC-related medical claims for NPN members. (Codebook to be provided upon award).

### SECTION 4.7.1 - Medical Claims Reimbursement Rate

As required by the Zadroga Act and the Program’s regulations at 42 C.F.R. 88.22, the WTC Health Program Administrator shall reimburse costs for providing a WTC Health Program member an initial health evaluation, medical monitoring, and/or medically necessary treatment for certified WTC-related health condition or a health condition medically associated with a WTC-related health condition according to the payment rates that apply to the provision of such treatment and services under the Office of Workers’ Compensation Program (OWCP) Federal Employees Compensation Act (FECA). The Administrator will reimburse costs for treatment for which FECA rates have not been established pursuant to the applicable Medicare fee for service rate, as determined appropriate by the Administrator; reimbursement for costs for treatment for which neither FECA nor Medicare fee for service rates have been established will be made at rates as determined appropriate by the Administrator. These rates are applicable to each individual claim. Information on the FECA rates can be found at <https://www.dol.gov/owcp/dfec/>.

The contractor shall ensure that all provider network agreements specify a provider fee ceiling set at rates paid under FECA, administered by the U.S. Department of Labor (DOL). For treatment not covered under FECA, the fee ceiling is pursuant to the applicable Medicare fee for service rate.

Fee Schedule (https://www.dol.gov/agencies/owcp/regs/feeschedule/fee): The contractor must use the applicable payment fee schedule provided by WTC Health Program to determine and apply reimbursable amounts for each authorized claim. The Program will provide a reference to FECA, Medicare, or another program that will allow the contractor to identify the appropriate fee schedule the contractor must use to pay claims. The Program will provide the contractor with all current and applicable Fee Schedules upon award. A modification is not required for the contractor to implement Fee Schedule revisions. The contractor shall have no more than 30 days to implement the new/updated Fee Schedules from the date it is provided to the contractor. Some Fee Schedule revisions taking place within a fiscal year may require retroactive payment adjustments based on date of service, but Contractor cannot collect if the new revised rate is retroactive and lower than the previous rate. If WTC Health Program identifies errors in the Fee Schedule, the contractor shall accept rate corrections to those errors within 30 days.

Maximum Allowable Charges Schedule: The WTC Program Administrator will determine the fee when codes are not available on the Fee Schedule.

### SECTION 4.7.2 – Claims Processing and Payment

The contractor shall receive, process, and adjudicate claims for all services provided to WTC Health Program members pursuant to this contract.The contractor shall ensure that its claims processing and payment system and capability meet industry standards and aligns with the Program’s medical policy. Once a claim is fully adjudicated, the contractor will submit the claims directly to National Government Services (NGS) for payment. The contractor’s claims system shall utilize an existing automated end-to-end claims processing system with modern software development based on the ability to create clean claims and route claims for optimal processing using systems capable of intelligent decision making that combines business rules management, decision processing, real-time event detection, decision governance and powerful advanced analytics to automate and manage decisions across the enterprise. The claims system shall also be capable of automated high-volume data capture and routing focused on the Government’s requirement for continuous delivery.

The contractor shall utilize an existing automated claims processing system to process and adjudicate claims with business rules to apply WTC Health Program’s distinct benefit coverage plans (to be provided by upon award). The contractor shall also work closely with the Program to enter into a data sharing agreement with the HPS contractor to exchange enrollment and certification information to ensure that the NPN maintains up-to-date information on member benefits and accurately adjudicates incoming claims.The contractor’s claims processing system must always determine if a claim is ready for processing by ensuring the claims processing system contains all the standard requirements of all standard EDI transaction types as well as those fields required for WTC Health Program claims processing. The contractor shall process claims in accordance with all applicable federal and state statutes and regulations. The contractor’s claims adjudication system shall validate claims against member profile (to ensure enrollment, certification, eligibility, and benefit coverage are in alignment) and provider enrollment and current provider reimbursement fees to properly adjudicate claims. The contractor shall develop rules to apply WTC Health Program policies from codebooks, care suites, benefit monitoring and treatment plans (provided during implementation), incorporating those policies in its claims adjudication system. The contractor’s claims processing system must always accept electronic claims in EDI 837P, EDI 837I, and EDI 837D format transactions, as appropriate, and create the EDI 835 remittance transaction.

The contractor shall ensure claims not processed to completion and any associated supporting documentation will be retrievable by Member name and WTC Health Program ID number. The contractor is responsible claims routing if or when the Program acquires a new clearinghouse. The contractor shall develop rules to apply the correct fee schedule based upon WTC Health Program payment policy and ensure that correct payment schedules are used to pay providers.

The Implementation Plan shall provide details on how the NPN contractor shall ensure that its claims processing system is ready to appropriately adjudicate claims at the start of healthcare delivery. Claims testing must be incorporated as part of the plan. The contractor’s claims adjudication system shall be available for testing with WTC Health Program staff within 30 days of “Go-Live” date. Following testing, the contractor shall submit a Claims Adjudication Readiness Attestation to affirm that systems and processes are available and fully functional. If claims adjudication issues emerge following the “Go-Live” date that prove the Attestation was not true, the contractor shall be assessed a penalty each week that the issues continue. The contractor is responsible for updating its own systems to meet Program’s payment policy.

### SECTION 4.7.3 – Payment Rules

The contractor shall establish business rules to guide Claims Adjudication and ensure processing complies with WTC Health Program medical policy, reimbursement rates, and provider guidance to ensure claims are appropriately adjudicated and paid. During implementation, the contractor shall submit a proposed Data Dictionary and claims adjudication rules to be validated and affirmed by the WTC Health Program. At a minimum, the contractor’s rules must ensure claims are based on FECA rates, up to date procedure codes, industry standards and best practices.

The contractor’s claims processing system must present adjudication rules during implementation to ensure benefits, reimbursement, eligibility, and certification is accounted for and applied. Example requirements include:

1. Administrative Charges: The contractor’s claims processing system must classify as non-covered and deny any administrative charges imposed by the provider related to completing and submitting the applicable claim form or any other related information.
2. Duplicate Claims: The contractor’s claims processing system must deny, as a duplicate claim, any claim that was previously submitted by a provider for the same service provided to a particular individual on a specified date of service.
3. Benefits: The contractor’s claims processing system must deny, as not being a covered benefit, any claims submitted for a medical service that is not included as part of the Member’s benefit plan, per the WTC Health Program Codebook.
4. Claim Forms: The contractor must reject any claims submitted on unapproved claim forms. When an unapproved claim form is submitted, the contractor must always notify the claimant in writing that in order to be considered for payment the claim must always be submitted on approved claim forms and that any additional information, if required, must always be submitted and received by the contractor within the timely filing deadline. Acceptable forms include those in Section 4.7.2, claim forms CMS 1500, UB04, and ADA (dental claims).
5. National Provider Identifier (NPI) Claims: The contractor must use the NPI to process claims from covered entities except for number 6 below. The contractor must always deny claim transactions received that do not include a valid NPI.
6. Non-NPI Claims: The contractor must use Taxpayer Identification Number (TIN) to process claims for providers who are not eligible to receive an NPI. The contractor must always deny claim transactions received from providers without their TIN.
7. Timely Filing Deadline and Clean Claims Requirements: See TGD 007 and 010 (to be provided upon award).
8. Secondary Payer: In instances when the WTC Health Program is not the primary payer, the contractor shall grant additional time to the claims filing deadline requirements for members with Other Health Insurance (OHI) or Other Workers Compensation Insurance (OWCI) when the provider first submitted the claim to the primary payer and the adjudication occurred past the WTC Health Program’s filing deadline. The contractor shall ensure claims for services denied by another insurer include the Explanation of Benefits (EOB) or Remittance Advice (RA) statement indicating the dates of service, amount of the claim, and reason(s) for denial. The Contractor shall deny all OHI and OWCI claims submitted beyond ninety (90) days from the date of the other insurer’s adjudication, unless covered by WTC Health Program exception(s).
9. WTC Health Program may also modify which CPT codes are part of the Fee Schedule.
10. Claim Adjustment: The contractor’s claims processing system must identify a request for a payment adjustment (positive/negative) to a prior payment for healthcare services by appending the original claim number with a suffix sufficient to identify and document the number and order of adjustment requests received and processed on the original claim. All claim adjustments must be completed within twelve (12) months from the original payment date.
11. Recovery of overpayment: The NPN Contractor shall provide a proven process for prompt recovery of overpayment to the government.
12. Balance Billing: The NPN Contractor and associated network providers are strictly prohibited from billing members enrolled in the Program. The NPN Contractor must:
    1. Provide a comprehensive approach to avoid balance billing members.
    2. Report all incidences of inappropriate billing with a corrective action plan.
    3. Specify prohibition of balance billing to member in the provider agreement.

Following validation from the WTC Health Program, the contractor shall deliver a finalized Data Dictionary as part of the operations manual that includes all capabilities for auto-adjudication, rejection, return, and denial of a claim. The contractor’s claims processing system must include standard business rules and edits in its Data Dictionary. The contractor’s claims processing system must be capable of adding rules and edits based on information from the Program, including the application of FECA, CMS, and WTC Health Program Fee Schedules. When the WTC Health Program requests a change, the contractor must implement the change within thirty (30) days, or as mutually agreed upon by the parties. When industry changes occur that require planning, testing, implementation, and compliance readiness dates, system change orders shall be made in accordance with industry standards.

### SECTION 4.7.4 – Paper Claims

Prior to submission to the WTC Health Program, paper Claims received by the contractor shall be converted to standard EDI transactions to be consistent with the most recent CMS approved Claims formats, specifically to include EDI transactional data requirements referenced in Section 4.7.2. WTC Health Program cites as reference the November 2011 National Uniform Claim Committee 1500 Claim Form Map to the X12N Healthcare Claim: Professional 837. The contractor must establish a billing and Claims adjudication process using the fields of the most current CMS-1500 Claim form for CIHS Claims as found on the CMS website

(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf).

### SECTION 4.7.5 – Issuance of Remittance Advice

The contractor shall provide an 835 RA to all providers via EDI when available. Where providers do not currently use EDI, 835 transactions shall be created, printed, and mailed to providers. Paper RAs shall contain all information available on the EDI 835 transaction.

### SECTION 4.7.6 – Claims Reporting

On a quarterly basis, the contractor shall submit Claims Audit Reports that include the claims processing data at a summary level for the past two quarters. The contractor must always retain all claims and claims processing information to allow processing to completion. The WTC Health Program reserves the right to audit all claims. The contractor must always retain the claims and sufficient information on all claims to permit audits pursuant to the record retention requirements contained in HIPAA regulations (45 C.F.R. pts. 160, 162 and 164).

Provide cost-savings and payment reports in the semi-annual reports. Such reports must include:

1. Expenditure savings related to any provider contracts negotiated at reimbursement rates lower than the OWCP FECA Fee Schedule.
2. Expenditure savings related coordination of benefits (SECTION 4.8)
3. Claims exceeding the OWCP FECA Fee Schedule set rates, as well as any other rates set by the Program.
4. High dollar claims – targeting claims higher than $400,000.00. Clinical information must be provided at request by the Program.
5. Recommendations to continuously seek ways to enhance efficiency and quality of care.
6. Provide quarterly and ad hoc claims reports demonstrating trends in utilization of services, including inpatient claims, diagnostic claims, cancer screening, IHE claims, AME claims, and treatment claims.
7. Provide a quarterly report on incidences of inappropriate billing including balance billing to members with associated provider corrective action plans.

**Deliverable(s):**

1. Semi-annual Internal Audit Reports
2. Quarterly Claims Audit Report and Ad Hoc Claims Reports

Cost Avoidance and Recoupments

To support WTC Health Program Integrity, the contractor shall coordinate with the Comprehensive Cost Avoidance and Recovery (CCA) contractor. The CCA contractor will provide Other Health Insurance Information (OHI) for Cost Avoidance efforts and initiate recoveries on paid claims from private payers based on overlapping dates of service. The NPN shall also perform improper payment reviews in conjunction with the CCA contractor. Results should be reported in the Semi-annual and annual reports and/or the internal audit reports. A summary of errors categorized by reason with total number of cases and dollar value to include the following:

1. Overpayment trends and suggested corrective actions
2. The number of cases, timeline associated, and estimated value
3. Any successfully collected amounts by claim and adjustments
4. Underpayments
5. The number of cases, timeline associated, and estimated value
6. Any successfully corrected payments
7. Variance analysis for overpayments or underpayments

The NPN Contractor shall work closely with the Program and enter into a data sharing agreement with the CCA contractor to incorporate Program's strategies and policies to ensure loss prevention, cost avoidance, COB, and recovery activities are coordinated and meet the Program's goal of maximum financial integrity.

Claims Data

The NPN must provide claims data either through regular data feeds to the Program and/or Program Contractor in a format mutually agreed upon and through ad hoc reporting. The data should include all elements of the claims including coordination of benefit (COB) information such as EOB and amount paid by the primary payer. Ensure that IHEs and AMEs are coded correctly per TGD 011 (to be provided upon award).

## SECTION 4.8 – Coordination of Benefits (COB)

The NPN contractor must submit a COB Plan in both the Implementation and Operations Manual.

Coordination of Benefits requirements essential to the NPN:

Under section 3331(c) of the Zadroga Act (42 U.S.C. § 300mm-41(c)), for Survivors who receive treatment for non-work-related WTC-related health conditions, the WTC Health Program is the payor of last resort, following the Survivor’s private insurance, Medicare, and Medicaid, respectively. The WTC Health Program will pay costs not reimbursed by the public or private health insurance plan due to the application of deductibles, co-payments, co-insurance, other cost sharing arrangements, or payment caps up to and in accordance with the rates described in 42 C.F.R. § 88.22(b). For Survivors with work-related WTC-related health conditions, payment for treatment of those conditions within the WTC Health Program is made first by a Worker’s Compensation fund, followed by the WTC Health Program, private insurance, Medicare, and Medicaid, in that order. COB requirements that the NPN is responsible for implementing and operationalizing include:

1. Verifying that members are maintaining required Minimal Essential Health Insurance Coverage (Section 3331(c)(3) of the Zadroga Act; 42 U.S.C. § 300mm-41(c)(3))
2. Coordination of Benefits of claims with Private and Public Insurers (Sections 3331(c)(1)-(2) of the Zadroga Act; 42 U.S.C. § 300mm-41(c)(1)-(2))
3. Provider Network/Contract Provisions (SECTION 4.5)
4. Benefits Counseling (SECTION 4.3.6)

Proof of Personal Health Insurance Coverage Requirements

To comply with this requirement the NPN contractor must:

1. Perform comprehensive coordination of benefits (COB) to avoid inappropriate claims payments, billing, and collections in conjunction with the Program’s Comprehensive Cost Avoidance, COB and Recovery (CCA) vendor.
2. Comply with COB for survivor members by acquiring documentation of personal health insurance directly from the CCA contractor, member, provider(s), or their claims as denoted on the claim form.
   1. All elements of insurance coverage should be collected for the purposes of billing, including:
      1. Insurance plan name,
      2. Claims address/phone/fax,
      3. Subscriber name,
      4. Member name,
      5. Member ID number,
      6. Group number,
      7. BIN number,
      8. Person code, etc.
3. Reviewing, confirming and updating all personal health insurance from members is required at every interaction or once per year, whichever is more frequent. This includes prescription, dental, vision, and other health coverage information. The NPN contractor shall have the ability to update existing personal health insurance information obtained from other sources with the CCA contractor’s provided personal health insurance data.
4. Establish a connection and transmit member demographic and claim data to the applicable Program Contractor and CCA contractor with each applicable claim submission and as requested for personal health insurance identification
   1. Transmit personal health insurance data to the pharmacy benefits manager (PBM) for pharmacy claims when appropriate.
   2. Can accept insurance information through data file exchanges and incorporate that information into systems either from the Program directly or entities contracted by the Program in a format that is mutually acceptable. The system must be able to track personal health insurance ingested from various sources for reporting purposes.
   3. Can send insurance information through data file exchanges to the Program or to entities contracted by the Program in a format that is mutually acceptable.
   4. Can integrate personal health insurance into their member medical record and claims processing system.

COB Claims Processing Requirements for Survivor Members

The contractor shall ensure that their systems can distinguish at the member level claims where the WTC Health Program is the primary payer or the secondary payer. The NPN must adjudicate all claims for Members when the WTC Health Program is designated as the primary payer (as recorded in the Member Profile). The contractor shall develop systems to ensure that payment made to providers and coordination with other insurance coverage (health or workers compensation) is in accordance with WTC Health Program benefit policy per the Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>) and the Zadroga Act. In situations in which the WTC Health Program is the secondary/subsequent payer, the contractor must ensure the following requirements are met:

1. The claims adjudication system can perform COB using personal health insurance based on the Programs Policies and Procedures. Or if applicable, ensure providers bill primary insurance directly (with EOB) when applicable before the system will allow NPN to adjudicate.
2. Obtain a copy of the personal health insurance /OWCI RA from the provider and/or member and submit the RA in addition to healthcare claim reimbursement invoices to the WTC Health Program. This includes cases where there will be no additional payment required as the secondary payer.
3. Upon completion of personal health insurance invoicing, the contractor shall submit, with every healthcare EDI claim to the WTC Health Program, an RA for services not included in the benefit policy for that Member’s certified condition.
4. Review a submitted COB claim along with the Explanation of Benefits (EOB) from the personal health insurance. The EOB is required for all claims for members with personal health insurance.
   1. The EOB must include the billed amount; the paid amount by the personal health insurance; any reason for rejection/non-coverage if applicable; and any deductible, co-insurance, and copay amounts (also known as the member responsibility).
   2. Any claims rejected due to lack of prior authorization or non-compliance with personal health insurance requirements must be remedied and re-adjudicated by personal health insurance prior to submission to the Program
5. Ensure the total payment of each claim does not exceed the OWCP FECA Fee Schedule/contracted rate value of each line and claim total to ensure providers are not overpaid.
6. The contractor shall identify and correct any situation in which personal health insurance /OWCI is invoiced by the provider for care provided on a covered benefit when the WTC Health Program should serve as primary payer. The contractor shall educate network providers on processes to identify personal health insurance /OWCI and designated primary payor on the member profile through the secure self-service portal.

COB Payment Distribution

Providers contracted with the WTC Health Program and NPN Contractor have agreed to accept from the WTC Health Program payment at no more than OWCP FECA rates and shall not bill members for any deductible, co-insurance, or copay amounts not paid by the personal health insurance. The WTC Health Program will not reimburse a provider such that they would receive a total amount in excess of the OWCP FECA rate for any service from the WTC Health Program; the provider will not receive any payment from the WTC Health Program if the member’s personal health insurance has paid more than the FECA rate.

If the member’s personal health insurance has paid what amounts to a portion of the OWCP rate or the personal health insurance rate, the WTC Health Program will only pay the remainder of the lesser of the personal health insurance rate or FECA rate, up to the total member’s responsibility.

The Contractor shall ensure that Members are held harmless and may not be invoiced for any services associated with a covered service related to the Member’s certified condition, even if the claim is denied (e.g., where services were denied for failure of the provider to obtain prior authorization approval by WTC Health Program) or the provider fails to meet the personal health insurance/OWCI Prior Authorization requirements of the personal health insurance/OWCI and receives a denial.

Reporting

Report all COB data and activities in the semi-annual and annual report. Reportable data must include:

1. Statistics related to the collection of primary insurance for survivor members such as the percentage of members with personal health insurance on file.
2. Statistics related to billing of personal health insurance including percentage of total survivor claims that are submitted to personal health insurance, percentage of claims paid by personal health insurance, total savings from personal health insurance payments, etc.
3. Provide to the program and designated contractors Monthly Cost Savings/Avoidance report, which includes the source of the personal health insurance data which lead to the cost avoidance. This includes the reporting out on fully denied claims.

## SECTION 4.9 – Quality Assurance

Quality Assurance and Internal Audit Plan

The NPN Contractor shall develop a Quality Assurance and Internal Audit Plan (QAP) to document its approach to Quality Assurance (QA) and demonstrate how the Contractor shall adhere to performance targets established by the Program. The oversight of Contractor performance will help ensure that service levels reach and maintain the required levels throughout the period of performance. The NPN Contractor shall address all performance metrics and whether the performance threshold missed, met and/or exceeded for each standard as part of the monthly progress report (See SECTION 8).

The QAP shall also include the Internal Audit Plan to focus on continuously improving program performance. The QAP shall include periodic operational assessments to evaluate effectiveness of policies, procedures, and workflows in compliance with the WTC Health Program requirements. The QAP shall include the proposed internal audit approach and must address the specific components listed in TGD 003 (to be provided upon award).

Semi-annual Internal Audit Report

The NPN contractor shall submit a semi-annual internal audit report. Each semi-annual internal audit report must address the specific metrics in the Zadroga Act (3301e) along with the components in TGD 003 (provided upon award).

The NPN’s QAP and the WTC Health Program’s Quality Assurance Plan should be complementary programs that ensure successful contract performance.

## SECTION 4.10 – Public Emergency Plan

The NPN contractor shall include a Continuity of Operations Plan to minimize disruptions during an emergency event to ensure continuation of services. The NPN contractor shall establish a routine and emergency communication plan with the WTC Health Program, members, stakeholders, and service providers to include:

1. Regularly update the appropriate Program points of contact and contracting officer representative (COR) on issues regarding delivery of services and on outstanding member issues.
2. Regularly update members on operational changes and status and provide direction for continuing care through the Program (See SECTION 4.4).
3. Regularly update service providers and stakeholders on operational status to provide direction (SECTION 4.5)
4. Ensure access to member’s records and medical documentation, including service provider information available in member’s records, access to providers near members, and alternate options to services with redundant backup systems in place.
5. Monitor and report on status of clinic operations, including call center, network access, claims administration and recovery time to ensure timely access to alternate or backup systems as requested by The Program.

## SECTION 4.11 – Fraud, Waste, and Abuse (FWA) Plan

The NPN contractor shall prepare an FWA Compliance Plan as part of the Operations Manual (See SECTION 8). Once approved, the NPN Contractor shall perform all required services in accordance with their established FWA Plan, document their activities, and include reports in the monthly, semi-annual, and annual reports, as appropriate (See SECTION 8). The Plan shall describe the policies and procedures which will be used to monitor and improve all project activities including reporting. As a part of the FWA Plan, the NPN contractor shall include:

FWA Surveillance:

The FWA Compliance Plan shall address how the NPN contractor will detect and mitigate FWA. Additionally, the NPN contractor shall describe how these activities link to or augment the NPN contractor’s internal Quality Assurance Plan. Please describe how and what HHS OIG resources are being used, such as the provider exclusion list. The NPN contractor must ensure that payment is not rendered on a service or prescription ordered or provided by or paid to any OIG-excluded entities. (See https://oig.hhs.gov/exclusions/advisories.asp for more information.)

As part of standard claims processing operations (SSECTION 4.7), the Contractor shall implement and maintain a FWA detection and appropriate prevention payment system for all services covered by this contract. The FWA plan should include the Contractors approach to identification, review, follow-up, recovery, and other actions it may take when FWA is discovered and validated. The plan shall include details for both automated and manual FWA identification and monitoring.

The Contractor shall ensure that FWA detection analytics are inherent in its claims processing system. The Contractor’s claims system shall apply rules to identify abusive provider practices that are inconsistent with industries for medical practices, business practices, fiscal practices, and may result in unnecessary costs to the WTC Health Program. Business rules shall identify services provided that were not medically necessary or fail to meet professional standards for health care. The Contractor shall apply business rules to identify potentially fraudulent activities including any intentional deception or misrepresentation with the intent that the deception would result in some unauthorized benefit, or acts that constitute Fraud under applicable State law. The Contractor shall make every reasonable attempt to recover all improper payments for services rendered to Members who were not eligible to receive a benefit.

FWA Incident Procedures:

The FWA Compliance Plan shall clearly document how the NPN contractor plans to respond to FWA incidents. The NPN contractor shall provide written documentation of any incidents. If determined to be an incident of fraud, the NPN contractor shall provide a report within (30 days) that describes the incident in detail. Such report shall be reviewed and signed by the key staff or designee and contain at least the following information:

1. The name of the individual or entity that committed the fraud, waste, or abuse
2. The source or surveillance method that identified the fraud, waste, or abuse
3. The type of provider, entity or organization that committed the fraud, waste, or abuse
4. A description of the fraud, waste, or abuse
5. The approximate dollar amount of the fraud, waste, or abuse if applicable
6. The legal and administrative disposition of the case including actions taken by law enforcement officials to whom the case has been referred
7. Other data/information deemed pertinent by the NPN contractor or as prescribed by the WTC Program Administrator.

## SECTION 4.12 – Audit Rights

Audit Rights: The NPN contractor shall allow WTC Health Program access to audit all aspects of the NPN program managed by the NPN contractor including financial terms, service agreements, administration, guarantees, and all applicable components of the program. This shall include paid claims, the claims processing system, member and provider portal, medical records, prior authorization systems, and customer service call monitoring. Audits will be conducted by a firm selected by the Program without restriction. The NPN contractor shall provide claims data to the Program’s audit firm as needed. The NPN contractor shall respond to preliminary audit discrepancies identified by the Program’s auditor within 30 calendar days.

Response/compliance with audit or inspection findings: The NPN contractor must take action to ensure its compliance with or correction of any finding of noncompliance with any law, regulation, or requirement related to Program services and/or contract terms within 30 calendar days of the close of the audit. This will include the NPN contractor’s delivery of a corrective action plan that addresses the deficiencies and payment or credit to the WTC Health Program for all monies attributed to the agreed upon findings.

Audit Remuneration: All monies recovered from audit programs that are not credited through the claims reversal process should be credited to the WTC Health Program within 30 days of recovery. A report containing line-item detail including the recovery claim IDs shall be provided by the NPN contractor on a monthly basis for all methods of audit.

## SECTION 4.13 – Data Management

The NPN contractor shall provide a comprehensive approach to manage member data, claims and billing records, and member and health records that meet Federal IT and data security laws and regulations with analytic capability to support operational decisions, quality improvement, and Program oversight. The NPN contractor shall collect and submit service and member health records, including monitoring exams and treatment, to the Program or location designed by the Program *See* Sections 3304, 3313 of the Zadroga Act; 42 U.S.C. §§ 300mm-3, 300mm-23.

The NPN contractor shall collect and submit service and member health records, including monitoring exams and treatment, to the Program or a location designated by the Program.

* Although there are no research activities conducted by the NPN contractor under this contract, a consent form provided by the WTC Health Program Administrator to the NPN contractor must be sent to all members to request their signatures to allow use of the information for research purposes and to provide that the NPN contractor can release their contact information to researchers for study recruitment purposes.

Privacy Act Requirements

* + - * 1. As stipulated by HHSAR 352.222-70, the draft data management plan shall include identification of system of records and disposition, including: Identifying the system(s) of records and the design, development, or operation work the Contractor is to perform
        2. and provide detailed description and point of contact (team or group) to the WTC Health Program.
        3. Specify the disposition to be made of such records upon completion of contract performance. The Contractor shall transfer all government records and all government furnished data within 30 days after the contract has ended or within the (to be) specified transition period.

The system of records for this requirement is CDC Privacy Act System of Records Notice 09-20-0147.

Records Management

The NPN contractor shall develop, implement, and administer a comprehensive records management program consistent with all HIPAA and records management requirements. This program shall ensure that WTC Health Program records (including medical records) are maintained in a manner such that the information is secure and readily accessible to authorized parties. The records management program shall also address assisting with obtaining medical records, including processing member requests to release protected information. This program shall be approved by the WTC Program Administrator and implemented by the NPN contractor within 1 month of the approval. The NPN’s Operations Manual shall provide the details of the records management program.

Data Management Plan (DMP):

CDC requires awardees for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data. If the public health data to be collected or created are not appropriate for release, provided a concise rationale or justification in the DMP.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

* + Descriptions of the data to be produced in the proposed project;
  + How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights);
  + Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
  + Plans for archival and long-term preservation of the data or explaining why long-term preservation and access cannot be justified

Examples of DMPs may be found at University of California [DMPTool website](https://cdlib.org/services/uc3/dmptool/) or [USGS](https://www.usgs.gov/products/data-and-tools/data-management/data-management-plans).

CDC [Additional Requirement (AR)-25](https://www.cdc.gov/grants/additionalrequirements/ar-25.html) outlines the components of a DMP and provides additional information for investigators about the requirements for data accessibility, storage, and preservation. The DMP should be developed during the project planning phase, prior to the initiation of collecting or generating public health data and be submitted with the application.

Phase-in / Phase-out Plan

Transfer of Data, Documentation, and Information for continuity of operations

The Contractor shall provide a phase-out plan describing actions, plans, and procedures to ensure a smooth transition from contract performance, in the current term, to future performance, perhaps by a different Contractor. Phase-out plans shall include provisions for completion of appropriate Contractor responsibilities should there be a contract termination proceeding.

The Contractor shall coordinate activities according to the agreed upon Phase In/Phase Out Plan with the successor Contractor to affect a smooth and orderly transition at the end of the contract period. The Contractor shall transfer all data and information necessary to transition operations including: medical records, data, and reference tables; WTC-specific data, configurations, process documents, and specifications that are available at the completion of the contract; documentation relating to software and interfaces; functional business process flows; and operational information, such as: correspondence, documentation of ongoing or outstanding issues, operations support documentation, and operational information regarding subcontractors to the successor contractor.

For purposes of this provision, "documentation" means all operations, technical, and user manuals used in conjunction with the software, services, and deliverables, in whole or in part, that the WTC Program Administrator determines are necessary to view and extract application data in a proper format. The Contractor shall provide the documentation in the format(s) it exists at the expiration or termination of the contract, unless otherwise defined by the Government.

The Contractor shall work with the WTC Health Program information security officer (ISO) and COR to provide all data, information, and services necessary and sufficient to enable the Government to map all data from the Contractor’s system(s) to the replacement system(s) of the Government or a successor contractor, including a comprehensive data dictionary that gives the names and definitions of all data fields in the database.

The NPN contractor shall provide to the Government all necessary data, information, and services in the format defined by the WTC Program Administrator and must be HIPAA compliant. All the data, information and services mentioned in this SECTION shall be provided and performed in a manner by the NPN contractor using its best efforts to ensure the efficient administration of the WTC Health Program. The data and information must be supplied in media and format specified by the WTC Program Administrator and according to the schedule approved by the WTC Program Administrator. All relevant data and information must be received and verified by the WTC Program Administrator. All the necessary data, information, logs, and services may be requested by the WTC Program Administrator at any point during this contract.

The NPN’s Operations Manual shall incorporate the Phase-in/Phase-out plan requirements which shall be addressed by the Contractor, as applicable, with the submission of a Change Request related to the scope and associated costs, if any, to execute the plan. Failure to execute this plan will be considered as contract noncompliance.

1. Phase-In Period

At the beginning of the contract period, the Contractor shall coordinate activities with the predecessor Contractor to ensure an efficient and seamless transition as well as continuity of services to the government. Upon award, until agreement that the phase-in period is complete, the Contractor shall provide weekly briefings to the Project Officer, COR, SMEs and/or Contracting Officer regarding all outstanding transition tasks, respective anticipated completion dates, and any respective anticipated problems.

1. Phase-Out Period

At the end of the contract period, the Contractor shall coordinate activities with the successor Contractor to ensure an efficient and seamless transition as well as continuity of services to the government. Upon notification by the Contracting Officer, until agreement that the phase-out period is complete, the Contractor shall provide weekly briefings to the Project Officer, COR, SMEs and Contracting Officer regarding all outstanding transition tasks, respective anticipated completion dates, and any respective anticipated problems. Transition tasks shall include: the transfer all data and information necessary to transition operations, on-the-job training, the removal of all belongings (such as supplies, tools, and equipment) of the Contractor from space furnished by the government prior to the end of the contract period.

## SECTION 4.14 TRANSITION OF DATA AND INFORMATION TURNOVER

At the end of the contract or at any time determined by the WTC Health Program, the NPN contractor shall transfer to the Program designee or a subsequent NPN contractor, in a timely manner without interruption or services to participants, all data and information necessary to transition operations, including:

* Medical records, data, and reference tables;
* WTC-specific data, configurations, process documents, and specifications that are available at the completion of the contract;
* Documentation relating to software and interfaces;
* Functional business process flows; and
* Operational information, including correspondence, documentation of ongoing or outstanding issues, operations support documentation, and operational information regarding subcontractors.

For purposes of this provision, "documentation" means all operations, technical, and user manuals used in conjunction with the software, services and deliverables, in whole or in part, that the Program designee determines are necessary to view and extract application data in a proper format.

The NPN contractor shall provide the documentation in the formats in which such documentation exists at the expiration or completion of the contract.

The NPN contractor shall provide to the Program designee all data, information, and services necessary and sufficient to enable the Program designee to map all data from the NPN’s system(s) to the replacement system(s) of the Program designee or a successor NPN contractor, including a comprehensive data dictionary with the names and definitions of all data fields in the database.

The NPN contractor shall provide to the Program designee all necessary data, information, and services in the format defined by the WTC Program Administrator. All data, information, and services must be HIPAA-compliant. All data, information and services mentioned in this section shall be provided and performed by the NPN contractor using its best efforts to ensure the efficient administration of the WTC Health Program. The data and information must be supplied in media and formats specified by the WTC Program Administrator and according to the schedule approved by the Program designee. All relevant data and information must be received and verified by the Program designee. Failure to perform this requirement will be considered contract non-compliance. The NPN further agrees that no dispute or objection it may have regarding the propriety of any transition of services by WTC Health Program will relieve it of these obligations.

The NPN contractor’s Operations Manual shall provide the details of the transfer of data and information and the turnover-of-services procedure.

# SECTION 5 – PERFORMANCE METRICS

The NPN Contractor shall monitor performance against the established schedule, milestones, risks and resource support requirements in the PWS. The Contractor shall report any deviations in the Monthly Progress Report.

The Program will utilize a Quality Assurance Surveillance Plan (QASP) throughout the life of the task order to ensure that the Contractor is performing the services required by this PWS in an acceptable manner.

## SECTION 5.1 – QUALITY ASSURANCE SURVEILLANCE PLAN

This Quality Assurance Surveillance Plan (QASP) provides a systematic method to evaluate this performance-based contract. This QASP explains the following:

* What will be monitored
* How monitoring will take place
* Who will conduct the monitoring
* How monitoring efforts and results will be documented
* Which QASP elements are included in the delivery Incentive and Disincentive Plan (Draft QASP is provided with performance requirements summary as part of the solicitation)

This QASP is a “living document” and the Government may review and/or revise it on a regular basis at a minimum of annually. The QASP describes the quantitative and qualitative measures as well as the methodology that the WTC Health Program will use to evaluate contract performance including required services selected for incentive and disincentive payments. Evaluation will be centered around results rather than processes, and specific metrics may be subject to change by the Government. This QASP incorporates the objectives/Acceptable Quality Level (AQL).

# SECTION 6 – GOVERNMENT FURNISHED MATERIALS

The Program will provide the following materials:

* Background Program Information
* WTC Health Program Administrative Manual (<https://www.cdc.gov/wtc/ppm.html>)
* Policy and Procedures that govern the Nationwide Provider Network program
* Pertinent contract documents

# SECTION 7 – PERIOD OF PERFORMANCE

See RFP document.

# SECTION 8 – DELIVERABLES/REPORTING SCHEDULE

All deliverables required under this contract shall be packaged, marked, and sent in accordance with the guidance found in this section. The NPN contractor shall guarantee that all required materials shall be delivered in immediately usable and acceptable condition. Reports submitted under the contract shall reference and cite the contract number and identify HHS as the sponsoring agency. All contract deliverables must be reviewed and approved by the COR and assigned, if applicable, WTC Health Program Subject Matter Experts (SME). Satisfactory reporting performance under the contract will be deemed to occur upon delivery and acceptance by the COR (COR and mailbox address will be provided upon award), or the duly authorized representative.

The WTC Health Program COR will determine the content and format of the reports, if no template is provided. The NPN contractor shall analyze the data collected during each reporting period, ensure that all reports provide summaries which highlight significant trends and include recommendations for improvement. All reports shall include narrative text in the document that summarizes the report data and explains any unusual occurrences or trends.

The required reports are described in the table below. The reports may include but are not limited to the information found under “deliverable title”:

When a timeframe for completion is specified (for example, “within 45 days”), “days” refers to calendar days unless otherwise stated. If the deadline calculated in this way falls on a weekend or a federal holiday, the contractor may comply with the deadline on the next business day, unless otherwise stated.

|  |  |  |
| --- | --- | --- |
| **Title** | **Date Due** | **Description or Reference** |
| Implementation Plan (Phase in) | Within 30 calendar days of contract start date; to be updated monthly until 60 calendar days after implementation. | SECTION 4.1  Claims Adjudication Readiness Attestation (SECTION 4.7.2) |
| Project Implementation Service Log, Agenda, and Pre-transition audit. | The NPN contractor shall conduct project implementation status meetings with appropriate WTC Health Program staff thereafter on an agreed-upon schedule | SECTION 4.1.1 and SECTION 4.1.2 |
|  |  |  |
| Provider Network Development Plan | Submit as applicable. | SECTION 4.5.2 |
| Operations Manual including all Plans | finalized version due within 60 calendar days of contract start date; to be resubmitted with latest updates at least annually | * Staffing Plan (SECTION 4.2.1) * Fraud Waste and Abuse Plan (SECTION 4.11) * Communications Plan (SECTION 4.4) * Quality Assurance and Internal Audit Plan (SECTION 4.9) * Continuity of Operations Plan (SECTION 4.10) * FWA Plan (SECTION 4.11) * Risk Management Plan (SECTION 4.2.9) * Member Retention Plan (SECTION 4.3.4) * HIPAA Compliance Activities (SECTION 9) * Case Management Plan (SECTION 4.6.7) * Utilization Management Plan (SECTION 4.6.8) * QASP (SECTION 5.1) * Data Dictionary (SECTION 4.7.3) * Claims Adjudication Rules (SECTION 4.7.3) * Claims Adjudication Process (SECTION 4.7.3) * Recovery of Overpayment (SECTION 4.7.3) * Coordination of Benefit (SECTION 4.7.3) |
| Data Management Plan | finalized version due within 60 calendar days of contract start date | SECTION 4.13 |
| Member Portal | The NPN contractor shall establish a web-based self-service portal | SECTION 4.2.7 and 4.3.1 |
| Communication Website | The NPN contractor shall develop a website with information about the NPN for members and potential NPN members. The contractor must have all content approved by the Program to ensure the website has accurate information and uses appropriate branding and link strategy. | SECTION 4.4.1 |
| Provider Portal | The NPN shall provide a comprehensive online self-service provider portal. The provider portal may be integrated with the claims portal and/or member portal to centralize and streamline access and control for secured data exchanges. | SECTION 4.5.5 |
| Data Sharing Agreement with HPS contractor | Within 60 days of contract start date | SECTION 4.7.2 |
| Claims Audit Report | Quarterly | May be in conjunction with Semi-annual Internal Audit Report |
| Ad-hoc reports | Within 10 business days of request or an agreed-upon time frame | Provide reports that include program data upon request |
| Monthly Program Status Reports | 15 calendar days after end of month | Provide a monthly report of prior month progress, including performance metrics and upcoming major activities and call center activities. Template will be provided. |
| Semi Annual Internal Audit Report | 45 calendar days after end of 2nd- and 4th- quarters | SECTION 4.9 |
| System Vulnerability Scans | Monthly Report | Provide monthly vulnerability scans on contractor systems used to perform all aspects of the scope of work. |
| Business Associate Agreement | One day after award. | Template will be provided with the solicitation |
| Status Meeting Agendas and Services Log | At least 24 hours in advance of the scheduled meeting | High level overview of discussion topics, issues requiring resolution, and project updates. Includes written updates from the previous meeting and action items. |
| Change Request Tracking Log | At least 24 hours in advance of the scheduled Status Meeting | Log detailing change request status and implementation progress. |
| Staffing List | Quarterly | Provide a draft staffing plan that describes organizational structure, full roster, dedicated hours and functions, assignment, management, and oversight to ensure highly qualified personnel are available to implement contract requirements. |
| Identified Other health Insurance (OHI) File | At least monthly, reconcile OHI records to maintain up to date information on survivor member records | Establish data exchange with the Program and its CCA and the TPA/HPS contractors to provide and consume OHI data |
| Deceased Member Identification | Quarterly data transfer to maintain up to date information on survivor member records | Database of deceased members identified shall be submitted to the WTC Health Program and its CCA and the TPA/HPS contractors. |
| Joint Operating Agreement with the CCA contractor | Within 60 days of contract start date | Establish a record of data exchange agreement with approved WTC Health contractors. |
| Closeout Report and Data Transfer (Phase out) | 10 days prior to end of contract performance period. | Deliver all closeout report and data to WTC Health Program |

**Covered Contractor Information System Deliverables**

| Deliverable Title/Description | Due Date |
| --- | --- |
| Roster | Within 14 days of the effective date of this contract and monthly thereafter or upon request; Within 14 days of any change to the roster |
| Contractor Employee Non-Disclosure Agreement (NDA). | Prior to performing any work on behalf of HHS. |
| Copy of training records for all mandatory training. | In conjunction with contract award and annually thereafter or upon request. |
| Signed Rules of Behavior (ROB) for all employees. | Initiation of contract and at least annually thereafter. |
| Incident Report (as incidents or breaches occur). | As soon as possible and without reasonable delay and no later than 1 hour of discovery. |
| List of Personnel with defined roles and responsibilities. | Prior to performing any work on behalf of HHS/CSC/NIOSH/WCTHP and annually thereafter or upon request; with a change of personnel, roles and responsibilities |
| Off-boarding documentation, equipment and badge when leaving contract. | Within 7 days of contractor departure and at contract expiration. |
| Onboarding documentation when beginning contract. | Prior to performing any work on behalf of HHS. |
| If the procurement involves a system or cloud service, Disposition/Decommission Plan. | 90 days prior to contract expiration |
| Develop, document, and periodically update System Security Plans (SSPs). Develop and implement Plan of Action and Milestones (POA&M) designed to correct deficiencies and reduce or eliminate vulnerabilities. | Every 365 days /as requested by CDC/NIOSH. |
| Retirement Checklist, all deliverables and data/records retained in accordance with Records Management and other requirements, Device sanitization documentation, Destruction documentation for all other CDC data/information(soft/hard copy). | Prior to system retirement/decommissioning. |
| POA&M updates; Revised security documentation/Agreements. | Monthly/as requested by CDC/NIOSH. |
| Incident reports (as needed) Incident Response Plan. | Annually and upon request. |
| Computer software, including the source code, if applicable | Prior to performing any work on behalf of HHS CDC/NIOSH/WTCHP and upon request |
| Other source code, if applicable. | Prior to performing any work on behalf of HHS CDC/NIOSH/WTCHP and upon request |
| Syslog-ng: daily audit logs. | Daily at minimum/as requested by CDC/NIOSH. |
| Government furnished data and all data and information generated on behalf of this contract. | Annually and upon request |
| Data User Agreement | Within 90 days upon Contract Award |

# SECTION 9– SUBCONTRACTING

The NPN shall provide transparency to the Government regarding any subcontracting efforts and manage all subcontractor staff on the project that will directly impact the Program’s day-to-day operations. The NPN contractor shall obtain CO and COR approval prior to awarding and managing any subcontracts. The NPN contractor agrees to ensure that any agents or subcontractors that create, receive, maintain, or transmit PHI on behalf of the NPN contractor agree through a written contract or other arrangement to the same restrictions, conditions, and requirements that apply to the NPN contractor with respect to such information.

The NPN is responsible for ensuring the same quality of work performed by its subcontractor(s) including contract management and oversight.

The Program requires thirty (30) business days to review and provide prior written approval for any subcontractor utilized by the NPN contractor for the program. This request for consent to subcontract should be sent to the CO and COR for prior approval before entering a new subcontract, in accordance with FAR 44.2.

# SECTION 10 – HIPAA COMPLIANCE and BUSINESS ASSOCIATE AGREEMENT

To the extent that the Business Associate performs functions or activities on behalf of, or provides certain services to, the Covered Entity where the Business Associate creates, receives, maintains, or transmits “protected health information” (PHI), the following “HIPAA provisions” apply:  the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191; 42 U.S.C. § 1320d); the Health Information Technology for Economic and Clinical Health (HITECH) Act[[4]](#footnote-5)[1] (Pub. L. 111-5; 42 U.S.C. §§ 300jj *et seq*.); the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164); and HHS HIPAA policies.

For purposes of this contract, “Business Associate” shall mean the NPN; “Covered Entity”[[5]](#footnote-6)[2] shall mean the WTC Health Program and any other NIOSH, CDC, or HHS components to the extent that they assist in administering the WTC Health Program and where PHI is involved.  These terms are used as defined in 45 C.F.R. § 160.103.

For any security/data breach that should occur (for WTC Health Program Members but is not reportable to NIOSH/WTC Health Program under the Business Associate Agreement) resulting in a reportable incident to the HHS Office for Civil Rights, the contractor shall notify the designated NIOSH/WTC Health Program HIPAA Compliance Officer within ten (10) days of the incident.  Notification to the Compliance Officer should be provided prior to the WTC Health Program learning of said incident from outside sources (HHS Office for Civil Rights, Organizational Press Release, Letter sent to WTC Health Program member, etc.).  Notification should include the date and nature of the incident (including the identification of each WTC Health Program member whose information was implicated in the incident and the extent of the information breached) and actions being taken by the contractor as a result of the breach.

The Business Associate Agreement provides the detailed legal obligations and requirements of the Business Associate and the Covered Entity and will be incorporated into this contract as an attachment.

At all times throughout the duration of this contract and until the Business Associate fulfills its obligations under this contract and the Business Associate Agreement, the Business Associate is subject to and shall comply with all applicable HIPAA provisions regarding business associates, as well as any updates to those provisions.

The parties acknowledge that the Business Associate is directly liable under HIPAA for the following violations:[[6]](#footnote-7)[3]

* Impermissible uses and disclosures of PHI;
* Failure to provide breach notification to the Covered Entity;
* Failure to provide access to a copy of electronic PHI to either the Covered Entity, the individual, or the individual’s designee, as specified in the Business Associate Agreement;
* Failure to disclose PHI where required by the Secretary of HHS to investigate or determine the Business Associate’s compliance with HIPAA;
* Failure to provide an accounting of disclosures; and
* Failure to comply with the requirements of the Security Rule.

# SECTION 11 – INFORMATION SECURITY

1. **Covered Contractor Information System**

**Covered Contractor Information System.** A Covered Contractor Information System is defined as “an information system that is owned and operated by a contractor and all sub-contractors that processes, stores, or transmits Federal contract information.”1

1. **Adequate Security**

**Definition of Adequate Security**: Adequate security is defined as protective measures that are commensurate with the consequences and probability of loss, misuse, or unauthorized access to, or modification of information.2

Contractor (and/or any subcontractor) shall provide adequate security on all covered contractor information systems for protecting the confidentiality of Controlled Unclassified Information (CUI). Contractor shall implement, at a minimum, the following information security protections:

1. The covered contractor information system shall be subject to the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 Rev 2, “Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations”3 in effect at the time the solicitation is issued or as authorized by the Contracting Officer. To document implementation of NIST SP 800-171 Rev.2, the Contractor shall provide the following system documentation to CDC/NIOSH to demonstrate implementation or planned implementation of the security requirements:
   1. **System Security Plan (SSP)** – Contractor shall develop, document, and annually update System Security Plans (SSPs). The system security plan describes system boundaries, system environments of operation, how security requirements are implemented, and the relationships with or connections to other systems. Contractor must ensure that the required information in [SP 800-171 Requirement] 3.12.4 is conveyed in those plans. Contractor must document the system security plan using the NIST suggested template.4
   2. **Plan of Action and Milestones (POA&M)** – Contractor shall develop and implement Plan of Action and Milestones designed to correct deficiencies and reduce or eliminate vulnerabilities in their systems. Contractor must document the POA&M using NIST suggested template.5
2. The Contractor shall implement NIST SP 800-171 Rev 2. The Contractor shall notify the NIOSH Information System Security Officer/Delegate, and the Contract Officer within 30 days of contract award, of any security requirements specified by NIST SP 800-171 Rev 2 not implemented at the time of contract award.
3. The Contractor shall submit requests to vary from NIST SP 800-171 Rev 2 in writing to the Contracting Officer, for consideration by the ISSO to determine if requests are applicable and if an alternative security measures are equally effective.
4. If CDC/NIOSH has previously adjudicated the contractor’s requests indicating that a requirement is not applicable or that an alternative security measure is equally effective, a copy of that approval shall be provided to the NIOSH Office of the Director of Information Technology (OD-IT) when requesting its recognition under this contract.
5. If the Contractor intends to use an external cloud service provider to store, process, or transmit any controlled unclassified information in performance of this contract, the Contractor shall require and ensure that the cloud service provider meets security requirements equivalent to those established by the Government for the Federal Risk and Authorization Management Program (FedRAMP) Moderate baseline6 and that the cloud service provider complies with requirements in this contract for cyber incident reporting, media preservation and protection, access to additional information and equipment necessary for forensic analysis, and cyber incident damage assessment.
6. Apply other information systems security measures when the Contractor reasonably determines that information systems security measures may be required to provide adequate security in a dynamic environment or to accommodate special circumstances (e.g., medical devices) and any individual, isolated, or temporary deficiencies based on an assessed risk or vulnerability. These measures may be addressed in a system security plan.
7. **Cyber Incident Reporting Requirement**

**Definition of an Incident:**“Cyber incident” means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.7

When the Contractor discovers a cyber incident that affects a covered contractor information system residing therein, or that affects the contractor’s ability to perform the requirements of the contract that are designated as operationally critical support and identified in the contract, the Contractor shall —

1. Conduct a review for evidence of compromise of controlled unclassified information.
2. All contractors and subcontractors shall report a suspected or confirmed breach in any medium as soon as possible and no later than 1 hour of discovery to the NIOSH Security Team and the Contracting Officer. NIOSH Security Team will coordinate and escalate reported incidents to CSIRT CDC – Computer Security Incident Response Team as soon as possible and without reasonable delay. NIOSH Security Operations: [NIOSHINFOSECOperations@cdc.gov](file:///C:\Users\ohi3\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\FOTH0Q5I\NIOSHINFOSECOperations@cdc.gov)
3. **Cyber Incident Report**

Tracking and documenting system security incidents includes maintaining records about each incident, the status of the incident, and other pertinent information necessary for forensics, evaluating incident details, trends, and handling. The cyber incident report shall be treated as information created by or for CDC/NIOSH and shall include, at a minimum, the required elements.

Contact Information for the Incident Reporter and Handler

* Name.
* Role.
* Organizational unit (e.g., agency, department, division, team) and affiliation.
* Email address.
* Phone number.
* Location (e.g., mailing address, office room number).

Incident Details

* Status change date/timestamps (including time zone): when the incident started, when the incident was discovered/detected, when the incident was reported, when the incident was resolved/ended, etc.
* Physical location of the incident (e.g., city, state).
* Current status of the incident (e.g., ongoing attack).
* Source/cause of the incident (if known), including hostnames and IP addresses.
* Description of the incident (e.g., how it was detected, what occurred).
* Description of affected resources (e.g., networks, hosts, applications, data), including systems’ hostnames, IP addresses, and function.
* If known, incident category, vectors of attack associated with the incident, and indicators related to the incident (traffic patterns, registry keys, etc.).
* Prioritization factors (functional impact, information impact, recoverability, etc.).
* Mitigating factors (e.g., stolen laptop containing sensitive data was using full disk encryption).
* Response actions performed (e.g., shut off host, disconnected host from network).
* Other organizations contacted (e.g., software vendor).

1. **Media Preservation and Protection**

**Definition of Media:** “Media” is defined as the physical devices or writing surfaces including, but is not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which covered defense information is recorded, stored, or printed within a covered contractor information system**.8**

When a Contractor discovers a cyber incident has occurred, the Contractor shall preserve and protect images of all known affected information systems and all relevant monitoring/packet capture data for at least 1 year from the submission of the cyber incident report to allow CDC/NIOSH to request the media or decline interest. Per the NIOSH Enhanced Based Security Controls, CDC/NIOSH requires audit records to be retained for 7 Years, this timeframe provides support for after-the-fact investigations of security incidents and to meet regulatory and CDC/NIOSH information retention requirements.

1. **Audit and Accountability**

The Contractor shall meet the information security requirements for Audit and Accountability (AU) to ensure audit records meet the following minimum requirements pertaining to AU and other privacy requirements:

* **Audit Records Reporting**: Provide audit logs for NIOSH to review for NIOSH specific data for investigation and response to indications of unlawful, unauthorized, suspicious, or unusual activity.
* **Anonymize Non-NIOSH associated data and PII**: Where feasible and within the limits of technology, locates and removes/redacts vendor specific non-NIOSH associated data and PII and/or uses anonymization and de-identification techniques to permit use of all NIOSH retained data while reducing its sensitivity and the risk resulting from disclosure.
* **Right to Receive Logs**: NIOSH shall have the right to receive NIOSH-specific application logs at a minimum of daily. Daily audit records shall be sent to the NIOSH Technical Operations (TechOps) group via a Syslog-ng. The point of contact to configure Syslog-ng will be provided to the Contractor upon the contract award. If Syslog-ng is not feasible or technically possible, an alternative option for receiving audit records may be considered as agreed upon by the Contractor and NIOSH Office of the Director of Information Technology (OD-IT). CDC/NIOSH requires audit records to be retained for 7 Years, this timeframe provides support for after-the-fact investigations of security incidents and to meet regulatory and CDC/NIOSH information retention requirements.

1. **Information Security Continuous Monitoring**

The Contractor shall ensure an assessment of the controls is conducted at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party). In addition, review all relevant documentation (SSP, POA&M, etc.) and provide updates by specified due date. NIOSH shall have the right to conduct a third-party audit. This audit shall assure appropriate safeguard of NIOSH information and compliance with the agreed security standards and procedures.

1. **Access to Additional Information or Equipment Necessary for Forensic Analysis**

**Definition of Forensic Analysis:** “Forensic analysis” means the practice of gathering, retaining, and analyzing computer-related data for investigative purposes in a manner that maintains the integrity of the data.9

Upon request, the Contractor shall provide access to additional information or equipment that is necessary to conduct a forensic analysis.

1. **Cyber Incident Damage Assessment Activities**

If CDC/NIOSH elects to conduct a damage assessment, the Contracting Officer will request that the Contractor provide all of the damage assessment information gathered in accordance to A. 4. Media Preservation and Protection.

1. **CDC/NIOSH Safeguarding and Use of Contractor Attributional/Proprietary Information**

The CDC/NIOSH shall protect against the unauthorized use or release of information obtained from the contractor (or derived from information obtained from the contractor) that includes contractor attributional/proprietary information. To the maximum extent practicable, the Contractor shall identify and mark attributional/proprietary information. In making an authorized release of such information, CDC/NIOSH will implement appropriate procedures to minimize the contractor attributional/proprietary information that is included in such authorized release, seeking to include only that information that is necessary for the authorized purpose(s) for which the information is being released.

1. **Use and release of contractor attributional/proprietary information not created by or for CDC/NIOSH**

**Definition of Contractor attributional/proprietary information**: “Contractor attributional/proprietary information” means information that identifies the contractor(s), whether directly or indirectly, by the grouping of information that can be traced back to the contractor(s) (e.g., program description, facility locations), personally identifiable information, as well as trade secrets, commercial or financial information, or other commercially sensitive information that is not customarily shared outside of the company.10

Information that is obtained from the contractor (or derived from information obtained from the contractor) under this contract that is not created by or for CDC/NIOSH is authorized to be released outside of CDC/NIOSH —

1. To entities with missions that may be affected by such information.
2. To entities that may be called upon to assist in the diagnosis, detection, or mitigation of cyber incidents,
3. To Government entities that conduct counterintelligence or law enforcement investigations.
4. To a support services contractor (“recipient”) that is directly supporting CDC/NIOSH activities, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information.
5. **Use and release of contractor attributional/proprietary information created by or for CDC/NIOSH**

Information that is obtained from the contractor (or derived from information obtained from the contractor) under this contract that is created by or for CDC/NIOSH of this contract is authorized to be used and released outside of CDC/NIOSH for any other lawful Government purpose or activity, subject to all applicable statutory, regulatory, and policy based restrictions on the Government’s use and release of such information.

1. **Other applicable laws and regulations**

The Contractor shall conduct activities that includes this contract in accordance with applicable laws and regulations on the interception, monitoring, access, use, and disclosure of electronic communications and data.

1. **Other Safeguarding or Reporting Requirements**

The safeguarding and cyber incident reporting required by this contract in no way abrogates the Contractor’s responsibility for other safeguarding or cyber incident reporting pertaining to its unclassified information system as required by other applicable requirements of this contract, or as a result of other applicable U.S. Government statutory or regulatory requirements.

1. **Subcontracts**

The Contractor shall —

* 1. Include this clause, including this paragraph (A.14. Subcontracts), in subcontracts, or similar contractual instruments, for operationally critical support, or for which subcontract performance will involve controlled unclassified information, including subcontracts for commercial items, without alteration, except to identify the parties. The Contractor shall determine if the information required for subcontractor performance retains its identity as controlled unclassified information and will require protection under this contract, and, if necessary, consult with the Contracting Officer; and
  2. Require subcontractors to —

1. Notify the prime Contractor (or next higher-tier subcontractor) when submitting a request to vary from a NIST SP 800-171 security requirement to the Contracting Officer.

Provide the incident report number, automatically assigned by CDC/NIOSH, to the prime Contractor (or next higher-tier subcontractor) as soon as practicable, when reporting a cyber incident to CDC/NIOSH as required in A.3. Cyber Incident Report of this contract.

1. Institute of Medicine. 1989. *Controlling Costs and Changing Patient Care?: The Role of Utilization Management*. Washington, DC: The National Academies Press. https://doi.org/10.17226/1359. [↑](#footnote-ref-2)
2. [Nursing Beyond the Bedside - Utilization Management and Utilization Review - Case Management Institute](https://casemanagementinstitute.com/nursing-beyond-the-bedside-utilization-management-and-utilization-review/) [↑](#footnote-ref-3)
3. See page 66: <https://www11.anthem.com/ca/provider/f1/s0/t0/pw_b134117.pdf?refer=provider> [↑](#footnote-ref-4)
4. [1] The HITECH Act was passed as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA).  [↑](#footnote-ref-5)
5. [2] The term “covered entity” is used in this section for ease of understanding.  However, a more precise description of the application of HIPAA to the WTC Health Program is as follows:

   HHS is a hybrid entity under HIPAA, meaning HHS is a covered entity that conducts business activities, including both covered and non-covered functions, and designates “health care components” in accordance with 45 C.F.R. § 164.105(a)(2)(iii)(D).  45 C.F.R. § 164.103.  As a hybrid entity, HHS must designate any component that would “meet the definition of a covered entity or business associate if it were a separate legal entity” as a health care component; a health care component also may include a component only to the extent that it performs covered functions.  45 C.F.R. § 164.105(a)(2)(iii)(D).  Accordingly, the WTC Health Program is a “health care component” of the covered entity, HHS; as are any other NIOSH, CDC, or HHS components if they would meet the definition of a covered entity or business associate if they were separate legal entities and only to the extent that they perform covered functions. [↑](#footnote-ref-6)
6. [3] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act;

   Other Modifications to the HIPAA Rules [Omnibus Rule], 78 Fed. Reg. 5566, 5598-99 (Jan. 25, 2013). [↑](#footnote-ref-7)