The purpose of the World Trade Center Health Program (WTC Health Program or the Program) Administrative Manual is to document the policies and procedures that provide the comprehensive framework for administering the Program. The audience for the PPM is internal staff, WTC Health Program support groups, and the public. The PPM

will be updated regularly. The purpose of this chapter is to provide a general overview of the WTC Health Program, including a brief description of the history and origins of the Program, a summary of the guiding legislation, and a description of the organization that has been developed to carry out the provisions of the legislation. The Program is established by Public Law 111-347, the James Zadroga 9/11 Health and Compensation Act of 2010 (the Zadroga Act). Title I of the Zadroga Act amended the Public Health Service (PHS) Act to add Title XXXIII, establishing the WTC Health Program within the Department of Health and Human Services. Title XXXIII of the PHS Act is codified at 42 U.S.C. §§ 300mm – 300mm-61. Program regulations were promulgated in Title 42, Part 88 of the Code of Federal Regulations (C.F.R.). Descriptions of the major provisions of the Zadroga Act and the Part 88 regulations are set forth in Section 4 below. Since the terrorist attacks of September 11, 2001, the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) and the National Institute for Occupational Safety and Health (NIOSH) have facilitated health evaluations and screenings for individuals who responded to those attacks in order to identify any health issues resulting from their exposures in the aftermath of the attacks. Procedures for the determination of eligibility and enrollment of WTC Health Program members are guided by the following sections of Title XXXIII of the Public Health Service Act (Act): Program eligibility criteria are established in the following sections of 42 C.F.R. Part 88: Many parts of the WTC Health Program have responsibilities related to eligibility and enrollment in the Program. The PHS Act identifies multiple member groups eligible to participate in the WTC Health Program. Membership groups include: responders from the Fire Department of New York City (FDNY); other specified New York responders; New York survivors; surviving immediate family members of the 343 FDNY responders who perished on September 11, 2001; Pentagon responders; and Shanksville, PA responders. Some responders and survivors were enrolled in predecessor programs prior to the start date of the WTC Health Program (July 1, 2011). Responders who were

enrolled with FDNY or the MMTP prior to July 1, 2011 and survivors who were enrolled in the EHC Community Program prior to January 2, 2011, were automatically enrolled (following Terrorist Watch List screening) in the WTC Health Program. These members were enrolled in batches. Responders and survivors who newly enroll in the WTC Health Program on or after July 1, 2011, and survivors who enrolled in the predecessor program between January 2, 2011 and June 30, 2011, are required to use the WTC Health Program Office of Management and Budget (OMB)-approved application forms to enroll in the Program. The application forms are specific to each member group, and describe the criteria necessary to qualify for the Program. FDNY responders, general New York responders, Pentagon and Shanksville responders, and survivors each have a distinct application form that is unique to the eligibility requirements for each group. These forms may be found in Appendices 2-A through 2-D. The “responder” member group of surviving immediate family members of the 343 FDNY responders who perished on September 11, 2001 is generally considered to be a closed group; however, if someone believes s/he is eligible for this cohort, that person may use the FDNY responder application and complete the appropriate sections (Appendix 2-A). Because of the Supreme Court decision in U.S. v. Windsor, 133 S.Ct. 2675 (2013), striking down Section 3 of the Defense of Marriage Act, there may be individuals who were in same-sex marriages as of September 11, 2001, who are newly eligible for certain benefits within the WTC Health Program. The WTC Health Program is also extending this eligibility to certain persons who were in same-sex or opposite-sex domestic partnerships as of September 11, 2001. Specifically, an applicant may be eligible if s/he (a) were in a same-sex marriage (see the following paragraph), civil union, or domestic partnership, with a member of the FDNY who was killed at the WTC site on September 11, 2001; and (b) received any treatment for a WTC-related mental health condition on or before September 1, 2008. For purposes of eligibility, the WTC Health Program recognizes a same-sex marriage or civil union if it was legally valid under the laws of

the state or other jurisdiction, whether foreign or domestic, when and where the marriage or civil union was performed. The WTC Health Program follows this approach regardless of where the couple lived on September 11, 2001. In addition, the WTC Health Program recognizes as a surviving immediate family member an individual who will attest via affidavit that, on September 11, 2001, s/he was in a same-sex or opposite-sex domestic partnership with a member of the FDNY who was killed at the WTC site on that date, regardless of where the domestic partners lived on September 11, 2001, or where the surviving domestic partner lives now. This policy is consistent with a post-Windsor policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. Information for WTC Health Program applicants, including application forms, can be found on the How to Apply page. Individuals can also call the WTC Health Program Call Center and request that an application be mailed to them. If applicants have questions about how to complete their enrollment application, they can contact the WTC Health Program Call Center. Trained Customer Service Representatives at the WTC Health Program Call Center are able to answer questions regarding the enrollment process. Assistance in languages other than English is available. The CCE outreach teams and the outreach and education contractors (see Chapter 9) also provide enrollment assistance to individuals as part of outreach activities.

Responder and survivor application forms are sent to the WTC Health Program mailroom (BSOC) at the following address:

WTC Enrollment

PO Box 7000

Rensselaer, NY 12144-7000

Alternatively, applications may be faxed to 1-877-646-5308. BSOC scans the enrollment form and any attachments, and assigns a Document Control Number (DCN),

a 12-character length field, in the following format: W (for World Trade Center); 2-digit year; 3-digit Julian date; 4-digit batch number; 3-digit sequential number. The scanned enrollments are delivered to the Enrollment Operations Team via a secure File Transport Protocol (SFTP) server. The Enrollment Operations Team, which is part of the HPS Member Services Team (MST), receives the application forms and attachments, assigns them to enrollment processors, and tracks the inventory. The enrollment processor creates the Member Record and the Enrollment Record in the claims processing system. Applications go through multiple assessment stages. The applications are accepted, entered in the claims processing system, and reviewed by the Enrollment Operations Team. By applying the processes outlined in 42 C.F.R. §§ 88.5 and 88.9, the team determines if more documentation is required to adequately support an application. If more documentation is needed, an enrollment processor reaches out to the applicant immediately to offer guidance. Once adequate documentation is attached to the application, and the application has been entered into the system, the application is sent to the Program's Member Services Team to make a formal enrollment decision. Information on all applicants who are deemed eligible for membership in the Program is then sent to the Federal Bureau of Investigation (FBI) to confirm, per the requirements of the Act, §§ 3311(a)(5) and 3321(a)(4), that they are not on the TWL. Once the applicant is cleared against the TWL, the Enrollment Operations Team is given the direction to officially enroll new members into the Program and the system is updated. The DCs are sent a list of all new enrollees and the NPN is notified of any new NPN enrollees on a weekly basis. Notification of membership status is provided to all new members; however, the method by which the members are notified is dependent upon their membership group. Methods have been developed between each member cohort and the Program, as described below. Eligibility criteria are defined by the Act in §§ 3311 and 3321, and found at 42 C.F.R. Part 88. Each application will be acknowledged with an appropriate letter, as follows. Letter templates

may be found in the “Eligibility Determinations, Health Condition Certifications, & Treatment Determinations Subject to Member Appeals” policy and procedure document, found in the Program’s file of record. If additional information is needed to complete an application, the Enrollment Operations Center will make repeated attempts to obtain the information. Letters are sent at 30 and 90 day intervals, as follows. Templates may be found in the “Eligibility Determinations, Health Condition Certifications, & Treatment Determinations Subject to Member Appeals” document: Upon receipt of a completed application, the Enrollment Operations Team prepares summary information for the HPS Member Services Team to review in considering the application. Each eligibility determination gives consideration to: As the Enrollment Operations Team processes applications for final decisions, the Enrollment Operations Team Manager will perform quality assurance by reviewing for accuracy all aspects of the application, including data entry and the decision logic for each recommendation sent to the Program’s Member Services lead. After review of the final application, the Enrollment Operations Team makes one of the following recommendations for dispensation of the application: The WTC Health Program may disenroll a WTC Health Program member, pursuant to 42 C.F.R. § 88.13, in the following circumstances: A disenrolled WTC Health Program member will be notified in writing by the WTC Health Program of a disenrollment decision, provided an explanation, as appropriate, for the decision, any administrative actions resulting from the decision, and provided information on how to appeal the decision. A disenrolled WTC Health Program member may appeal the disenrollment decision in accordance with Section 8 below. All applicants have the right to appeal an enrollment denial or disenrollment decision, pursuant to 42 C.F.R. § 88.14. Requests to appeal a denial of enrollment or a disenrollment decision must be postmarked within 120 calendar days of the date of the letter from the Administrator notifying the denied applicant or disenrolled member of the adverse decision. A valid request for an appeal must (1) be made in writing and

signed; (2) identify the denied applicant or disenrolled WTC Health Program member and designated representative (if applicable); (3) describe the decision being appealed and state the reasons why the denied applicant, disenrolled WTC Health Program member, or designated representative believes the enrollment denial or disenrollment was incorrect and should be reversed; and (4) be sent to the WTC Health Program at the address specified in the notice of denial or disenrollment. The appeal request may include relevant new information not previously considered by the WTC Health Program. 1 An appeal request that meets the above requirements, however, will still be considered invalid and outside the scope of the WTC Health Program's administrative appeal process if its sole argument is a challenge to existing law, regulations, or Program policies. In other words, if the issues raised in the appeal have already been determined by law, regulation, or Program policy, then the appeal may not move forward because there are no outstanding issues for the Program to resolve with respect to the individual appellant. For example, an appeal request may not challenge the enrollment criteria established in the Zadroga Act or the Program's regulation because those criteria are established by law and may only be changed by an act of Congress amending the law or the Program promulgating an amendment to the regulation, respectively. Similarly, an appeal request may not challenge a Program policy that has been established by the Administrator and is applicable to all Program applicants and/or members. Any challenge to criteria established by law, regulation, or Program policy through the appeal process would be ineffectual because revisions to such criteria require a broader legal, regulatory, or policy action that would be applicable to all Program members; therefore, the challenge cannot be addressed in the appeal of an individual applicant or member. An appeal request may, however, challenge the Program's application of the enrollment criteria (e.g., the individual could argue that the Program incorrectly determined the number of hours he/she worked or volunteered during a covered time period). An individual wishing to voice concerns or

request that the Administrator change a Program regulation or Program policy may write to the Administrator (separate and distinct from any individual appeal process). Changes to the Zadroga Act require an act of Congress. In accordance with the regulations, the Administrator will appoint a Federal Official to review the appeal request. The Federal Official is independent of the WTC Health Program and not engaged in any enrollment and eligibility or disenrollment decisions other than appeals, allowing for an objective third-party review of the facts.

The appeal request can be mailed or submitted electronically to the appeal coordinator at:

Appeal Coordinator

WTC Health Program

P.O. Box 7000

Rensselaer, NY 12144

Fax: 1.404.471.8338

The appeal procedure is as follows:

Templates of these letters may be found in the “Eligibility Determinations, Health Condition Certifications, & Treatment Determinations Subject to Member Appeals” document:

142 C.F.R. § 88.14(b)(1)-(2). Last Revised – April, 2024 The purpose of this chapter is to describe the circumstances in which a health condition may be certified under Title XXXIII of the PHS Act, the certification process, responsibilities in the certification process, conditions that may be certified, communications regarding certifications, and appeals of certification decisions. Further detail on the certification process is provided in the WTC Health Program Member Services Operations Manual, found in the Program’s file of record. The following sections of Title XXXIII of the PHS

Act are applicable to this Chapter: The following provisions in the WTC Health Program regulations in 42 C.F.R. Part 88 are also applicable to this Chapter: The parties involved in certifying health conditions and their responsibilities are detailed below. These are histologically-proven, metastatic, malignant neoplasms the primary origin of which cannot be identified during pre-treatment evaluation. The date of diagnosis of the metastatic disease will be used to evaluate eligibility for certification of CUPs. For malignant neoplasms diagnosed before September 11, 2001, and those diagnosed after September 11, 2001 but with insufficient latency, any recurrence or metastasis from such malignant neoplasms will not be considered for certification regardless of the amount of time that passes between remission of the pre-existing neoplasm and its recurrence or metastatic spread. An exhaustive search of the scientific literature has failed to identify evidence that toxic exposures aggravate, cause, or contribute to a pre-existing cancer resulting in a recurrence or metastasis that requires a change in treatment. A second primary cancer is a histologically-proven, new primary malignant neoplasm developing in a person with a history of cancer. The term applies to malignant neoplasms that have arisen independently and not as a result of recurrence or metastasis of the original primary malignant neoplasm. A second primary cancer is considered eligible for certification if it was diagnosed after September 11, 2001 and meets the WTC Health Program's minimum latency criteria for the specific cancer. Alleged cases of second primary cancers originating from the same tissue and/or of the same histological type as a malignant neoplasm that is certified, certifiable, or ineligible for certification will be evaluated on a case-by-case basis. The review will include consideration of the peer-reviewed scientific literature and Surveillance, Epidemiology, and End Results (SEER) Program Multiple Primary and Histology Coding Rules. Such reviews will be documented and included in the member file where relevant to a specific cancer certification evaluation. Special Note on Acute Traumatic Injuries and Musculoskeletal Disorders

Acute Traumatic Injuries

A WTC-related acute traumatic injury (ATI) is physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. Such health conditions include eye injuries, burns, head trauma, fractures, tendon tears, complex sprains, and other similar acute traumatic injuries.

In order for an ATI to be certified by the Program, the injury must be directly related to a member's 9/11 exposures and activities and must have occurred during one of the following time periods: September 11, 2001 – July 31, 2002 for acute traumatic injuries occurring at one of the New York City Area Sites; September 11, 2001 – November 19, 2001 for acute traumatic injuries occurring at the Pentagon Site; or September 11, 2001 – October 3, 2001 for acute traumatic injuries occurring at the Shanksville, Pennsylvania Site. In addition, the WTC responder or screening-eligible or certified-eligible survivor must have received medical treatment for the acute traumatic injury on or before September 11, 2003.

Musculoskeletal Disorders

A WTC-related musculoskeletal disorder (MSD) is a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. Such health conditions include low back pain, carpal tunnel

syndrome (CTS), and other musculoskeletal disorders.

In order for an MSD to be certified by the Program, the injury must be directly related to a member's 9/11 exposures and activities and must have occurred during the following time period: September 11, 2001 – July 31, 2002. The Zadroga Act only allows coverage of MSDs for WTC Responders; therefore, Survivors and Pentagon and Shanksville, PA Responders cannot be certified for an MSD. In addition, the WTC responder must have received medical treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003.

Health Conditions Medically Associated with WTC-Related Health Conditions

A condition that is medically associated with a WTC-related health condition is also eligible for certification and treatment within the WTC Health Program. In order for a medically associated health condition to be certified, the condition must result from the treatment or progression of a WTC-related health condition. The underlying WTC-related health condition must first be certified by the WTC Health Program before any conditions may be certified as medically associated with the underlying condition. Medically associated conditions are evaluated and certified on a case-by-case basis

The WTC Health Program requires that the CCE or NPN physician provide a detailed explanation in the WTC-3 Certification Request form (Appendix 3-A), and medical records as appropriate, that the health condition under consideration as medically associated resulted from either treatment or progression of the underlying certified WTC-related health condition. See Health Conditions Medically Associated with World Trade Center-Related Health Conditions. [5 pages, 484 KB]

Establishing that the Medically Associated Health Condition

“Results from” Treatment of a Certified WTC-Related Health Condition.

The WTC Health Program will review the CCE or NPN’s explanation to determine if: (i) the relationship linking the medically associated health condition the WTC-related health condition occurs without the influence of an intermediary health condition or event; and (ii) the linkage between the certified WTC-related health condition and the medically associated health condition resulting from treatment of the certified WTC-related health condition has been well-established by published peer-reviewed scientific literature.

“Results from” Treatment. The CCE or NPN physician must demonstrate by means of a detailed narrative (including medical records when appropriate) that the health condition “results from” medical treatment of the underlying certified WTC-related health condition without the influence of an intermediary health condition or event. The WTC Health Program will certify as medically associated only those conditions which directly result from treatment of a WTC-related health condition, i.e., that the medically associated condition occurred in absence of intervening medical events.

Note: CCE and NPN physicians are encouraged to consult with the Director, WTC Health Program Medical Benefits, about medically associated health conditions that result from treatment of a certified WTC-related health condition as certification will depend on the particular medical facts of each case.

Previously Published in Peer-Reviewed Literature. The CCE or NPN physician must demonstrate that the medical association between the underlying [certified

WTC-related] health condition and the medically associated health condition resulting from treatment of the underlying [certified WTC-related] health condition has been established in previously published peer-reviewed medical literature. The establishment of this medical association in the literature must be documented in the member file, whether included as part of the physician's narrative or otherwise captured by Program staff.

Establishing that the Medically Associated Health Condition "Results from" Progression of a Certified WTC-Related Health Condition.

The WTC Health Program will review the CCE or NPN physician's explanation to determine if: (i) the relationship linking the medically associated condition with the WTC-related health condition occurs without the influence of an intermediary health condition or event; and (ii) the linkage between the certified WTC-related health condition and the medically associated condition resulting from progression of the certified WTC-related health condition has been well-established in published, peer-reviewed scientific literature.

"Result from" Progression. The CCE or NPN physician must demonstrate by means of a detailed narrative (including medical records when appropriate) that the health condition "results from" progression of the underlying certified WTC-related health condition without the influence of an intermediary health condition or event.

Note: CCE and NPN physicians are encouraged to consult with the Director, WTC Health Program Medical Benefits, about medically associated health conditions that are the

result of progression of a certified WTC-related health condition as certification will depend on the particular medical facts of each case.

Previously Published in Peer-Reviewed Literature. The CCE or NPN physician must demonstrate that the medical association between the underlying [certified WTC-related] health condition and the medically associated health condition resulting from progression of the underlying [certified WTC-related] health condition has been established in previously published peer-reviewed medical literature. The establishment of this medical association in the literature must be documented in the member file, whether included as part of the physician's narrative or otherwise captured by Program staff.

A condition that is medically associated with a WTC-related health condition is also eligible for certification and treatment within the WTC Health Program. In order for a medically associated health condition to be certified, the condition must result from the treatment or progression of a WTC-related health condition. The underlying WTC-related health condition must first be certified by the WTC Health Program before any conditions may be certified as medically associated with the underlying condition. Medically associated conditions are evaluated and certified on a case-by-case basis The WTC Health Program requires that the CCE or NPN physician provide a detailed explanation in the WTC-3 Certification Request form (Appendix 3-A), and medical records as appropriate, that the health condition under consideration as medically associated resulted from either treatment or progression of the underlying certified WTC-related health condition. See Health Conditions Medically Associated with World Trade Center-Related Health Conditions. [5 pages, 484 KB] Note: CCE and NPN

physicians are encouraged to consult with the Director, WTC Health Program Medical Benefits, about medically associated health conditions that result from treatment of a certified WTC-related health condition as certification will depend on the particular medical facts of each case. The WTC Health Program will review the CCE or NPN physician's explanation to determine if: (i) the relationship linking the medically associated condition with the WTC-related health condition occurs without the influence of an intermediary health condition or event; and (ii) the linkage between the certified WTC-related health condition and the medically associated condition resulting from progression of the certified WTC-related health condition has been well-established in published, peer-reviewed scientific literature. Note: CCE and NPN physicians are encouraged to consult with the Director, WTC Health Program Medical Benefits, about medically associated health conditions that are the result of progression of a certified WTC-related health condition as certification will depend on the particular medical facts of each case. When a member is diagnosed with a health condition that the provider believes is related to a 9/11 exposure, the member may be eligible for medical treatment for that condition under the Program. If, following an initial health evaluation or monitoring or treatment exam, the treating CCE or NPN physician determines that the member has a health condition which is a qualifying condition covered by the Program, as described in Section 4, and that member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition or mental health condition, then the physician must submit this determination to the Program and request certification of the health condition in order to provide treatment under the Program.

Where a member's CCE/NPN makes a negative determination (a finding that exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, is not substantially

likely to be a significant factor in aggravating, contributing to, or causing the health condition or mental health condition) and declines to request certification of the health condition by the WTC Health Program, the member may request a secondary review of this decision by writing the Clinical Director of the CCE or NPN. The procedure for a secondary review is as follows:

The WTC-3 Certification Package is the standard documentation completed by a CCE/NPN physician to request certification for a member's health condition; it provides the medical rationale linking the exposure to the stated health condition. A sample of the form is provided in Appendix 3-A. This form must be used for any condition which a physician has determined to be WTC-related since the Program CCE contracts were implemented [i.e., as of July 1, 2011 for enrolled responders; as of September 29, 2011 for enrolled survivors; and as of October, 2013 for enrolled members assigned to the Nationwide Provider Network (NPN)]. The Clinical Director of the CCE or the NPN reviews, approves and securely submits the completed WTC-3 Certification Package signed by the examining or responsible physician to the Program. Such forms are also used to request certification of health conditions as medically associated with a WTC-related health condition. The WTC-3 Certification Package contains identifying information for the member and examiner, diagnostic codes for the condition(s) for which the member is requesting certification, and either a medical rationale linking 9/11 exposure to the health condition or the medical rationale linking the medically associated health condition to an existing WTC-related health condition. For a health condition medically associated with a WTC-related health condition, the physician's determination shall contain information on how the health condition has resulted from treatment of a previously certified WTC-related health condition, or how it has resulted from progression of the certified WTC-related health condition. All cancer certification requests require a pathology report to be submitted with the WTC-3 Certification Package. Specific guidance regarding how to complete the WTC-3

Certification Package, including reasonable practice examples using Program-approved templates, is provided below. When providing a rationale for the certification, requesters use an explanatory narrative that may be combined with Program-approved template within the WTC-3 form. The rationale should contain pertinent information about 9/11 exposure and time-linked emergence of symptoms. Facts available from the standardized monitoring or screening examination, including exposure assessment, presenting symptoms and temporal relationship of these symptoms relative to 9/11 exposure, should be included. Medical findings should be documented in the institutional medical record, which include the screening or monitoring exams and any additional medical testing or imaging studies required to establish the diagnosis. By procedure, the member's institutional medical record is incorporated by reference when the CCE provider or NPN Clinical Director requests certification using the WTC-3 Certification Package. This process provides the Program with all relevant information required to make an informed decision regarding the member's certification. See Appendix 3-B for instructions specific to completing the WTC-3 form for cancer. The WTC-3 submission must include a signed affirmative statement by the physician that the member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition or mental health condition. If the physician is unable to make such and affirmative finding, then the WTC-3 cannot be submitted or considered. The WTC-2 batch certification process was used for a subset of program members who had treatment initiated for qualifying conditions as part of the previous federally-sponsored programs (the Medical Monitoring and Treatment Program (MMTP) for responders and/or the Environmental Health Clinic (EHC) for community members). This process was implemented to ensure treatment continuity for members already receiving care under predecessor programs and is no longer being used. If the certifications for

qualified conditions were supported by documentation in the members' medical records, the Clinical Director of the CCE or the NPN submitted an attestation for all members and their associated conditions via electronic spreadsheet. The spreadsheet contained identifying member information and diagnostic codes for each qualifying WTC-related or medically associated condition that required certification. The CCE/NPN then transmitted the WTC-2 batch certification request to the Program in a secure manner (as described in Section 6, below). The Program verified the requested conditions against the Codebook (described further in Section 9, below) and returned any discrepant data to the submitter for rectification. Periodic summary reports of certified conditions by member were then sent to the CCE/NPN by the HPS contractor. The CCE/NPN is responsible for maintaining a record of a member's certifications to enable appropriate service authorization decisions. As part of their Quality Assurance Program the CCE/NPN conducts internal audits of their contracted part of the WTC Health Program at a minimum of every quarter. These data are made available to the Administrator of the WTC Health Program or designee. Where data is obtained, through a quality assurance audit or otherwise, that indicates that the certification issued through the WTC-2 process was incorrect, the Administrator of the WTC Health Program may de-certify a condition as appropriate. Certification is the lynchpin by which the Program ensures members receive appropriate services and that all services are provided in accordance with statutory and regulatory requirements. A CCE/NPN is responsible for submitting requests for health condition certification using the WTC-3 form. The WTC Health Program then reviews and evaluates the request (WTC-3) and makes one of three possible decisions for each health condition contained within the request: Authorization of Treatment Pending Certification is permitted pursuant to Sections 3312(b)(5) (responders) and 3322(a) (survivors) of the PHS Act and 42 C.F.R. § 88.20(c). Treatment pending certification is offered, where specifically requested by a CCE/NPN physician, in order to provide timely institution of therapy or continuity of care

while a certification request is being reviewed. A CCE or NPN physician is responsible for submitting requests for certification of a health condition using the WTC-3 form. The WTC Health Program then reviews and evaluates the request (WTC-3) and makes one of the three following decisions for each health condition contained within the request: The Program makes every effort to make informed decisions regarding WTC-related health condition certifications in a timely manner and to communicate those decisions to the member efficiently. For certification requests of health conditions medically associated with a WTC-related health condition, the Program will render a decision and notify the member in writing of the decision and the reason for the decision within 60 calendar days after the date the physician's determination was received. To that end, the Program has developed decision letters addressing the range of decisions that could be made in the certification process (e.g., approval or denial of certification request, the need for additional information to inform the certification decision, etc.). When a member's health condition is approved for certification as either a WTC-related health condition or a medically associated health condition, the Program sends the member a letter informing him/her of the certification and provides electronic notification to the CCE/NPN that requested the certification. When a member's requested health condition is denied certification, the Program sends the member letter informing him/her of the denial and provides an electronic copy of the letter to the requesting CCE/NPN. The denial letter discusses the condition requested, the reason for the denial, and the information submitted to the Program for review from the CCE or NPN. The letter also answers frequently asked questions and provides instructions about how appeal the denial decision. A suspended request for certification is neither certified nor denied, but has been placed in an administratively pended status until specific facts are either supplied (when missing) or clarified (when too vague or misleading) by the CCE or NPN submitting the request for certification. The WTC Health Program will notify the CCE or NPN that submitted the request for certification when

more information is required to complete processing of the request for certification. This notification will be made in writing by electronic message (via secure portal). The CCE or NPN has 60 days from the date of the written notification from the WTC Health Program to provide the Program with the requested additional information. The WTC Health Program will provide weekly updates to each CCE or NPN regarding any outstanding requests for certification that have been suspended pending additional information and the number of days that have elapsed since the notification and request for additional information for each case was sent to the CCE or NPN. As a result of the request for certification being suspended, the WTC Health Program member is generally not eligible to receive medical or pharmacy benefits for the health condition subject to request for certification. However, if the original submission requesting certification of a given condition included a time-limited authorization of treatment pending certification, the requesting CCE or NPN may choose to continue providing benefits to the member at their own expense. In the event that the suspended request for certification is subsequently approved through timely rectification of the record, reimbursement of treatment services will be permitted with an effective date of the signature date of the original WTC-3 submission. In the event that the condition is denied certification, any care provided outside the parameters of the Diagnostic Plan will not be covered and the CCE or NPN providing the care will be responsible for the costs of such care. If the concerns resulting in the suspended request are not resolved after 60 days as outlined above, then any authorization for treatment pending certification is terminated and the member is notified as per protocol. There are five potential outcomes for a request for certification that has been placed in a suspended status; those outcomes are as follows: The CCE or NPN responds to the notification of a suspended request for certification with additional or clarifying information. Based on this information, the Program is able to certify the health condition. The CCE or NPN responds to the notification of a suspended request for certification with additional or

clarifying information. This additional information does not satisfy the requirements for certification, however, and results in a denial of certification for the health condition. The member has the right to appeal the denial decision. The CCE or NPN responds to the notification of a suspended request for certification by indicating in writing that they would like to withdraw the original request for certification. If a withdrawal is requested, the WTC Health Program will no longer evaluate the request for certification and will administratively close the request file. Reasons for withdrawal may include the CCE/NPN determining that the requested information cannot be supplied in a timely manner or newly recognizing that the request for certification cannot be supported based on established WTC Health Program criteria. The CCE/NPN will inform the member of the withdrawal of the request for certification, and advise the member of their right to a secondary review. If the CCE or NPN responds to the WTC Health Program's notification of suspended request for certification but is unable to provide the requested information necessary to resolve the suspended certification request within the 60 day time limit allowed for final resolution of the request, then the WTC Health Program will take the following actions. The WTC Health Program will send a written communication to the CCE/NPN (via electronic message) asking for confirmation that they cannot provide additional information but that they still wish to request certification for the health condition. If the CCE/NPN responds in writing (via electronic message) that this is the case, then the WTC Health Program will deny the request for certification of the health condition due to lack of sufficient information to make a definitive evaluation of the link between 9/11 exposure and the requested health condition or between the WTC-related health condition and the requested medically associated health condition. The WTC Health Program will inform the member of the denial and his or her right to request an appeal of the denial decision. If the CCE or NPN does not respond at all to the notification of a suspended request for certification within the 60 day time limit allowed for final resolution of the request, then the WTC

Health Program will administratively close the request for certification of the health condition due to lack of sufficient information to support a physician's determination (upon which a certification decision could be based). Similarly, if the WTC Health Program asks the CCE/NPN for a confirmation that they cannot provide additional information but that they still wish to request certification for the health condition (as outlined above) and the response from the CCE/NPN is unclear or equivocal as to the intent to request certification, then the WTC Health Program will administratively close the request for certification of the health condition due to lack of sufficient information to support the physician's determination. In either case, the WTC Health Program will notify the CCE or NPN in writing via electronic message that the request for certification has been administratively closed. The CCE/NPN will inform the member of the administrative closure of the request for certification, and advise the member of his or her right to a secondary review. The CCE/NPN may submit a new WTC-3 at a later date should additional or clarifying information becomes available.

The WTC Health Program does not certify health conditions for deceased members. The WTC Health Program may cover medically necessary treatment for certified health conditions from the effective date of the certification (or from the effective date of the certification request in cases of appropriately requested treatment pending certification). The WTC Health Program will not review certification requests dated after a member's death.

WTC-related health conditions identified in 42 C.F.R. § 88.15 have been grouped into certification categories to align the limited coverage intent of the Program with standards of care and principles of medical necessity. The WTC Health Program defined the business rules used in the processing (adjudication) of healthcare claims to ensure compliance with the limited coverage intent of the Program. Each member category – General Responder, Screening-eligible Survivor, Certified-eligible Survivor, FDNY Responder, and FDNY Family Member – is associated with one or more

designated benefit plans. The WTC Health Program Codebook contains the covered diagnosis codes (ICD-9, or if after October 1, 2015, ICD-10), procedural codes (CPT-4 and HCPCS), and pharmaceutical codes (Rx) for the Program. Providers are responsible for working with the CCE/NPN to determine allowable services. A more complete description of these categories and benefit plans may be found in Chapter 4. Requests to appeal a denial of certification of a health condition as a WTC-related health condition or as a health condition medically associated with a WTC-related health condition, a decertification of a health condition, or a denial of authorization for treatment must be postmarked within 120 calendar days of the date of the letter from the Administrator notifying the member of the adverse decision. A valid request for an appeal must (1) be made in writing and signed; (2) identify the WTC Health Program member and designated representative (if applicable); (3) describe the decision being appealed and the reasons why the member or designated representative believes the decision is incorrect and should be reversed; and (4) be sent to the WTC Health Program at the address specified in the notice of denial.1 The description in the request may include scientific or medical information correcting factual errors that may have been submitted to the WTC Health Program by the CCE or NPN; information demonstrating that the WTC Health Program did not correctly follow or apply relevant WTC Health Program policies or procedures; or any information demonstrating that the WTC Health Program's decision was not reasonable given the facts of the case. The basis provided in the appeal request must be sufficiently detailed and supported by information to permit a review of the appeal. Any new information not previously considered by the WTC Health Program must be included with the appeal request, unless later requested by the WTC Health Program.2 For more detailed information about what may or may not be considered during the appeal process, please see Chapter 4, Section 3.6 of this Administrative Manual. An appeal request that meets the above requirements, however, will still be considered invalid and outside the scope of

the WTC Health Program's administrative appeal process if its sole argument is a challenge to existing law, regulations, or Program policies. In other words, if the issues raised in the appeal have already been determined by law, regulation, or Program policy, then the appeal may not move forward because there are no outstanding issues for the Program to resolve with respect to the individual appellant. For example, an appeal request may not challenge a denial of certification of a health condition where the denial was based on certification requirements established in the Zadroga Act or the health condition not being included on the List of WTC-Related Health Conditions (List) in the Program's regulation at 42 C.F.R. § 88.15 because those criteria are established by law and may only be changed by an act of Congress amending the law or the Program publishing an amendment to the regulation, respectively. Similarly, an appeal request may not challenge a denial of certification based on a Program policy that has been established by the Administrator and is applicable to all Program members, such as the latency requirements in the Program's Minimum Latency & Types or Categories of Cancer. Any challenge to criteria established by law, regulation, or Program policy through the appeal process would be ineffectual because revisions to such criteria require a broader legal, regulatory, or policy action that would be applicable to all Program members; therefore, the challenge cannot be addressed in the appeal of an individual member. An appeal request may, however, challenge the Program's application of the certification criteria (e.g., the member could argue that the Program incorrectly determined the amount of time that elapsed between the member's initial 9/11 exposure and the date of his/her initial cancer diagnosis). An individual wishing to voice concerns or request that the Administrator change a Program regulation or policy may write to the Administrator. An individual may also petition the Administrator to add a health condition to the List of WTC-Related Health Conditions (List); for more information on the petition process, see https://www.cdc.gov/wtc/petitions.html. The petition process can only be used to

request the addition of a WTC-related health condition to the List. It cannot be used to request that the Program cover a specific health condition medically associated with a certified WTC-related health condition, cover a certain type of treatment, or amend Program regulations or policies. Changes to the Zadroga Act require an act of Congress. When a denial of health condition certification or a decision to decertify a health condition is issued by the Program, the member may appeal the decision. An appeal must be made in writing within 120 calendars days from the date of the WTC Health Program's letter notifying the member of the denial or decertification decision. The written, signed appeal request should include a full explanation of why the member (or the member's designated representative) believes that the denial decision is incorrect. See Overview of the Appeal Process for Denial of Health Condition [PDF, 9 pages, 684 KB] The following mailing address or fax number should be used to submit a request for appeal:

Appeal Coordinator

WTC Health Program

Po Box 7000

Rensselaer, NY 12144

Fax: 1-404-471-8338

142 C.F.R. § 88.21(b).

242 C.F.R. § 88.21(b)(2)(iii).

Last Revised – May, 2024 4-A WTC Health Program Instructions for Completing WTC-3 Package Requesting Certification for Types of Cancer 4-B Medical Change Review Request Form 4-C Transplant Authorization Form 4-D Home Health Care CMS Form 485 4-E Dental Prior Authorization Level 3 Request Form 4-F Policy and Procedures for Cancer Screening This chapter describes the medical benefits that are

available through the World Trade Center (WTC) Health Program under the James Zadroga 9/11 Health and Compensation Act of 2010 (the Act), including: (1) the Program's responsibilities regarding the provision of medical benefits and the roles of various parties; (2) the types of medical benefits and treatment provided; (3) communications regarding medical benefits; (4) appeals of treatment authorization decisions; (5) the process for requesting changes to medical treatment that is permitted under the WTC Health Program; and (6) unique considerations relative to certain permitted services. The following Sections of the Act are applicable to this chapter: Program regulations relating to medical benefits are established in the following sections of 42 C.F.R. Part 88: The parties involved in providing WTC Health Program medical benefits and their roles are detailed below: The WTC Health Program provides medical treatment services for the conditions specified in the Act and 42 C.F.R. § 88.15, as well as any other condition added to the List through the rulemaking procedures specified by the Act.

Pursuant to Section 3312(b)(4) of the Act, the scope of treatment covered includes services of physicians and other health care providers, diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other medically necessary treatment. Transportation expenses to secure medically necessary treatment through the NPN, involving travel of more than 250 miles, are also authorized under

Section 3312(b)(4)(C).1

Section 3312(b)(3)(A) requires physicians and other providers to provide medically necessary treatment that is in accordance with medical treatment protocols when providing treatment for a WTC-related health condition. Medical treatment protocols, also referred to as "medical guidelines," are developed by the Data Centers (DCs) in accordance with accepted medical practice and recommendations from professional

organizations, such as the American Medical Association, American College of Chest Physicians, and the like. The protocols are subsequently approved by the Administrator of the WTC Health Program or Designee for use with WTC Health Program members. Protocols are maintained by the DCs/CCEs as well as in NIOSH's official file of record. Section 3312(b)(3)(B) requires that the Administrator of the WTC Health Program issue regulations specifying a standard for determining medical necessity, a process for determining whether the standard is being met, and an appeals process for medical necessity determinations. 2 The WTC Health Program uses benefit plans to determine the type of medical procedures or treatment a member is eligible to receive. "Benefit plans" are groupings developed by the WTC Health Program that define the acceptable ranges of care for specific categories of covered health conditions. The WTC Health Program offers multiple benefit plans, which are open to members based on their status as defined in the Act (e.g., Responder or Survivor) and their certified health condition(s). The WTC Health Program Codebook also lists approved medical procedures and treatment by benefit plan (For further information, see Section 3.2 WTC Health Program Codebooks). The benefit plans include procedures for the initial health evaluation for survivors, annual medical monitoring for responders and certified-eligible survivors, diagnostic evaluation to enable a nonspecific symptom or abnormal finding to be properly diagnosed for the purpose of certification, and treatment benefit plans organized by the category of certified health condition(s). Screening-eligible Survivor WTC Health Program Benefit Plan: Survivor Screening (during initial health evaluation period); Diagnostics (during initial health evaluation period); Cancer Diagnostics (during initial health evaluation period 3) Certified-eligible Survivor WTC Health Program Benefit Plan: Monitoring; Diagnostics; Cancer Diagnostics; Treatment; Cancer Treatment if certified for WTC-related cancer condition. General & FDNY Responder WTC Health Program Benefit Plan: Monitoring; Diagnostics; Cancer Diagnostics; Treatment; Cancer Treatment if certified for WTC-related cancer condition. FDNY Family

WTC Health Program Benefit Plan: Diagnostics (coverage limited to mental health conditions); Treatment (coverage limited to certified mental health conditions) Shanksville Responder WTC Health Program Benefit Plan: Monitoring; Diagnostics; Cancer Diagnostics; Treatment; Cancer Treatment if certified for WTC-related cancer condition. Pentagon Responder WTC Health Program Benefit Plan: Monitoring; Diagnostics; Cancer Diagnostics; Treatment; Cancer Treatment if certified for WTC-related cancer condition. Section 3321(b)(1) of the Act provides for an initial health evaluation (screening) for screening-eligible WTC survivors. The purpose of the screening is to determine whether the member has a WTC-related health condition and is eligible for follow-up monitoring and treatment benefits under the WTC Health Program. Unlike annual monitoring exams, the screening is a one-time evaluation. However, the member may seek additional screenings at his or her own expense. 4 Upon enrollment in the WTC Health Program, survivors are classified as screening-eligible survivors without a certified health condition and are eligible for the Survivor Screening Benefit Plan. As screening-eligible survivors, they have access to all of the services in the Survivor Screening Benefit Plan and the services in the Cancer Screening Benefit Plan. The initial health evaluation for screening-eligible survivors is listed in the WTC Health Program Codebook, Volume B, under the Survivor Screening Benefit Plan. Use of codes included under the Survivor Screening Benefit Plan indicates to the claims processing system that a given procedure is part of the survivor’s initial health evaluation. The initial health evaluation includes all of the following elements, which have been implemented for the WTC Health Program responder and survivor populations based largely on USPSTF guidelines:

Once a health condition is certified, the screening-eligible survivor’s status changes to certified-eligible survivor and they are authorized to receive annual medical monitoring and medically necessary treatment to manage that condition following the medical protocols approved by the Program. 8 Under rare

circumstances, a survivor may obtain certification prior to completion of the full initial health evaluation exam if specific requirements, including medical record documentation and other certification requirements are met.9 The member is still required to receive the appropriate initial health evaluation to identify other health conditions that may be a result of exposure.10

Sections 3311(b) and 3321(b)(1) authorize monitoring benefits for enrolled WTC responders and certified-eligible survivors, respectively. These monitoring benefits consist of yearly medical examinations and long-term health monitoring and analysis. Monitoring benefits are provided through the CCEs, or the NPN for enrolled members who live outside of the New York metropolitan area.11 The purpose of medical monitoring is to identify health concerns for early intervention, characterize the health of Program members over time, facilitate efforts for continuous quality improvement in the healthcare rendered by the Program, and inform emergency preparedness efforts for future disasters.12 Monitoring benefits for WTC responders and certified-eligible survivors are listed in the WTC Health Program Codebook, Volume B, under the Monitoring Benefit Plan. Use of procedure codes included under the Monitoring Benefit Plan indicates to the claims processing system that a given procedure is part of the standard monitoring exam. The monitoring exam includes the following elements, which have been implemented for the WTC Health Program responder and survivor populations based largely on USPSTF guidelines: All members are eligible for the Diagnostics Benefit Plan, including members who have a certified health condition(s) and members who do not have a certified health condition(s). Screening-eligible survivors who do not have a certified health condition(s) have access to the Diagnostics Benefit Plan only during the initial health evaluation period. Codes in this benefit plan should be used when evaluating a member’s symptoms to determine whether a member has a WTC-related health condition, including both cancer and non-cancer conditions. Mental health conditions under the Diagnostics Benefit Plan are also

available to FDNY family members. All diagnostic claims should be coded using an approved ICD-10 code in the Diagnostics Benefit Plan. Following certification of the WTC-related health condition (as appropriate), the ICD-10 codes available for that condition can be used as part of the Treatment Benefit Plan. Under the Treatment Benefit Plan, the WTC Health Program provides coverage for medical diagnoses and procedures related to a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The Treatment Benefit Plan should be used for all non-cancer certifications, while the Cancer Treatment Benefit Plan should be used for all cancer certifications. FDNY family members are eligible for treatment of mental health conditions under the Treatment Benefit Plan. For responders and certified-eligible survivors, providers may use any of the procedure codes located in the Treatment Benefit Plan, as long as the codes correspond with the condition-specific Care Suite. Care Suites are used in the Treatment Benefit Plan to further group medical diagnosis codes (ICD-10) into specific treatment categories. When a member is certified for a WTC-related health condition, the member is assigned to a Care Suite that correlates with their certified health condition(s). The medical services associated with each covered condition arise from standard coding references, including the American Medical Association's (AMA's) Current Procedural Terminology (CPT®) codes, and the Centers for Medicare and Medicaid Services' (CMS') Healthcare Common Procedural Coding System (HCPCS) Level II codes. The table below provides an example of ICD-10 diagnosis codes that are in the Gastroesophageal Reflux Disorder (GERD) Care Suite. Certification of any of the following WTC-related ICD-10 diagnosis codes opens up the GERD Care Suite, so that the member has access to all the medical services within the GERD Care Suite. Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: J39.2 ICD-10 Code Description: Diseases of Pharynx- Other Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K20.0 ICD-10 Code Description: Esophagitis- Eosinophilic

Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K20.8 ICD-10 Code Description: Esophagitis- Other Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K21.0 ICD-10 Code Description: Gastro-esophageal reflux with esophagitis Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K21.9 ICD-10 Code Description: Gastro-esophageal reflux without esophagitis Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.30 ICD-10 Code Description: Chronic superficial gastritis without bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.31 ICD-10 Code Description: Chronic superficial gastritis with bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.40 ICD-10 Code Description: Chronic atrophic gastritis without bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.41 ICD-10 Code Description: Chronic atrophic gastritis with bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.50 ICD-10 Code Description: Chronic gastritis without bleeding – Unspecified Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.51 ICD-10 Code Description: Chronic gastritis with bleeding—Unspecified Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.60 ICD-10 Code Description: Other gastritis without bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.61 ICD-10 Code Description: Other gastritis with bleeding Gastroesophageal Reflux Disorder WTC-Related ICD-10 Code: K29.90 ICD-10 Code Description: Gastroduodenitis without bleeding—Unspecified The Care Suites provide an important fiscal control for the Program by defining additional business rules guiding the adjudication of healthcare claims for payment. The examining physician submits information about a specific health condition to the WTC Health Program to review for certification (see Chapter 3, Certification of Health Conditions). The Codebooks provide the medical coding for all medically necessary care to manage the certified health condition under a specific Care Suite. The Care Suites enable the claims adjudication process to approve the appropriate care for that health condition, but withstand the variability that may occur

between providers or referral specialists using different specific diagnosis codes when billing for procedures. The conditions listed within a given Care Suite either share target symptoms (like cough), or share a mechanism of injury (like inflammation) within a given organ system. The Program uses the following Care Suites in the Treatment Benefit Plan: Once a member receives certification for a new non-cancer health condition, the condition is assigned to a specific Care Suite listed above. The claims processing system compares the billed diagnosis code on a claim against the Care Suite for the member's health condition, and verifies that the diagnosis on a claim is among the accepted diagnoses within that Care Suite. This process provides important checks and balances to ensure only approved care for the member's certified condition is delivered under the WTC Health Program. Health conditions medically associated to the WTC-related health condition due to the progression or treatment of the certified WTC-related health condition are also treated through the Care Suite model and require certification. "Ancillary condition" refers to a health condition that does not meet the requirements for certification under the Program, but must be treated in order to manage, ameliorate or cure a certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition. Ancillary conditions are typically within the same organ system as the certified-WTC related health condition or certified health condition medically associated with a certified-WTC related health condition. This includes the acute complications of WTC-related health conditions or common treatment side effects that are generally inexpensive to manage (ex. Cough, nausea). WTC Health Program cancer screening benefits are based upon guidelines recommended by the U.S. Preventive Services Task Force (USPSTF). The Program only covers cancer screening services with a USPSTF Grade A or Grade B recommendation15. Cancer screening is currently limited to breast, cervical, colon, and lung cancers. Cancer screening procedures can be billed with any valid diagnosis code listed in the WTC Health Program, Codebook Volume B. Cancer screening is available to

all WTC Health Program members16 (except FDNY family members) who meet the age and risk guidelines set forth by the USPSTF. The timing and frequency of cancer screening are based on the following guidelines: Exclusion criteria for all forms of cancer screening covered by the WTC Health Program are based on best medical practice and include: When a CCE or NPN health provider determines that a member has an abnormality which merits diagnostic evaluation for a possible WTC-related cancer, the provider uses codes in the Cancer Diagnostic Benefit Plan. The Cancer Diagnostic Benefit Plan is assigned to all enrolled responders (except FDNY family members), and is also available to enrolled survivors during the initial health evaluation period. If the survivor has a certified WTC-related health condition, the Cancer Diagnostic Benefit Plan is available on a continuous basis along with the Monitoring Benefit Plan. CCE and NPN providers should use their clinical judgment to determine when clinical, laboratory, or imaging findings merit further evaluation for a possible WTC-related cancer, while considering the exposure history of the member and the likelihood of finding a form of cancer that is covered by the WTC Health Program. The services (procedure codes) that are permitted for cancer under the Cancer Diagnostic Benefit Plan are found in the WTC Health Program Codebook, Volume A. In addition, numerous ICD-10 condition codes (some that correlate with various signs and symptoms that could be indicative of cancer) may be used for services billed under the Cancer Diagnostic Benefit Plan. These allowable condition codes (ICD-10) are listed in the WTC Health Program Codebook, Volume B. When a CCE or NPN physician determines that a member’s 9/11 exposures are substantially likely to have been a significant factor in aggravating, contributing to, or causing a cancer condition, the physician may request certification of the member’s condition with the submission of a WTC-3 certification request. To assist the CCE or NPN provider with certification requests for cancer conditions, a supplemental information packet has been developed entitled “Instructions for Completing WTC-3 Package Requesting Certification for Types

of Cancer."21 Once a member has been certified for a WTC-related cancer, the member is assigned to the Cancer Treatment Benefit Plan. The Cancer Treatment Benefit Plan contains the medical services (procedure codes) necessary to treat certified cancer conditions, medically associated conditions, and ancillary conditions.22 The procedure codes for these services are found in the WTC Health Program Codebook, Volume A. The cancer diagnosis (ICD-10) codes are found in the WTC Health Program Codebook, Volume B. The National Comprehensive Cancer Network has developed "Clinical Practice Guidelines in Oncology" (NCCN Guidelines23) for cancer treatment. To the extent practical and possible, these guidelines will be used to guide cancer treatment under the Program. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The WTC Health Program Codebook lists approved medical procedures and diagnosis codes that may be used for members, depending on the members' Member Category (Responder or Survivor) and their certified health condition(s). The WTC Health Program Codebook is divided into two volumes, which are further organized by benefit plans that define the acceptable ranges of care for specific categories of health conditions. The treatment benefit plan is further organized by care suites. (For further information, see Approved Benefit Plans, Section 2.0). The Codebook should be consulted by the CCE/NPN providers to determine payable services and to review applicable guidelines and authorization requirements. Limitations and authorization requirements are further described in Guidelines for Covered Services, Section 4.0 . The Codebook lists the available procedure/service code, code description, mapping to the respective benefit plan, relevant effective dates, prior authorization levels (if applicable), guidelines (if applicable), service limitations (if applicable), and code history. The WTC Health Program Codebook, Volume A is reviewed and updated on a regular basis, and is provided to the CCEs and NPN. The diagnosis codes arise from standard coding references, including the International Classification of Diseases,

Revision 10 (ICD-10). The WTC Health Program Codebook, Volume B lists the available diagnosis code, code description, mapping to the respective benefit plan or Care Suite, relevant effective dates, guidelines (if applicable), and code history. The WTC Health Program Codebook, Volume B is reviewed and updated on a regular basis, and is provided to the CCEs and NPN. To ensure members receive ongoing high-quality, WTC Health Program-approved care, the Program maintains a mechanism for making necessary changes to the WTC Health Program Codebook. WTC Health Program-initiated changes in covered health condition diagnostic and treatment codes are made on an ongoing basis. These changes may be enacted to refine treatment protocols, align code coverage with WTC Health Program approved coverage, or bring codes in line with updates made by organizations that oversee the codes (such as the American Medical Association or the Centers for Medicare and Medicaid Services). The CCE/NPN may determine 26 that a diagnosis, procedure, or medical product is necessary for quality patient care, but is not currently covered by the WTC Health Program. The CCE/NPN may also need to request changes to covered health condition diagnostic and treatment codes. In both of these scenarios, the CCE/NPN Clinical Director may request coverage for the diagnosis, procedure, or medical product, or a change to the code, by properly completing and submitting a WTC-5 Medical Code Request Form (Appendix 5.2) to the WTC Health Program MBM via the Medical Code Request Process. The submission of this form triggers the process, which begins with a review of the request and a subsequent decision by the WTC Health Program MBM through the HPS. The WTC Health Program MBM will review the CCE/NPN-completed WTC-5 Medical Code Request Form (Appendix 5.2) and render one of the following decisions: The CCE/NPN and Program staff are required to use the most current version of the Codebook. Because the Codebook undergoes frequent revisions, the CCE/NPN and Program staff should always consult the most current version of the Codebooks when referencing any procedure or diagnosis codes cited in this manual to determine if

the code is still valid. Codebooks are updated and posted monthly in the SAMS Portal for the CCEs/NPN to access. Certain medical services, devices, and drugs have limited use guidelines and/or require Prior Authorization (PA). Brief guidelines, including those related to PAs, are listed in the Codebook and direct the treating provider to use services in limited or specific clinical situations that align with the Program's limited health plan model. More information on coverage limitations and service specific coverage decisions can be viewed in Section 4.0 "Guidelines for Covered Services (A-Z)." The Codebook will list the code, definition, authorization requirement, and guideline (if applicable). The CCE/NPN Clinical Director may designate individuals to serve as designees for Level 2 Prior Authorization (PA2) and Level 3 Prior Authorization (PA3) requests. The CCE/NPN Clinical Director is liable for all PA2/PA3 decisions. The CCE/NPN Clinical Director may designate a limited number of staff members to sign PA2/PA3 requests on the CCE/NPN Clinical Director's behalf only if they have the appropriate training and expertise. The name and credentials of the designee must be sent to the WTC Health Program for approval as a selected "treatment authorization designee." Medical necessity documentation must clearly state the justification for use of the service, drug, or device. If the member is certified, documentation must clearly state how the service/drug/device manages, ameliorates, or cures the certified WTC-related health condition or health condition medically associated with a certified WTC-related condition. Some services are for diagnostic and evaluation purposes and should have clear documentation in the member medical record or other CCE/NPN tracking system as to why the service, drug, or device is necessary to diagnose and evaluate a suspected WTC-related health condition.

No further notification to the WTC Health Program is required for PA2s, since the CCE/NPN stamp on a paper-based or electronically-submitted medical claim (described in Chapter 5) reflects the CCE/NPN acknowledgement that the claim is valid in accordance with all WTC Health Program

requirements, including those related to PAs.

If the CCE/NPN Clinical Director denies the PA2, the members may request a secondary review. Each CCE/NPN must have an established secondary review process. Please contact the CCE/NPN for instructions on the secondary review process. Some services which require a PA3 (e.g. home health aide, hospice inpatient respite care, etc.) have a Medical Coverage Determination (MCD) with specific guidance on use and limitations (see MCDs in Section 4.0 “Guidelines for Covered Services A-Z”). The CCE/NPN Clinical Director must submit a PA3 Request to the WTC Health Program for any service, drug, or device that requires a PA3. Prior to performing or authorizing a service that requires a PA3, the CCE/NPN Clinical Director must submit a PA3 Request to the WTC Health Program and receive authorization from the Program. If the PA3 Request is not received, the WTC Health Program will not provide payment for the service. The WTC Health Program will either approve, deny, or administratively close the PA3 Request and will return the form, along with the decision, to the Health Program Support (HPS) contractor for distribution to the requesting CCE/NPN. In the event there is an urgent need for the medical service, the CCE/NPN Clinical Director may submit a PA3 Request for the medically necessary, urgent services retrospectively. This retrospective PA3 Request must be submitted within the timeframe parameters stated within the MCD. For those services which do not currently have an MCD, the retrospective PA3 should be submitted within 14 calendar days of the start date of services. Each medical service will generally be authorized as a single service unless otherwise requested by the CCE/NPN in the PA3 Request. The rationale for additional services must be included in the medical justification. For PA3 Requests extending beyond a single service, the CCE/NPN must specify an authorization date range and intended quantity (or unit) of service. The HPS contractor coordinates with the MBM to process the authorization request. The HPS contractor will notify the CCE/NPN Clinical Director of the approval, denial, or administrative closure. While certification is pending,

authorization for time-limited treatment of a WTC-related health condition or health condition medically associated with a WTC-related health condition may be requested at the CCE/NPN physician's discretion through the WTC-3 Form. The purpose of this authorization is to ensure continuity of appropriate medical care that is time sensitive and consistent with Program policy. Such authorization must be obtained from the WTC Health Program before treatment is provided, except for the provision of treatment for a medical emergency. 28 Treatment rendered after WTC-3 submission, but prior to certification, will only be covered if the request for treatment pending certification was included in the WTC-3 submittal, the request for certification is ultimately granted, and the treatment provided is medically necessary, does not require a Level 3 Prior Authorization, follows Program guidelines, and is rendered by a CCE/NPN-affiliated provider. In the event that the condition is denied certification, any care provided for the condition that is outside the parameters of the Diagnostic Plan or Cancer Diagnostics Benefit Plan shall be discontinued immediately and the CCE or NPN providing the care will be responsible for the costs of such care.29 Requests to appeal a denial of authorization for treatment must be postmarked within 120 calendar days of the date of the letter from the Administrator notifying the member of the adverse decision. A valid request for an appeal must (1) be made in writing and signed; (2) identify the WTC Health Program member and designated representative (if applicable); (3) describe the decision being appealed and the reasons why the member or designated representative believes the decision is incorrect and should be reversed; and (4) be sent to the WTC Health Program at the address specified in the notice of denial.30 The description in the request may include scientific or medical information correcting factual errors that may have been submitted to the WTC Health Program by the CCE or NPN; information demonstrating that the WTC Health Program did not correctly follow or apply relevant WTC Health Program policies or procedures; or any information demonstrating that the WTC Health Program's decision was not reasonable

given the facts of the case. The basis provided in the appeal request must be sufficiently detailed and supported by information to permit a review of the appeal. Any new information not previously considered by the WTC Health Program must be included with the appeal request, unless later requested by the WTC Health Program.31 An appeal request that meets the above requirements, however, will still be considered invalid and outside the scope of the WTC Health Program's administrative appeal process if its sole argument is a challenge to existing law, regulations, or Program policies. In other words, if the issues raised in the appeal have already been determined by law, regulation, or Program policy, then the appeal may not move forward because there are no outstanding issues for the Program to resolve with respect to the individual appellant. For example, an appeal request may not challenge a denial of certification of a health condition where the denial was based on certification requirements established in the Zadroga Act or the health condition not being included on the List of WTC-Related Health Conditions (List) in the Program's regulation at 42 C.F.R. § 88.15 because those criteria are established by law and may only be changed by an act of Congress amending the law or the Program publishing an amendment to the regulation, respectively. An individual wishing to voice concerns or request that the Administrator change a Program regulation or policy may write to the Administrator. An individual may also petition the Administrator to add a health condition to the List of WTC-Related Health Conditions (List); for more information on the petition process, see https://www.cdc.gov/wtc/petitions.html. The petition process can only be used to request the addition of a WTC-related health condition to the List. It cannot be used to request that the Program cover a specific health condition medically associated with a certified WTC-related health condition, cover a certain type of treatment, or amend Program regulations or policies. Changes to the Zadroga Act require an act of Congress. When a denial of authorization for treatment is issued by the Program, the member may appeal the decision. An appeal must be made in writing within 120 calendars days

from the date of the WTC Health Program's letter notifying the member of the denial or decertification decision. The written, signed appeal request should include a full explanation of why the member (or the member's designated representative) believes that the denial decision is incorrect. See Overview of the Appeal Process for Denial of Health Condition [PDF, 10 pages, 591KB] . The following mailing address or fax number should be used to submit a request for appeal:

Appeal Coordinator

WTC Health Program

P.O. Box 7000

Rensselaer, NY 12144

Fax: 1-404-471-8338

Covered services, procedures, and devices are given codes and listed in the Program Codebooks for use by CCE/NPN and network providers. Some codes include additional guidelines for use, which are listed in the Codebook. Certain subsets of services have exceptions, limitations, and/or authorization criteria, which are desribed in the section below. For those services, procedures, and devices with more detailed exceptions and limitations, the Program has created Policy and Procedure (P&P) documents that broadly delineate the Program's stance on benefit or pharmaceutical coverage, outline high-level Program procedure, or clarify current law and regulation. Some P&Ps generate more comprehensive coverage information contained in documents called Medical Coverage Determinations (MCDs). MCDs are an administrative tool which provide coverage information for specific services, along with qualifying criteria for coverage and instructions for authorization. Certain MCDs may also have applicable forms, such as prior authorization forms or reimbursement forms, intended for use by WTC Health Program providers. The below section outlines Program guidelines for certain covered services, procedures, and devices. The content in this section undergoes regular programmatic evaluation, as the Program revises its policies

and procedures to reflect the latest administrative regulations. As a result, this section may have frequent program updates or new language in development. Acupuncture involves the manipulation of a bodily system by inserting small needles into identified anatomical points. Acupuncture methods may also include the use of heat, pressure, friction, suction, and electromagnetic impulses. The WTC Health Program provides coverage of such acupuncture services in certain instances. The WTC Health Program will cover medically necessary acupuncture services for members with certified WTC-related cancer when authorized by a WTC Health Program provider. The WTC Health Program follows the National Comprehensive Cancer Network (NCCN) guidelines which recommend the use of acupuncture for cancer-related pain, fatigue, nausea, and/or vomiting. The WTC Health Program will also cover acupuncture services for members with chronic pain resulting from certified WTC-related acute traumatic injuries (ATI), musculoskeletal disorders (MSD), and health conditions causing chronic pain that are medically associated with the ATI or MSD condition. The WTC Health Program must authorize acupuncture services for ATI and MSD conditions. Members may receive up to 12 acupuncture visits in 90 days if they meet certain criteria for authorization. Members showing improvement may receive subsequent authorization for an additional eight acupuncture visits for a total of 20 acupuncture visits during the 12-month period from the date of their first treatment.

Authorization Required – Medical Coverage Determination [PDF, 6 pages, 208 KB]

Acupuncture PA3 Request Form for Providers [PDF, 4 pages, 207 KB]

CAR-T therapy is a type of cancer treatment that is used when standard cancer treatments have failed or cancer has relapsed. In CAR-T therapy, a type of immune system cell called a T-cell is taken from a patient’s blood and altered in the laboratory so it will attack cancer cells. Large numbers of CAR-T cells are grown in the laboratory and given to the patient by infusion. CAR-T therapy may be covered by

the WTC Health Program when the services are medically necessary for the member's certified WTC-related cancer, or health condition medically associated with a certified WTC-related cancer.

Members may receive medically necessary CAR-T therapy when they meet certain criteria for authorization. CAR-T therapy must be administered at a healthcare facility enrolled in the FDA Risk Evaluation and Mitigation Strategies (REMS) compliance program; the therapy must be used for either an FDA-approved indication or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia. Coverage of CAR-T therapy services is permitted only when in accordance with other Program guidelines.

Authorization Required – Medical Coverage Determination [PDF, 204 KB, 5 pages, June 2023]
CAR-T PA3 Request Form for Providers [PDF, 216 KB, 3 pages, June 2023]

The WTC Health Program will only cover medically necessary healthcare services within the United States and its territories, including the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. The WTC Health Program will not cover medical care, pharmacy products, or supplies received outside of the United States or its territories.

COVID-19 is a systemic respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or SARS-CoV-2 infection). The virus spreads through respiratory droplets or very small particulates produced when an infected person coughs, sneezes, or talks. Some people infected may be asymptomatic. For those who are symptomatic, illness may range from mild to severe. Adults 65 years

and older and people with certain underlying medical conditions are at higher risk for severe COVID-19. The WTC Health Program may provide coverage of acute COVID-19 diagnostic and treatment services that are medically necessary to manage, ameliorate, or cure a certified WTC-related health condition or medically associated health condition and which meet relevant prior authorization criteria. The CCE/NPN Clinical Director may authorize acute COVID-19-related services only when the member meets all of the applicable requirements described in this medical coverage determination (MCD).

Authorization Required – Medical Coverage Determination – COVID-19 [PDF, 221 KB, 10 pages, July 2021]

The WTC Health Program provides limited coverage of medically necessary dental services for members undergoing certain cancer treatments or organ transplantation for a certified WTC-related health condition. Members receiving either a solid organ or hematopoietic stem cell (HSC) transplant or cancer treatment involving radiation and chemotherapy for a certified WTC-related health condition may receive a dental exam and medically necessary dental treatment prior to undergoing the transplant or treatment. In addition, members with certified WTC-related head or neck cancers may receive additional dental services that are medically necessary to address dental trauma or other adverse effects resulting from cancer treatment.

The WTC Health Program provides coverage of medically necessary dental services only when certain criteria for authorization are met. Some dental services may be authorized by a WTC Health Program provider. Other dental services must be authorized by the Program. The Program may cover medically necessary dental services related to other certified WTC-related health conditions on a case-by-case basis, including coverage for fitting an oral device in limited situations for

members certified for sleep apnea.

Authorization Required – Medical Coverage Determination [PDF, 278 KB, 7 pages, June 2023]

Dental PA3 Request Form for Providers [PDF, 229 KB, 5 pages, June 2023]

Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) rental or purchase is a covered health service by the WTC Health Program. The CCE/NPN Clinical Director must provide a Level 2 Prior Authorization (PA), when indicated in the WTC Health Program Codebook, Volume A, and the DMEPOS must be ordered via prescription 37 by a WTC Health Program provider or a WTC Health Program-affiliated provider to treat a certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition. DMEPOS is a covered health service when the member is under the care of a CCE/NPN provider or a CCE/NPN-affiliated provider; the DMEPOS is ordered by the provider via prescription; the CCE/NPN Clinical Director provides a Level 2 PA Request, when indicated in the WTC Health Program Codebook, Volume A; and the DMEPOS is to be used primarily at home to treat a certified WTC-related health condition or a health condition medically associated with a certified WTC-related health condition. Suppliers of DMEPOS must be enrolled in Medicare and have a Medicare supplier number. The WTC Health Program will not pay a claim for equipment that is provided by a supplier that does not have a Medicare supplier number. The following three (3) requirements must be met and documented by the CCE/NPN in order for the WTC Health Program to provide payment for the DMEPOS: 38 Equipment which is primarily and customarily used for non-medical purposes may not be considered “medical” equipment for which payment can be made under the WTC Health Program. This is true even though the item has some remote medically-related use. For example, in the case of a member with lung cancer, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in

the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a non-medical one, the air conditioner may not be deemed to be DMEPOS for which payment can be made.46 Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DMEPOS. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions, or is primarily for the convenience of a person caring for the member, such as elevators, stairway elevators, and posture chairs, do not constitute DMEPOS. Similarly, physical fitness equipment (such as an exer-cycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature. 47 The following DMEPOS are excluded from coverage under the WTC Health Program: The CCE/NPN Clinical Director must provide a Level 2 PA Request when indicated in the WTC Health Program Codebook, Volume A. The CCE/NPN is responsible for ensuring that the DMEPOS supplier is enrolled in the WTC Health Program. The WTC Health Program will pay for a member to receive DMEPOS if all established conditions are met.

Reimbursement rates for DMEPOS are in accordance with the FECA fee schedule.

Payment for DMEPOS is either on a rental or lump-sum purchase basis. In the case of rental, the item(s) are to be paid monthly.48 Separate maintenance and servicing payments are not made for any rented DMEPOS, nor are delivery and service charges for rental or purchased DMEPOS. Such costs are assumed to have been taken into account by suppliers (along with all other overhead expenses) in setting the prices they charge for covered items and services.

The WTC Health Program will continue to review available

DMEPOS codes and add them to the WTC Health Program Codebook, as appropriate. DMEPOS items, with established CPT/HCPCS codes, that are prescribed and considered to be medically necessary for treatment of a member's certified condition(s), may be requested for addition to the WTC Health Program Codebook by the CCE/NPN through the usual change request process using a WTC-5 Medical Code Request Form. If there is no established CPT/HCPCS code for a necessary DMEPOS item, the CCE/NPN should contact the HPS Contractor for guidance. The WTC Health Program follows the definition of emergency medical condition established in the Medicare regulations implementing the Emergency Medical Treatment and Active Labor Act (EMTALA) which define an emergency medical condition as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention [via emergency care services] could reasonably be expected to result in: placing the health of the individual… in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part…."49 The WTC Health Program follows the Centers for Medicare & Medicaid Services (CMS) definition of emergency care services, which are defined as "inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services."50 Payment for treatment that is not related to a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, or a health condition likely to be certified as a WTC health condition due to exposure, will be denied. Claims submitted directly to the WTC Health Program by external providers will be returned to the CCE/NPN for review and authorization. When the CCE/NPN submits the ED claim to the WTC Health Program, the CCE/NPN is responsible for ensuring that the medical facility providing emergency services is enrolled as a provider with the WTC Health Program, through either a Single

Case Agreement (SCA) or a full contract. The standard review stamp or submission through Electronic Data Interchange (EDI) represents the CCE/NPN's acknowledgement that the CCE/NPN has an authorization on file. ED claims must be accompanied by any available medical documents/reports to facilitate the medical review. Whenever possible, ED claims should contain valid codes found in the WTC Health Program Codebook for the date of service. If after medical review, the WTC Health Program finds that codes other than those found in the WTC Health Program Codebook are acceptable for the claim, the additional charges will be paid and the Codebook will be updated accordingly. All coding and reimbursement is subject to the requirements of coding rules and guidelines in the WTC Health Program Codebook located on the Secure Access Managements services (SAMs) portal. As with other CCE/NPN documentation, all authorizations are subject to audit and utilization reviews. The Program will not pay for the following services provided by an emergency care provider: Members should follow-up with their respective CCE/NPN for further treatment and monitoring following their ED visit within 14 calendar days. As with other external provider bills, ER claims must be submitted through the member's CCE/NPN. The CCE/NPN is responsible for ensuring that the medical facility providing emergency services is enrolled as a provider in the WTC Health Program. Claims submitted directly to the WTC Health Program by external providers will be returned to the CCE/NPN for review and authorization. When the ER claim is submitted to the WTC Health Program via the CCE/NPN, the standard review stamp or submission through Electronic Data Interchange (EDI) represents the CCE's/NPN's acknowledgement that the CCE/NPN has an ER-A on file. As with other CCE/NPN documentation, ER-As are subject to audit and utilization reviews. ER claims must be accompanied by any available medical reports to facilitate the medical review. Whenever possible, ER claims should contain valid codes found in the WTC Health Program Codebook for the date of service. If after medical review the WTC Health Program finds that codes other than those found in the WTC Health Program Codebook

are acceptable for the claim, the additional charges will be paid and the Codebook will be updated accordingly. All coding and reimbursement is subject to requirements of coding rules and guidelines. All ER treatment will be evaluated during the processing of the claim to ensure that treatment beyond screening and stabilization was directly related to the care of a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, or to an initial or emergency presentation of a condition that is likely to be certified as a WTC-related health condition (based on the exposure history on file). Payment for treatment beyond screening and stabilization that is not related to a certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition, or a WTC exposure, will be denied. The hospital providing emergency services may follow reasonable registration procedures once the member has been screened and stabilized. EMTALA does not prohibit an inquiry into availability of medical insurance, but it does provide that neither examination nor treatment may be delayed to make the inquiry.53 A pre-authorization requirement imposed by the WTC Health Program should not prevent or delay the performance of a medical screening evaluation or the institution of necessary stabilizing treatment once it is determined that an emergency medical condition exists. Hospitals may ask members to complete financial responsibility forms upon registration. Such forms are common practice and are standard consent forms that are signed at the time of hospital registration. These forms may result in the member being responsible for payment for services not covered by WTC Health Program. An ER or ED is not the appropriate medical environment for a WTC Health Program member to seek care for a routine illness. Where the member's medical condition never was, or never appeared to be, an emergency, a physician's office or CCE/NPN clinic, for example, would be a more appropriate and adequate medical environment for providing such non-emergency care. Non-emergency visits to the ER or ED compromise the coordination and continuity of care for individual WTC

Health Program members; therefore, they are not covered by the WTC Health Program. Members should be referred back to their CCE/NPN for appropriate follow-up care. To ensure proper receipt and payment of claims, the member should inform the treating hospital/ED that the CCE/NPN should be notified of the member's visit to the ER or ED.

WTC Health Program members may require hospitalization in the treatment of their covered conditions. Such treatment is covered by the WTC Health Program, in accordance with the provisions below. Only claims that relate to certified WTC-related health conditions, or health conditions medically associated with certified WTC-related health conditions, should be submitted to the WTC Health Program.

All inpatient hospitalizations require a Level 2 PA by the CCE/NPN Clinical Director, unless Level 3 PA by the WTC Health Program is required (e.g., transplants, some surgeries). See Section 3.4, "Prior Authorizations" above for further information regarding PA requirements.

The CCE/NPN Clinical Director may authorize admission for inpatient services when the admitting diagnosis (primary diagnosis-related group [DRG]) is directly related to the member's certified WTC-related health condition, or directly related to a health condition medically associated with a certified WTC-related health condition. The CCE/NPN Clinical Director may also authorize admission for inpatient services when the admitting diagnosis is documented as consistent with WTC Health Program policy pertaining to diagnostic evaluation services for WTC-related conditions.54

If the hospitalization also involves a procedure that requires prior authorization by the WTC Health Program (Level 3 PA) and the CCE/NPN is aware prior to hospitalization that a Level 3 PA procedure will be performed, then the admission must be authorized by both the CCE/NPN Clinical Directorand the WTC Health Program, in accordance with established procedures for a Level 3 PA. If the need for a Level 3 PA55 procedure arises during the hospitalization, authorization will be handled on a case-by-case basis.

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If the hospitalization also involves a procedure that requires prior authorization by the WTC Health Program (Level 3 PA) and the CCE/NPN is aware prior to hospitalization that a Level 3 PA procedure will be performed, then the admission must be authorized by both the CCE/NPN Clinical Directorand the WTC Health Program, in accordance with established procedures for a Level 3 PA. If the need for a Level 3 PA55 procedure arises during the hospitalization, authorization will be handled on a case-by-case basis.

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pertaining to diagnostic evaluation services for WTC-related conditions.54

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pertaining to diagnostic evaluation services for WTC-related conditions.54

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Claims for inpatient hospitalizations must be submitted using standard UB-04 (CMS-1450) format or electronically using the 837 5010 ANSI standard format. Hospital-based inpatient services should be billed on the UB-04 showing revenue center charges, ICD-10 diagnosis codes, procedure codes, and the hospital's Medicare number. Inaccurate coding may cause inappropriate reimbursement, erroneous reductions in allowable amounts, and/or delays in bill processing. The physician's professional

services should be coded and billed on Form CMS-1500 or the electronic equivalent. The WTC Health Program may request detailed inpatient hospital claims, notes, and discharge summaries for some claims after submission. Failure to respond to requests for additional information related to claims for inpatient hospitalizations may result in delay in processing or denial of the claim. The CCE/NPN is responsible for ensuring that the hospital is enrolled as a provider in the WTC Health Program. See Chapter 6 of this manual for more information regarding enrolling providers. All acute inpatient hospital claims processed by the WTC Health Program will be priced using diagnosis-related group (DRG)-based pricing, as modified by the FECA Program. The amount paid will be the lesser of the DRG-based price or the amount billed. See Chapter 5 for more information regarding billing of claims.

The WTC Health Program does not cover costs associated with medical marijuana.56

As of May 2019, 33 States and Washington D.C. allow the purchase and use of medical marijuana. Although WTC Health Program members may be able to access and purchase medical marijuana in their state of residence, its use is not approved by the FDA57 and is considered an illegal substance (Schedule 1)58 by the federal government.

The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. In certain circumstances, psychotherapy

services for a member's family may be covered as part of the treatment of the member's certified WTC-related health condition. Family members include a parent, spouse, or child who lives in the same household as the member. As part of a comprehensive mental health assessment with a qualified provider, a diagnostic interview session with other family members may be needed to assess the family context contributing to or being impacted by the member's mental health related to the attacks on September 11th. When conducted with the explicit verbal and written consent of a WTC Health Program member, a single diagnostic interview session may be billed (CPT 90791) to the WTC Health Program as part of the member's benefit under the Diagnostics Benefit Plan in order to evaluate whether the member's situation meets the Program's criteria for certification. This single session may involve more than one family member, if clinically desirable. In addition, marriage or family counseling may be medically indicated to treat a WTC Health Program member's certified mental health condition. During the course of such therapy, the non-member may require an individual therapeutic evaluation/intervention to manage traumatic reactions or trust issues emerging from the family treatment. The WTC Health Program Codebook, Volume A identifies the appropriate codes for use when marriage or family counseling is needed to treat the member's certified mental health condition. The WTC Health Program may provide a maximum of two family therapy sessions without the member present (CPT 90846) every 3 months for up to eight sessions in total with the expressed consent of the member for this specific reason. Use of the member's treatment plan benefit for this purpose must be documented as medically necessary in the treatment record and a Level 2 PA by the CCE/NPN Clinical Director is required. The CMS-1500 form (or EDI equivalent) should be completed using the member's ID number, the member's name as the "Insured's Name" (box 4), and the member's name as the "Patient's Name" (box 2). The remittance advice will reflect the member name only.

Mental health conditions detected or emerging in the non-member during the course of

family therapy, including ongoing trust issues, should be referred to community resources for treatment. The WTC Health Program does not cover the cost of such treatment for non-members. To the extent permitted under State law, mental health services can be delivered by a:

MGUS is a condition in which abnormal levels of certain proteins are found in the blood. These abnormal levels of protein must be monitored by regular blood tests to check for any signs of cancer that could develop over time. The WTC Health Program may provide coverage of medically necessary MGUS services (i.e., initial diagnostic studies and, after diagnosis, further monitoring) when there are symptoms of a plasma cell neoplasm or clinical findings suggestive of MGUS. WTC Health Program providers may authorize a follow-up evaluation and ongoing monitoring of MGUS when the member meets all the applicable requirements. MGUS is NOT eligible for certification.

Authorization Required – Medical Coverage Determination [PDF, 6 pages, 259 KB]

Non-invasive neoplasms of the cervix uteri are ineligible for certification but further surveillance, management, and/or treatment of these conditions may be covered under the diagnostic benefit plan. Initial diagnostic studies of abnormal cervical screening results will be covered only if being used to evaluate for potential WTC-related invasive cervical cancer.

After initial diagnosis, further surveillance, management, and/or treatment may be covered for identification of potential WTC-related cervical cancer following the guidelines established by the American Society for Colposcopy and Cervical Pathology (ASCCP). These services are available under the cancer diagnostic

plan for all Responders and Certified-eligible survivors. These services are available for Screening-eligible survivors during the initial health evaluation period only.

Any medically associated nonmalignant condition resulting from surveillance or management/treatment of non-invasive neoplasms of the cervix uteri is not eligible for certification or treatment. This includes any medically associated conditions that affect fertility or pregnancy outcomes. Types of non-invasive neoplasms that are ineligible for certification include cervical intraepithelial neoplasia (CIN) grades I-III and carcinoma in situ of the cervix uteri.

Home Health Care services are personal care and related support services that enable WTC Health Program members to live at home while receiving medically necessary care for a certified WTC-related health condition or health condition medically associated with a certified WTC-related health conditions certified by the Administrator of the WTC Health Program or Designee. Under certain circumstances, care received at home may be a substitute for receiving medically necessary care in a hospital or skilled nursing facility for members who are homebound.60 The Administrator of the WTC Health Program has elected to follow the definition of “confined to his home” used by CMS to determine whether a WTC Health Program member is “homebound.” In establishing conditions required for payment of services, CMS defines an individual as being “confined to his home” when: CMS further clarifies that the individual may leave home for medical treatment or short, infrequent absences for non-medical reasons, such as attending religious services, and may still receive home health care if he/she attends adult day care. In order for a qualified service provider to be eligible for payment for home health services, CMS requires that the individual submit a written request and that an enrolled physician certify the below requirements:62 Home health care is intended to provide treatment for an illness or injury with the goal of maintaining health. In order for a member’s home health care to

be eligible for payment by the WTC Health Program, the following requirements must be met and documented by the CCE or NPN: The CCE or NPN Clinical Director shall provide authorizations in 60-day episodes of care. The HHA will be required to obtain additional authorization if there is a need for subsequent episodes of care. If the member still requires home health care at the end of the initial 60-day episode of care, a new authorization will be required to justify a new episode of care on day 61. Re-authorization continues to be required (the next episode would start on day 121, the next on day 181, etc.) as long as the member is receiving services under the HHA's plan of care. More than one episode may be authorized for the same or different dates of service when there is a transfer to another HHA, or discharge with readmission to the same HHA. Authorization for service extending beyond 120 days may be subject to audit by the WTC Health Program for medical necessity. Medical social services that are provided by a qualified medical social worker or a social work assistant under the supervision of a qualified medical social worker may be covered as home health care services where the beneficiary meets the qualifying criteria specified below: When a home health aide visits a member to provide a health related service as discussed above, the home health aide may also perform some incidental services which do not meet the definition of a home health aide service (e.g., light cleaning, preparation of a meal, taking out the trash, shopping, etc.). However, the main purpose of a home health aide visit may not be to provide these incidental services as they are not health related services Hospice provides medical, psychological, and spiritual support during end-of-life care. Hospice care68 allows the member to remain at home in a personal, comfortable setting, or in special in-patient facilities, hospitals, or nursing homes. It also supports caregivers and families with bereavement counseling. The WTC Health Program will pay for hospice services when therapies for a covered condition are no longer controlling the illness and, if the illness runs its normal course, the member's life expectancy is 6 months or less69. If the member's condition improves or the illness

goes into remission, hospice care can be discontinued and active treatment may resume.70 Acceptance into hospice care requires a Level 2 Prior Authorization (PA2) by the CCE or NPN Clinical Director specifying that the member has a life expectancy of 6 months or less if the illness runs its normal course. The member also signs a statement saying that he or she is choosing hospice care. (Hospice care can be continued if the member lives longer than 6 months, as long as the CCE or NPN Clinical Director reconfirms the member's terminal illness and provides a new PA2 for continuity of hospice care.) In order for a member's hospice care to be eligible for payment by the WTC Health Program, the CCE/NPN must meet and document the following requirements: Extended care services are provided to WTC Health Program members who require skilled nursing or rehabilitation staff to manage, observe, and evaluate their care for a condition or conditions certified by the Administrator of the WTC Health Program or Designee. Inpatient skilled nursing facility (SNF) care, including room and board, skilled nursing care, and other customarily provided services in a Medicare-certified skilled nursing facility, are covered by the WTC Health Program when certain factors are met.73 The Administrator of the WTC Health Program has elected to follow factors similar to those used by CMS. 74 All of the following conditions must be established and documented by the CCE/NPN in order for the WTC Health Program to provide payment for services:75 If any one of these factors is not met, a stay in a SNF, even though it might include the delivery of some skilled services, will not be covered by the WTC Health Program. The CCE/NPN Clinical Director shall provide an initial Level 2 PA for a 30-day SNF episode of care. The SNF will be required to obtain additional authorization(s) if there is need for subsequent episodes of care (in 30-day increments). Level 2 PA continues to be required (in 30 day increments) as long as the member is receiving SNF services. Extended care services are considered post-hospital if initiated within 30 days following discharge. In order to be eligible for coverage of post-hospital extended care services, the member must be receiving inpatient hospital care for a

WTC Health Program certified condition for not less than 3 consecutive days of medically necessary services before discharge, and must also require a skilled level of care. The member must also require at least one of the following: 80 The following are excluded from the SNF benefit: The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. WTC Health Program immunization benefits are based upon the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) recommendations86. For the immunizations described in this section, the WTC Health Program will cover the vaccine product and the procedure to administer the vaccine when clinically indicated and advised by CDC ACIP recommendations. Further coding guidance may be found in the WTC Health Program Codebook, Volume A. Please refer to CDC ACIP recommendations for further clinical guidance on the appropriate use of these vaccines. The WTC Health Program provides vaccine coverage based on the member's benefit plan. The benefit plan determines what type of medical treatment or services a member is eligible to receive, according to their member category and certification status. The table below shows what vaccines are payable under the WTC Health Program for eligible members of each benefit plan (except for FDNY family members). For more information on benefit plans, see Section 2.0 "Approved Benefit Plans." The WTC Health Program provides smoking cessation therapy for (1) those members with at least one certified WTC-related health condition or (2) eligible members who are current smokers and are referred as part of the lung cancer screening program. For members with at least one certified WTC-related health condition, smoking cessation therapy services will be available for use in the benefit

plan for the certified condition. For those members who are eligible though a referral from the lung cancer screening program, smoking cessation services will be accessible through the benefit plan being used at the time of the lung cancer screening. Service limitations and/or prior authorization requirements may apply if the member is not certified for at least one WTC-related health condition. The available pharmaceutical formulary will include medications for use in conjunction with smoking cessation therapy (See Chapter 12 Pharmacy Benefits). When a member is referred for smoking cessation therapy, this information should be documented in the member's medical record. This medical record documentation is subject to audit by the WTC Health Program.

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive, non-systemic treatment using an FDA-approved device to generate brief magnetic pulses that induce an electrical field in a localized region of the brain for the purpose of treating major depressive disorder (MDD) without psychosis. The technique involves placing a small electromagnetic coil over the scalp and passing a rapidly alternating current through the coil wire to produce a magnetic field that passes unimpeded through the brain.

Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), rTMS applied to specific cortical regions can change the excitability of the affected brain structures. The procedure is usually carried out in an outpatient setting and does not require anesthesia or analgesia. When used as antidepressant therapy, rTMS produces a clinical benefit without the systemic side effects of standard oral medications and without adverse effects on cognition. Unlike electroconvulsive therapy (ECT), rTMS does not induce amnesia or intentionally induce seizures.

The WTC Health Program may provide coverage of medically necessary rTMS services which meet relevant Level 2 Prior Authorization (PA2) criteria. The CCE/NPN Clinical Director or Designee may authorize rTMS services only when there is clinical documentation that the member has MDD that is a certified WTC-related health condition or medically associated health condition, or the MDD is ancillary to another certified WTC-related health condition. Members with certain medical or psychiatric conditions may not be a candidate for rTMS treatment. Coverage of rTMS services must be in accordance with Program guidelines.

Authorization Required – Medical Coverage Determination [PDF, 582 KB, 7 pages, August 2023]

rTMS PA2 Request Form for Providers [PDF, 1140 KB, 6 pages, September 2023]

The WTC Health Program only covers medically necessary treatment for certified WTC-related health conditions or medically associated conditions that result from treatment or progression of a certified condition. The Program does not cover routine medical care. Members should always maintain their own primary care provider for health conditions not covered by the Program.

Member-initiated second opinions by a CCE/NPN-affiliated provider may be covered by the WTC Health Program only when assessing the medical need for a covered surgery or for major nonsurgical diagnostic and therapeutic procedures (e.g., invasive diagnostic techniques such as biopsy or differing therapeutic options for a covered cancer). Second opinions may be covered to address the appropriate approach to evaluating allowable clinical findings, as consistent with policies for managing (treating) a member’s certified health condition(s). In the event that the recommendation of the first and second physician differs regarding the need for surgery (or other major procedure), a third opinion may also be covered. Second and

third opinions are covered even if a therapeutic modality under consideration is not covered by the WTC Health Program. Payment may be made for the history and examination of the member, and for other covered diagnostic services required to properly evaluate the member's need for a procedure and to render a professional opinion. Sleep apnea is a common sleep disorder characterized by brief interruptions of breathing during sleep. The most common type of sleep apnea is obstructive sleep apnea (OSA). OSA occurs when the upper airway collapses or becomes blocked during sleep, thus reducing or stopping airflow. Central sleep apnea (CSA) is caused by irregularities in the brain's normal signals to breathe. Most people with sleep apnea will have a combination of both types. Sleep apnea may be covered by the WTC Health Program in three different ways: as a certified WTC-related health condition included on the List of WTC-Related Health Conditions (List), as a health condition medically associated with a certified WTC-related condition, or where medically necessary to treat certain certified WTC-related health conditions.

Medical Coverage Determination – Sleep Apnea [PDF, 309 KB, 12 pages, December 2021]

(Section 4.10 revised—March 5, 2021)

WTC Health Program policies regarding solid organ transplants are consistent with best clinical practices and nationally recognized guidelines. The WTC Health Program may cover solid organ transplants if specific requirements are met and a Level 3 PA is in place. The transplant must be non-experimental and non-investigational. The specific medical condition(s) being treated by the solid organ transplant must be certified by the WTC Health Program and must be a contributory cause to the deterioration of the organ being transplanted. The specific medical condition(s) being treated with the solid organ transplant must be shown to be chronic and severe/end-stage despite maximal treatment with other known standard treatment

options. The solid organ transplant should be considered to have a high likelihood of a positive health outcome, with potential benefits effectively outweighing any potential harms. All appropriate indications and absolute and relative contraindications must be considered. All pre-transplant and transplant services must be non-experimental, non-investigational procedures, and all other WTC Health Program requirements must be met. All pre-transplant and transplant authorizations and services are subject to WTC Health Program utilization review and/or audit. The CCE/NPN Clinical Director should consult with the WTC Health Program Medical Benefits Team regarding additional requirements related to specific solid organ transplant requests. Denials of requests for transplants are subject to appeal by the member, pursuant to regulation, as a denial of medically necessary treatment. Appeal rights will be provided when the outcome of the WTC Health Program evaluation is a denial decision (see Section 3.6 for additional information on appeals). Diagnostic and reparative surgery and any surgery requiring inpatient hospitalization are generally subject to a Level 2 PA by the CCE/NPN Clinical Director in accordance with medical protocols and WTC Health Program policy. Transplants and certain dental surgeries require a Level 3 PA from the WTC Health Program. The WTC Health Program Codebook, Volume A should be consulted to determine whether a PA is required for any particular surgery. Diagnostic and reparative surgeries requiring inpatient hospitalization are covered by the WTC Health Program for a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, with Level 2 PA by the CCE/NPN Clincial Director. Special circumstances surrounding transplants, dental surgeries, or procedures related to cancer treatment may require additional authorization. Special circumstances must be considered when a member has multiple surgical procedures. Multiple surgeries are separate procedures performed by a physician on the same patient during the same operative session or on the same date. Multiple surgeries are distinguished from procedures that are components of, or

incidental to, a primary procedure. Intraoperative services, incidental surgeries, or components of surgeries will not be separately reimbursed.

All multiple surgeries on a single claim are reimbursed by paying 100 percent of the FECA rate for the procedure with the highest cost (highest fee schedule amount) and 50 percent for all remaining procedures. In addition, the claims processing system checks for multiple surgeries across multiple claims. The claims processing system applies the 50 percent reduction to surgeries on subsequent claims for the same member on the same day by the same provider.87 When submitting a claim for multiple surgeries, the most costly procedure (the one that will result in the highest fee schedule amount) should be listed first. Each additional procedure should be billed using “51” as a modifier. Payable amounts for multiple surgeries will be determined by paying the full FECA fee schedule amount for the most costly procedure, plus 50 percent of the FECA fee schedule amount for each additional procedure. Payment will be made at 50 percent for additional procedures whether or not modifier 51 is used. Limitations on multiple surgeries do not apply to bilateral procedures. Bilateral procedures should be billed using modifier “50” and with one (1) unit, and are reimbursed at 150 percent of the FECA fee schedule amount (to account for the dual procedure). The WTC Health Program does not use a special pricing algorithm for endoscopic procedures. Multiple endoscopic procedures will be priced according to the same formula as other multiple surgeries. The Medical Coverage Determination (MCD) and coverage guidelines for this section are under development. This section will be updated once finalized. The WTC Health Program may provide members assigned to the Nationwide Provider Network (NPN) coverage of expenses for necessary and reasonable, non-emergency general transportation services, and those expenses that are incident to the necessary and reasonable, non-emergency general transportation. This transportation must be for the purpose of the member securing medically necessary treatment for a certified

WTC-related health condition, or a health condition medically associated with a certified WTC-related health condition. In addition, the travel must exceed 250 miles roundtrip from the member's place of residence or a WTC Health Program-affiliated healthcare facility or office to a WTC Health Program-affiliated healthcare facility or office. Travel is reimbursed according to General Services Administration (GSA) rates and practices. Authorization Required – Medical Coverage Determination [6 pages, 531 KB] Applicable Form The WTC Health Program only provides coverage of medically necessary, non-emergency medical transportation services by ambulette or ambulance for members when it is determined that no other means of transportation could be used without posing a threat to the member's survival or seriously endangering the member's health. Any expenses must be for the purpose of the member accessing medically necessary treatment from a CCE- or NPN-affiliated provider for a certified WTC-related health condition, or a health condition medically associated with a certified WTC-related health condition. The WTC Health Program does not pay for expenses incident to medically necessary, non-emergency medical transportation services for a CCE- or NPN-assigned member. Authorization Required – Medical Coverage Determination [6 pages, 632 KB] Applicable Forms An urgent medical condition is a condition which is not considered to be an emergency, but must be addressed within 12 hours in order to avoid the likely onset of an emergency medical condition.88 Unlike emergency care services which are immediately necessary to prevent serious health impairment or death, urgent care services may not be immediately necessarily, though the member does require care within 12 hours in order to avoid adverse consequences.89 Urgent care facilities include freestanding, walk-in ambulatory clinics that are generally open seven days per week with extended hours. Urgent care facilities provide urgent medical treatment and unscheduled, episodic care to individuals who require timely care, but whose condition is not immediately life-threatening.90 Members who visit an urgent care center and need a higher level of service will be

referred to a specialist or an ED. Acutely ill members may be referred by ambulance through activation of the 911 system because most urgent care centers are not equipped or staffed to handle life-threatening emergencies. The urgent care facility is not required to be a WTC Health Program-affiliated provider on the date of service to the member. No prior authorization is required for urgent care services. To ensure proper receipt and payment of claims, the member should have the urgent care facility notify the CCE/NPN of their visit. When the CCE/NPN has been notified of the urgent care visit, or when the bill and medical records are sent from the external urgent care provider to the member's CCE/NPN, the CCE/NPN will retrospectively review the urgent care medical records and ensure that the treatment was related to a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, or a health condition likely to be certified as a WTC health condition due to exposure. Payment for treatment that is not related to a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, or a health condition likely to be certified as a WTC health condition due to exposure, will be denied. Claims submitted directly to the WTC Health Program by external providers will be returned to the CCE/NPN for review and authorization. When the CCE/NPN submits the urgent care claim to the WTC Health Program, the CCE/NPN is responsible for ensuring that the medical facility providing urgent care services is enrolled as a provider with the WTC Health Program, through either a Single Case Agreement (SCA) or a full contract. The standard review stamp or submission through Electronic Data Interchange (EDI) represents the CCE's/NPN's acknowledgement that the CCE/NPN has an authorization on file. Urgent care claims must be accompanied by any available medical documents/reports to facilitate the medical review. Whenever possible, urgent care claims should contain valid codes found in the WTC Health Program Codebook for the date of service. If after medical review, the WTC Health Program finds that codes other than those found in the WTC

Health Program Codebook are acceptable for the claim, the additional charges will be paid and the Codebook will be updated accordingly. All coding and reimbursement is subject to the requirements of coding rules and guidelines in the WTC Health Program Codebook located on the Secure Access Managements services (SAMs) portal. As with other CCE/NPN documentation, all authorizations are subject to audit and utilization reviews. Where determined to be related to a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, or a health condition likely to be certified as a WTC health condition due to exposure, WTC Health Program coverage of urgent care services may include orthopedic-related services, onsite laboratory and diagnostic testing, pharmacy services, and other treatments and services (i.e., intravenous (IV) fluids).91 Coverage of urgent care services is permitted only when in accordance the program formulary and other program guidelines.92 Some examples of urgent medical conditions may include, but are not limited to: A range of laboratory and diagnostic tests may be provided to a member during an urgent care visit. A laboratory test is a medical procedure which involves testing a sample of blood, urine, or other substance from the body. Laboratory tests can help determine a diagnosis, plan treatment, verify that treatment is working, or monitor the disease over time.93 A diagnostic test is a type of test used to diagnose a disease or condition.94 Examples include x-rays, and ultrasounds. In general, when an urgent care provider orders a laboratory or diagnostic test for a member, this test will be utilized to determine a diagnosis and treatment plan. Members should follow-up with their respective CCE/NPN for further treatment and monitoring following their urgent care visit within 14 calendar days. Orthopedic services focus on injuries and diseases of the body’s musculoskeletal system. This complex system, which includes your bones, joints, ligaments, tendons, muscles, and nerves, allows you to move, work, and be active.95 Examples of orthopedic services that may be provided at an urgent care center include dislocations, fractures, and sprains. Pharmacy services (including

prepackaged pharmaceuticals and limited pain management)96 may be covered in an urgent care when an urgent care provider prescribes medication to treat the urgent medical problem, and thus to manage, ameliorate, or cure a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition Other urgent care treatments and services which may be provided to a member include, but are not limited to: Non-urgent visits to an urgent care center compromise the coordination and continuity of care for individual WTC Health Program members; therefore, they are not covered by the WTC Health Program. Members should be referred back to their CCE/NPN for appropriate follow-up care. The Program will not pay for the following services provided at an urgent care facility: *In limited situations, the NPN may utilize urgent care centers for monitoring exams and survivor screenings when reimbursing the urgent care center at the FECA rate; Members should follow-up with their respective CCE/NPN for further treatment and/or monitoring following their urgent care visit within 14 calendar days.

Uterine cancer is a common term for cancer of the female reproductive tract. Uterine cancer is

also referred to as endometrial cancer since it occurs in the inner lining of

the uterine body called the endometrium.

The WTC Health Program covers medically necessary treatment of certified endometrial cancer

following the clinical practice guidelines set forth by the National Comprehensive Cancer Network (NCCN).

The WTC Health Program also covers medically necessary treatment of atypical endometrial hyperplasia, also known as EIN. EIN is an abnormal change in the uterine lining that can lead to cancer of the uterus.

The WTC Health Program may authorize fertility-sparing treatment via hormone-based therapy when requested by a WTC Health Program provider for members with certified low-grade endometrial cancer or EIN. Coverage of fertility-sparing treatment is limited to those services related to endometrial disease only. Coverage includes appropriate clinical counseling, additional diagnostics as needed, medically necessary hormonal therapy, and follow-up disease surveillance per NCCN guidelines. Certain criteria must be met for the Program to authorize coverage of fertility-sparing treatment.

Authorization Required – Medical Coverage Determination [PDF, 6 pages, 223 KB]

Fertility-Sparing Treatment PA3 Request Form for Providers [PDF, 4 pages, 774 KB]

4-AWTC Health Program Instructions for Completing WTC-3

Package Requesting Certification for Types of Cancer 4-BMedical Change Review Request Form 4-CTransplant Authorization Form 4-DHome Health Care CMS Form 485 4-E Dental Prior Authorization Level 3 Request Form 4-F Policy and Procedures for Cancer Screening Last Revised – August 2014 Appendix 5-A—CMS-1500 Appendix 5-B—UB-04 Appendix 5-C Policy and Procedures for Coordination of Benefits for Treatment Costs for Non-Work-Related, Certified WTC-Related Health Conditions: Coordination with Health Insurance Appendix 5-D Policy and Procedures for Recoupment: Lump-Sum Workers' Compensation Settlements Appendix 5-E Policy and Procedures for Recoupment & Coordination of Benefits: Workers' Compensation Payment This Chapter provides a high level overview of the process for submitting and processing claims for medical benefits under the WTC Health Program. This process is managed by the Health Program Support (HPS) contractor. A more complete description of the claims processing function is found in the WTC Health Program Claims Processing Procedure Manual, found in the WTC Health Program file of record. The sections of the Public Health Service (PHS) Act applicable to this Chapter include Section 3312(c), Payment for Initial Health Evaluation, Monitoring, and Treatment of WTC-Related Health Conditions, and Section 3331, Payment of Claims. The sections of the WTC Health Program regulations applicable to this Chapter include 42 C.F.R. §§ 88.20, 88.22, 88.23. The parties involved in developing, submitting, processing, and paying claims are described below. The Program uses Plexis Healthcare System's Quantum Choice claims processing software to manage enrollee and provider information and to process claims. The claims processing function is scaled to the relatively small size of the WTC Health Program and is designed to quickly, efficiently, and accurately process claims submitted for payment, in accordance with the provisions of the Act. Approximately 90 percent of all claims are submitted to the HPS contractor via EDI using the 837 5010 ANSI standard format. The Program encourages use of EDI as it improves the efficiency and effectiveness of claims processing, reduces the potential for error, and speeds

transaction times. CCEs/NPN, their TPAs, and approved external providers submit claims to the EDI clearing house using the 837 format. The clearing house then delivers the claims to the HPS contractor for claims processing. Prescriptions covered under the Program are issued in accordance with the WTC Health Program-approved pharmaceutical guidelines and the Program's formulary. The formulary and guidelines are aligned with the Program's pharmacy benefit plans, which are described in WTC Health Program Bulletin No. 13-2, "Implementing Pharmacy Benefit Plans by Health Condition Certification Status." These plans, implemented to improve programmatic oversight and minimize fraud, waste and abuse, are documented in the WTC Health Program file of record. As noted in the Overview above and in Chapter 4, Medical Benefits, billing for covered services under the program is consistent with industry best practices and uses standard procedures and forms. The categories of health conditions are defined by ICD-10 diagnosis codes. The medical services associated with each covered condition/diagnosis code are defined by Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), DRG, and Revenue Coding Center (RCC) codes. These codes, documented appropriately on standard CMS-1500, UB-04, and EDI claims, are the basis by which member claims are paid. The codes acceptable for submission of claims for healthcare services for covered conditions under the Program have been defined and are documented in the Codebook, found in the WTC Health Program file of record. Special circumstances apply when considering the use of a procedure or service code that is not currently listed in the Codebook. On a weekly basis, claim lines are gathered into a claim payment run (or file) which is transmitted to the payment contractor. The process is outlined in the below graphic. Using MicroStrategy's business intelligence reporting tool, Microstrategy 9, and Quantum Choice, a variety of reports are generated to provide the WTC Health Program insight into the claims and payments processed, and to ensure quality assurance of the claims processing function. Accurate payments and timely payment corrections, when

necessary, are important to maintain the integrity of the WTC Health Program. The Program has an established process to ensure payments are accurate. After exhausting procedural and/or contractual administrative remedies, a CCE or NPN Clinical Director or affiliated provider may submit a written appeal of a WTC Health Program decision to withhold reimbursement or payment for treatment found to be not medically necessary or not in accordance with approved Program medical treatment protocols. Appeal procedures will be published on the WTC Health Program website. Policy and Procedures for Coordination of Benefits for Treatment Costs for Non-Work-Related, Certified WTC-Related Health Conditions: Coordination with Health Insurance Policy and Procedures for Recoupment: Lump-Sum Workers' Compensation Settlements Policy and Procedures for Recoupment & Coordination of Benefits: Workers' Compensation Payment The purpose of this chapter is to provide a high-level overview of the Clinical Centers of Excellence's (CCEs') roles, responsibilities and processes for the WTC Health Program. In addition to this procedure manual, further details regarding CCE operations can be referenced in the CCE Clinical Guide and the CCE Operations Manual developed by each CCE, both found in the Program's file of record. Of note, the Nationwide Provider Network (NPN) is discussed separately in Chapter 7 of this manual. This chapter is guided by Sections 3305(a)(1) and 3305(b)(1) of the PHS Act, which describe requirements for the contracts put in place with the CCEs, as well as various sections of 42 C.F.R. Part 88. In addition, the CCEs play a pivotal role in implementing the general provisions of the Act, as described below. The roles and responsibilities associated with the CCEs and providers in the WTC Health Program are detailed below. The WTC Health Program CCEs offer unique expertise in the provision of healthcare services to NY metropolitan area-based members. Currently, there are seven CCEs that provide WTC Health Program services: Five CCEs serving general responders: Each CCE operates under contract with the federal government to administer healthcare (within the limited care model defined by Title XXXIII of the PHS Act) to the responders or survivors of the

September 11, 2001, terrorist attacks. (The NPN, discussed in Chapter 8, provides care for enrolled members residing outside the NY metropolitan area, including responders to the plane crashes in Shanksville, PA, and Arlington, VA – the site of the Pentagon.) Each CCE is responsible for all aspects of WTC Health Program-related care for each member they serve. In addition to services provided directly by the CCEs, services are also provided through the CCEs by external providers who have expertise in the diagnosis and treatment of 9/11-related health conditions and have been approved by the CCEs and the Program to provide WTC Health Program benefits. Section 6 below provides more detail regarding external providers. Each CCE educates its staff and network providers in WTC Health Program policies and procedures such as the proper completion of paperwork, limitations of coverage, protocol changes, and benefits counseling, and maintaining a complete Operations Manual to document them. CCE representatives participate in periodic meetings with the Program leadership, their associated data center, the HPS contractor, and other vendors, as required, to coordinate activities, address and resolve issues, and share information. The work performed by CCEs is grouped into the following four categories and is discussed in detail, below: As provided by the PHS Act, the WTC Health Program reimburses providers for healthcare expenses for health conditions that have been certified by the Administrator of the WTC Health Program as WTC-related or as medically associated to a certified WTC-related health condition. Health condition certification is required for treatment services to be paid by the Program. The certification of a WTC-related or medically associated condition is based on a review of a CCE physician’s clinical assessment of the relationship between a given Program member’s WTC exposure and the type and temporal sequence of symptoms, or diagnosis, of a qualifying health condition. This review must find that the member’s exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating,

contributing to, or causing the health condition. A list of the ICD-10 diagnosis codes that correlate with the List of WTC-Related Health Conditions and medically associated health conditions covered by the Program is found in the WTC Health Program Codebook. CCEs provide guidance to external providers on allowable benefits, including proper use of the WTC Health Program Codebook if disseminated. A member's health benefit profile is comprised of all Care Suites and certification gates that reflect the conditions that have been certified for that member (Care Suites are discussed in section 9 of Chapter 3 of this manual). The member benefit profile continues to be updated to reflect any new conditions that are certified over time. The claims processing system verifies that each health care service claim line maps a medical procedure to a diagnosis contained within the Care Suites and certification gates comprising a member's benefit profile.

A. Monitoring and Initial Health Evaluations

Each CCE schedules and provides a baseline exam for new enrollees and follow-up monitoring examinations to WTC responder and certified-eligible survivor members as applicable. The purpose of the monitoring exams is to: (1) provide periodic physical and mental health assessment designed to identify acute and latent health effects that are WTC-related; (2) serve as an avenue for clinical data collection, analysis and reporting to ensure that all services provided adhere to the appropriate protocols; and (3) inform the diagnosis of WTC-related diseases that could lead to a referral for treatment. The table below describes the extent of these exams.

If a test result indicates the presence of a WTC-related condition, or is inconclusive, the monitoring physician will refer the member for additional diagnostic testing and/or treatment. The CCE medical monitoring evaluation process consists of the following tasks: For services provided by a clinician in his or her offices, claims submitted on paper rather than Electronic Data Interchange (EDI) must use a Professional claim form (CMS-1500). For inpatient or outpatient hospitalizations, claims

submitted on paper rather than EDI should use an Institutional claim form (UB-04). Professional services provided in a hospital setting that are not included in the institutional billing should be billed on the CMS-1500 form. Paper claims originating with external providers must first be submitted to the appropriate CCE. The CCE is responsible for authorizing treatment for the member. Therefore, the CCE must review and authorize claims to be processed. A stamp provided to the CCE by the WTC Health Program is used for this purpose, along with initialing by an authorized CCE approver. Once approved by the CCE, paper claims should be submitted to the WTC Health Program for processing and disposition (i.e., payment, partial payment, or denial). The information entered on the claim form is captured through an automated data collection process; therefore, all paper claim submissions must be legible and of sufficient quality for imaging. Information must be completed in the appropriate field on the billing form in order to expedite claims processing. Pharmacy benefit plans have been implemented to improve oversight and minimize fraud, waste, and abuse. Each CCE develops and implements procedures for providing services to its members. The establishment and management of the internal and external provider network are coordinated through the respective CCEs. In order for a provider to have a claim for WTC Health Program services paid, the CCE must have enrolled the provider as a participating provider in the WTC Health Program. Provider enrollment into the WTC Health Program and the management of a reliable provider network are critical to efficient claims processing. The complete and accurate enrollment of providers ensures that claims are not suspended for review of provider validity issues, and that claims may be promptly adjudicated.

Each CCE is responsible for submitting provider enrollment requests to the HPS contractor and updating provider details when necessary. All medical providers, including physicians, group practices, hospitals, Durable Medical Equipment (DME) suppliers, nursing facilities, hospice services, and others, must enroll

as participating providers in the WTC Health Program for claims to be adjudicated through the Program's claims processing system. Each CCE determines the nature of its provider relationships (i.e., internal or external) and is also responsible for providing the appropriate level of education and information regarding the Program to external providers so that they may provide an approved level of care for WTC Health Program-certified conditions.

The HPS contractor uses the information provided by the CCEs to add providers to the claims system.

Financial information is also provided using an EFT Form or other document provided by the Program so that providers may receive payment for their claims. Before submitting the provider enrollment, the CCE confirms: 1) that all data are complete and accurate; 2) that the provider's status as either an internal or external provider is documented; and 3) whether the provider should also be enrolled with the following specialties:

Once a provider enrollment has been received and validated by the CCE, the CCE submits the enrollment to the HPS contractor for processing. If incomplete information is received, the enrollment form will be returned to the CCE for completion. Chapter 8 provides more detail regarding the steps taken to complete the enrollment process.

The management and maintenance of the information in a provider record are the CCEs' responsibility. Changes to provider information may be necessary over time (e.g., an address or financial information changes, or a provider ceases her association with the WTC Health Program). Any changes to provider information that are received by the CCEs are processed in the same way as for an initial enrollment. Changes to provider information that are not first identified by the CCE must be routed to the CCE for validation and to ensure consistency among, and accuracy of, Program records. This could occur, for example, when a claim being

processed for payment reveals that the provider’s EFT information has changed Enrollment and management of a reliable provider network is critical to ensure that claims will efficiently and accurately adjudicate. In the interest of supporting the CCEs’ responsibility to manage their provider and prescriber enrollees, the HPS contractor annually distributes to each CCE a list of all its providers enrolled in the Program. The CCE must review the list and make any updates or note any discrepancies between the providers held on record by the Program and those held on record by the CCE. The HPS contractor is responsible for working with the CCE to resolve any discrepancies in a timely fashion. Each CCE submits to the Program monthly status reports on member and administrative services activities to allow Program leadership to track the CCE’s program activities and progress. In addition to summarizing the activities and accomplishments of the past month, the report identifies any potential risks to continued program success and communicates the CCE’s plans to mitigate those risks. A variety of reports are required, as detailed below. Member Service Function Information to Be Reported Member Retention A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Member Retention services performed during the period and the associated cost for these services invoiced to the government. Member Outreach and Education A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Member Outreach and Education services performed during the period and the associated cost for these services invoiced to the government. Program Benefits Counseling A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Program Benefits Counseling services performed during the period and the associated cost for these services invoiced to the government. Case Management A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Case Management services performed during the period and the associated cost for these

services invoiced to the government. Social Services Functions A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Social Services Functions performed during the period and the associated cost for these services invoiced to the government. Member Transfers A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Member Transfer services performed during the period (including the status of all outstanding requests for medical records) and the associated cost for these services invoiced to the government. Medical Reviews A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Administrative Services related to Medical Reviews that were performed during the period and the associated cost for these services invoiced to the government. Workers' Compensation Assistance A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Workers' Compensation Assistance performed during the period and the associated cost for these services invoiced to the government. Other Member Services A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Other Member services performed during the period and the associated cost for these services invoiced to the government. Administrative Service Function Information to Be Reported Healthcare Provider Network A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Healthcare Provider Network services performed during the period and the associated cost for these services invoiced to the government. Pharmacy Benefit Management A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Pharmacy Benefit Management services performed during the period and the associated cost for these services invoiced to the government. Quality Assurance and Internal Audits A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Quality Assurance and Internal

Audits performed during the period and the associated cost for these services invoiced to the government. Records Management A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Records Management services performed during the period and the associated cost for these services invoiced to the government. Transfer of Data and Information (at the end of the contract) A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Transfer of Data and Information services performed during the period and the associated cost for these services invoiced to the government. Attending administrative, steering, benefits, and clinical WTC meetings A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all attendance at administrative, steering, benefits, and clinical WTC meetings during the period and the associated cost for these services invoiced to the government. Report Writing and IRB Submissions A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Report Writing and IRB Submissions that were performed during the period and the associated cost for these services invoiced to the government. Data Entry for Claims Submission and to Meet Reporting Requirements A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Data Entry services performed during the period and the associated cost for these services invoiced to the government. Data Entry of Healthcare Information into the DC’s Data System A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Case Management services performed during the period and the associated cost for these services invoiced to the government. Healthcare Protocol Development—provide intellectual input on the refinement of medical guidance and protocols as needed by the program (and coordinated by the DC), or in support of member treatment needs A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all

Healthcare Protocol Development services performed during the period and the associated cost for these services invoiced to the government. Providing Translational and Interpretive Services

A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Providing Translational and Interpretive Services performed during the period and the associated cost for these services invoiced to the government.

General and Administrative Charges

General and Administrative Charges A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all General and Administrative Charges during the period and the associated cost for these services invoiced to the government. Other Administrative Services A complete listing of activities, descriptions of activities, number of actions, and evaluation of effectiveness of all Other Administrative Services performed during the period and the associated cost for these services invoiced to the government. Operations Manual Difficulties encountered and proposed updates to the Operations Manual. Updates shall be approved by the Administrator of the WTC Health Program after review and discussion of the issues, as needed. Complaints A summary of all complaints received by the CCE during the preceding month and the status of their resolutions. Fraud and Abuse Report A) The CCE shall submit monthly the number of complaints of fraud or abuse made to the CCE related to covered services that warrant preliminary investigation by the CCE. B) The CCE shall also submit to the Administrator of the WTC Health Program the following on an ongoing basis for each confirmed case of fraud or abuse it identifies through complaints, organizational monitoring, contractors, subcontractors, providers, and members, etc. related to covered services: 1) The name of the individual or entity that committed the fraud or abuse; 2) The source that identified the fraud or abuse; 3) The type of provider, entity, or organization

that committed the fraud or abuse; 4) A description of the fraud or abuse; 5) The approximate dollar amount of the fraud or abuse; 6) The legal and administrative disposition of the case including actions taken by law enforcement officials to whom the case has been referred; and 7) Other data/information as prescribed by the Administrator of the WTC Health Program. Such report shall be submitted when cases of fraud or abuse are confirmed, and shall be reviewed and signed by an executive officer of the CCE.

The roles and responsibilities with respect to the NPN are detailed below.

The NPN manages a network of providers who are licensed, credentialed, insured and/or certified in accordance with the WTC Health Program requirements. Participating providers receive training on WTC Health Program covered health conditions and protocols from the NPN. In many cases, an enrollee may receive care from more than one NPN provider. The chart below describes the process used by the NPN to select and maintain providers within the NPN provider network.

1. Clinical Management Team Searches for Provider 2. Provider Contacted 3. Complete Services Confirmation Checklist 4. Provider Qualification 5. Provider Completes Subcontractor Agreement 6. Collect and Verify Credentialing Information 7. Update Provider Information Using Workflow Management Technology 8. Provider Training 9. Information Retrieval All contracting documents, training history, credentialing and licensing reports are maintained for audit access upon request The NPN has a team of individuals whose responsibility it is to ensure all Healthcare Practitioners (HCPs) within the NPN are licensed within the state where they will be performing services. The NPN ensures that all HCPs have unrestricted, valid current licenses, certifications, and registrations as required for their particular profession within the state, district or territory in which they are performing services. The NPN uses both trained credentialing staff and an accredited Credentialing Verification

Organization (CVO) to meet the provider credentialing requirements of its WTC Health Program contract. The NPN tracks the credentialing requirements in its data system for each provider to ensure all documentation is accurate and current. A qualifying practitioner is not activated within the NPN until the credentialing verification process is complete and the NPN Clinical Director has provided final approval. The NPN performs ongoing monitoring to identify any sanctionable activities or instances of malpractice, fraud, waste or abuse. HCPs are re-credentialed every 36 months. All subcontracted providers receive training and monitoring of their quality of care and overall performance in the provision of clinical services. All providers receive training from the NPN's Medical Provider Training department prior to scheduling appointments. Forms, procedures, and expectations are reviewed in the initial training session to ensure compliance with WTC Health Program processes. As Chapter 2 details, eligibility for all members of the WTC Health Program is determined by the Program. Members are assigned to the NPN by the Program based on their geographic location. These WTC Health Program members may be newly enrolled members or members who transfer from a CCE. Newly enrolled WTC Health Program members are assigned to the NPN by the WTC Health Program's Member Services Team based on the new member's location outside the NY metropolitan area. If a newly enrolled WTC Health Program member who has not been assigned to the NPN contacts the NPN directly, the NPN will work with the member and the Program to confirm eligibility and assignment. If a WTC Health Program member wishes to transfer from a CCE to the NPN or from the NPN to a CCE, the NPN and relevant CCE will work together to coordinate the transfer using the established WTC Health Program transfer policy, detailed in the Member Services Operations Manual. Coordination of member intake is managed by the NPN case manager. Ongoing communication with a WTC Health Program member occurs through a variety of media, as necessary, including telephone, email, and fax, and may include the use of Integrated Voice Recognition (IVR) technology. New Member: The NPN

contacts the member to answer questions and schedule an initial monitoring exam or initial health evaluation. Since the member is not transferring from a WTC Health Program CCE, there are no prior medical records to retrieve. Transfer Member: The NPN contacts the member to answer questions and encourage the member to return the Medical Record Release Form(s), provided in the Welcome Packet. The NPN makes up to six call attempts to reach the member to obtain the completed Medical Record Release Forms, as necessary. Once the forms are received, the NPN coordinates with the member's CCE to collect the medical records via trackable shipping service, enters information from the records into the NPN database and assigns a case manager to review the records and document the member's WTC-certified health conditions and medical history. Upon completion of documentation, the case manager schedules the intake interview. The intake process consists of three parts: an intake interview; testing; and a monitoring exam or initial health evaluation.

Intake Interview

Since NPN members are located throughout the country, face-to-face meetings are not feasible, so the NPN case manager conducts intake interviews by telephone. During the intake interview, the case manager verifies all demographic information with the member, making updates when necessary, in order to ensure proper identification and confidentiality. A Medical Health Questionnaire (MHQ) is completed by the case manager and typically takes between 45 minutes to 1 ½ hours. The MHQ is completed for both new WTC Health Program members and transfers into the NPN to ensure completeness of NPN documentation. If a member uses English as a second language and prefers to speak his/her primary language, the NPN engages a company that offers interpreter services to assist in interpreting the interview.

After the MHQ is conducted, the case manager schedules testing and monitoring exam or initial health evaluation appointments with the assigned provider.

These appointments are scheduled immediately for new members; for transfers into the NPN, the appointments are scheduled based on the due date of the member's next exam. All eligible members are encouraged to have an annual monitoring exam.

Testing and Monitoring Exams

The initial monitoring exam or health evaluation is consistent with those performed by the CCEs and includes a review of the completed MHQ, a general health assessment, vital signs assessment, spirometry testing, blood work, urine collection, and a chest X-ray. The follow-up monitoring exam, where appropriate for the type of member, includes the same components as the initial monitoring exam with the exception of the chest X-ray, which is performed every two years unless an increased frequency is clinically indicated. Follow-up exams or additional testing, scheduled through the case manager, may be required as a result of the monitoring exam to complete a diagnosis. Chapter 6 provides more detail on the components of the monitoring exams.

Within 48 hours of a member completing his/her appointment(s), all documentation is forwarded from the provider to the NPN so that the NPN Clinical Director may determine whether or not to request certification of a health condition. Chapter 3 provides detailed information regarding the certification process. The NPN scans all received documents and archives them in its database. The completeness of the documents is reviewed using a system-generated checklist. If any required materials are missing, the NPN contacts the provider to retrieve the missing component(s) and/or to complete any missing exam elements. In the event providers are not completing the exams/evaluations accurately or completely, re-training may be recommended.

Inform Member of Results

Once all documents are received by the NPN and quality reviews are completed, the case manager conducts a thorough review of the exam findings and

drafts a letter to the member informing him/her of the results and any referrals to the treatment program that stemmed from their exam. All exam results are sent no later than two weeks after the monitoring exam or health evaluation services have been completed.

If referrals are identified, the case manager follows up with the member within five days after the letter and exam/evaluation documentation has been sent to the member to discuss the conclusions reached from the initial work-up and the member's ongoing participation in the Program. The case manager discusses covered health conditions and assists in the coordination of treatment, as necessary. Additionally, the case manager outlines those health conditions that the member may have that are not covered under the WTC Health Program and instructs the member to see his/her primary care provider for treatment of those health conditions. If necessary, the case manager engages the NPN social worker who assists in the processing of social work referrals and benefits counseling for the member. The NPN's Social Services Specialist will reach out to provide assistance when a member's answer to the MHQ either in the mental health section or social benefits section indicates it may be needed, when a need is identified by the case manager through conversation with the member, or when a monitoring exam/initial health evaluation physician identifies the need for a social service referral. Areas of need addressed may include utility needs such as electricity and heating, transportation needs, mental health needs, assistance with Victim Compensation Fund questions, coordination of benefits with other programs such as Medicaid or workers' compensation, provision of guidance in accessing resource programs such as food stamps or financial assistance, offering guidance in accessing medication assistance or medical assistance programs, providing assistance in accessing local resources in other regions of the country, or other items as requested by the member. If referrals are not indicated as part of the monitoring exam/initial health evaluation, the NPN will begin the process for scheduling the next monitoring

exam 60 days prior to its due date, where appropriate. If a member is referred for treatment, the NPN will begin the request for certification process for all covered health conditions which the clinical director determines that the member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition. Chapter 3 describes the process for certifying covered conditions under the program. When a member's health condition is approved for certification by the WTC Health Program, the Program notifies the NPN electronically and sends the member a letter to inform him/her of the Program's decision.

The NPN also issues a Member ID Card to all NPN members consistent with the Program's practices for all members. The card contains a member identification number and the customer service telephone numbers for the NPN and for the Pharmacy Benefits Manager (PBM).

4.5 Processing and Paying Claims

The NPN reimburses every subcontracted provider within 30 days of receipt of their invoice. In order to receive reimbursement, the services rendered must be medically necessary, performed completely and in accordance with the NPN's authorization, protocols, and direction.

Upon receipt of an invoice, the NPN reviews it for accuracy and completeness. Once the NPN determines that the invoiced services are appropriate and in accordance with WTC Health Program requirements, the invoice is electronically submitted to the HPS contractor for processing and payment. If the NPN determines that the invoiced services are not in accordance with Program requirements, it denies the invoice and sends the provider a letter of explanation permitting the provider to correct any errors and, if appropriate, resubmit a corrected claim to the NPN. See Chapter 5 for more

detail on how NPN medical and pharmaceutical claims are processed, paid and can be appealed.

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Member services are a key function of most WTC Health Program entities. A variety of activities are implemented to ensure effective and full communication with all Program stakeholders. The Program has a variety of mechanisms in place to communicate Program benefits to and meet with potentially eligible populations. 9/11 Environmental Action WTC Health Program Outreach and Education Activities: 9/11 Environmental Action's outreach project will use innovative social networking techniques, short upbeat videos, as well as traditional grassroots outreach methods, to reach 9/11-affected residents, students and area workers, referred to as WTC survivors. 9/11EA will utilize its relationships and networks within the NYC Disaster Area to disseminate information about the World Trade Center (WTC) Health Program, who is eligible and how to apply. 9/11 EA will closely partner with the survivor organization, StuyHealth, to reach a population of former students, now young adults, locally and nationally. Both organizations will offer enrollment guidance. FealGood Foundation, Inc. WTC Health Program Outreach and Education Activities: FealGood Foundation |Outreach & Education (FGF OnE) will assist First Responders in the NYC Area and other identified areas of need who may have been injured, physically or mentally as a direct result of their rescue, recovery and clean-up efforts at the World Trade Center Site. FGF OnE will conduct four large events to assist in registering the Responders in World Trade Center Health Program. New York Committee for Occupational Safety and Health (NYCOSH) WTC Health Program Outreach and Education Activities: NYCOSH will reach responders through one-on-one engagement directed at union members. Establishing one-on-one contact with these individuals through their organizations and working to ensure that they understand their potential benefits, how to apply to the program, and are guided through the application process itself is the critical next phase of this project. Voices of September 11th WTC Health Program Outreach and Education Activities: Voices of September 11th (VOICES) provides a wide range of support services and programs to address long-term needs of those impacted by 9/11. The plan for outreach is

broad-based and uses proven engagement techniques, direct-contact printed materials, web-based activities and social networks as well as community-based and corporate presentations, conferences and forums. The plan targets outreach to companies, organizations, local residents, and subgroups such as parents, immigrants, seniors, retirees and children. The CCEs and the NPN are responsible for undertaking activities designed to retain members in the Program. These activities include maintaining regular contact with currently enrolled members and encouraging these members to continue to participate in the program. See Chapter 6 for additional information about CCE member retention activities, and Chapter 7 for additional information about NPN member retention activities. The Program has established comprehensive phone information services via its Member Call Center to support education and outreach activities. The Member Services team also coordinates appeal processes for the Program. Members may appeal decisions made regarding denial of enrollment, a decision to disenroll the member from the Program, a decision not to certify a health condition as a WTC-related condition, a decision not to certify a health condition as medically associated with a WTC-related health condition, a decision to decertify a health condition, or a decision not to authorize treatment due to a determination by the WTC Health Program that the treatment is not medically necessary for the certified health condition. Appeals are specific to the type of decision rendered. A comprehensive discussion of the appeals process may be found at www.cdc.gov/wtc/appeals.html. Summaries of the appeals processes may be found in Chapter 2, Eligibility and Enrollment, for denials of enrollment and disenrollments; Chapter 3, Certification of Health Conditions, for denials of certification of a health condition and decertification; and Chapter 4, Medical Benefits, for denial of treatment authorization. Appendix 9-A contains a fact sheet, distributed to any members receiving a denial decision for certification of a health condition, which outlines the appeals process. Member concerns are addressed through a variety of mechanisms. In addition

to the regular communication channels available to members (described above) through which concerns may be expressed, the Program also hears concerns through ad hoc meetings with stakeholders and community groups and via individual communications on a case-by-case basis. Because of the close working relationships and frequent communication between the Program and member groups, the Program has multiple, regular opportunities to identify and address member concerns. Member concerns are also reviewed through congressional inquiries and through letters sent by members directly to the Program or to the Administrator. 9-A—An Overview of the Appeal Process for Denial of Health Condition Certification Last Revised – August, 2014 The purpose of this WTC Health Program Fraud, Waste, and Abuse (FWA) policy is to describe the measures taken to prevent, detect, and deter the FWA of public funds. FWA activities target the potential causes of FWA from inadvertent errors to willful deception. The scope of the WTC Health Program FWA policy includes all areas of the WTC Health Program that could be vulnerable to FWA. These areas include, but are not limited to The Public Health Service Act The following sections of Title XXXIII of the Public Health Service (PHS) Act are applicable to this chapter: https://www.gpo.gov/fdsys/pkg/USCODE-2015-title42/pdf/USCODE-2015-title42-chap6A-subchapXXXI.pdf Other laws and statutes also have direct impact on protecting against FWA. Federal laws include, but are not limited to, the following: Health Care Fraud Statute The Health Care Fraud Statute makes it a criminal offense to knowingly and willfully execute a scheme to defraud a health care benefit program. Health care fraud is punishable by imprisonment for up to 10 years. It is also subject to criminal fines of up to $250,000. Specific intent to violate this section is not required for conviction. 18 U.S.C. § 1347. https://www.gpo.gov/fdsys/pkg/USCODE-2015-title18/pdf/USCODE-2015-title18-partI-chap63-sec1347.pdf False Claims Act The False Claims Act establishes civil liability for offenses related to certain acts, including knowingly presenting a false or fraudulent

claim to the government for payment, and making a false record or statement that is material to the false or fraudulent claim. “Knowingly” includes not only actual knowledge but also deliberate ignorance or reckless disregard for the truth or falsity of the information. No specific intent to defraud the government is required. Depending on the circumstances, some examples of potential False Claims Act violations in the health care fraud context include upcoding, billing for unnecessary services, billing for services or items that were not rendered, and billing for services performed by an excluded individual. 31 U.S.C. § 3729. Individuals and entities that make false claims are subject to civil penalties of up to $11,000 for each false claim, plus three times the amount of damages the government sustains by reason of each claim. Violation of the False Claims Act may lead to exclusion from Federal health care programs. 31 U.S.C. § 3729. Civil legal actions for penalties and damages under the False Claims Act may be brought not only by the government, but by private persons, such as competitors or employees of a provider, on behalf of the government. If the legal action is successful, the private person is entitled to a percentage of the recovery. The False Claims Act protects all persons from retaliation for reporting false claims or bringing legal actions to recover money paid on false claims. 31 U.S.C. § 3730. Failure to return overpayments may lead to liability under the False Claims Act. Under section 1128J(d) of the Social Security Act, persons who have received an overpayment from a Federal health care program must report and return the overpayment within 60 days of the date the overpayment was identified. Failure to do so may make the overpayment a false claim. 42 U.S.C. § 1320a-7k; 31 U.S.C. § 3729. False claims made knowingly may also be subject to criminal prosecution. Persons who knowingly make a false claim may be subject to criminal fines up to $250,000 and imprisonment of up to 5 years. 18 U.S.C. §§ 287; 3571. Anti-Kickback Statute The Anti-Kickback Statute, found in Section 1128B(b) of the Social Security Act, prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, in cash or in kind, to induce or in return for

referring an individual for the furnishing or arranging of any item or service for which payment may be made under a Federal health care program. Remuneration means anything of value and can include gifts, under-market rent, or payments that are above fair market value for the services provided. Criminal penalties for violation are a fine of up to $25,000 and imprisonment for up to 5 years. 42 U.S.C. § 1320a-7b. Compliance with the Anti-Kickback Statute is a condition of payment in Federal health care programs. Claims that include items or services resulting from a violation are not payable and may constitute false or fraudulent claims under the False Claims Act. 42 U.S.C. § 1320a-7b. Under the Civil Monetary Penalties Law, Social Security Act Section 1128A(a)(7), the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) may impose civil penalties for violations of the Anti-Kickback Statute. The penalties are up to $50,000 per violation plus three times the amount of the remuneration. Violation of the Anti-Kickback Statute may also lead to exclusion from Federal health care programs. 42 U.S.C. § 1320a-7a. The Anti-Kickback Statute provides safe harbors for certain arrangements, such as personal services and rental agreements, investments in ambulatory surgery centers, and payments to bona fide employees. Physicians with questions about the Anti-Kickback Statute and these safe harbor arrangements should consult the regulations and guidance documents available from HHS-OIG. 42 C.F.R. § 1001.952. Exclusion Provisions Under Section 1128 of the Social Security Act, HHS-OIG has authority to exclude individuals from participating in Federal health care programs, including Medicaid, for various reasons. Exclusions can be mandatory, meaning HHS-OIG has no choice about whether to exclude, or discretionary, which means the HHS-OIG does have a choice. Exclusion is mandatory for convictions of program-related crimes, convictions related to patient abuse, felony convictions related to health care fraud, and felony convictions related to controlled substances. Exclusion is discretionary for loss of license due to professional competence or financial integrity, convictions related to fraud, convictions related to

obstruction of an investigation or audit, misdemeanor convictions related to controlled substances, and participation in prohibited conduct such as kickbacks and false statements. 42 U.S.C. § 1320a-7. Generally, Federal health care programs will not pay for items or services furnished, ordered, prescribed, or supplied by an excluded individual or entity. 42 C.F.R. § 1001.1901. Under the Civil Monetary Penalties Law, Social Security Act Section 1128A, HHS-OIG may impose civil monetary penalties of up to $10,000 per item or service claimed while excluded. HHS-OIG may also impose an assessment of up to three times the amount claimed. 42 U.S.C. § 1320a-7a. 1 While a health care professional who provides services through Medicaid may employ an excluded individual who does not provide any items or services paid for, directly or indirectly, by Federal health care programs, practitioners should exercise caution. A professional who contracts with or employs "a person that the provider knows or should know is excluded by OIG … may be subject to CMP (Civil Monetary Penalty) liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program." The prohibition is not limited to items or services involving direct patient care, but extends for example to filling prescriptions, providing transportation services, and performing administrative and management services that are not separately billable. See U.S. Department of Health and Human Services, Office of Inspector General, "Updated Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Care Programs," (May 8, 2013). Available at https://oig.hhs.gov/exclusions/files/sab-05092013.pdf. If, for example, a biller is excluded from a government health care program, payments on claims submitted by the practice through the biller may be considered overpayments subject to recoupment. Any person who has received an overpayment must return the money within 60 days of the date on which the overpayment was identified. Failure to do so may subject the person to liability under the False Claims Act and the Civil Monetary Penalties Law. 42 U.S.C. 1320a-7k. 2 It is in the best interest of physicians and other

providers to screen potential employees and contractors prior to employment or hiring to ensure they are not excluded from participating in Federal health care programs. In addition, providers should regularly check the exclusions database to ensure that none of the practice's employees or contractors have been excluded. The Centers for Medicare & Medicaid Services (CMS) has issued guidance to State Medicaid agencies that they should require providers to screen their employees and contractors for exclusions by checking the database on a monthly basis. The guidance further advises States to require all providers to report any exclusion information discovered immediately. The List of Excluded Individuals/Entities (LEIE) database is available at https://exclusions.oig.hhs.gov/ on the HHS-OIG website. Both licensed and unlicensed individuals may be excluded, so it is best to check for both. In addition to checking the LEIE, providers should check the Exclusions Extract, which can be accessed by visiting https://www.sam.gov/ on the System for Award Management website. Centers for Medicare & Medicaid Services, State Medicaid Director Letter 09-001 (p. 4), (Jan. 16, 2009). Available at https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD011609.pdf. Civil Monetary Penalties Law As previously noted, the Civil Monetary Penalties Law, Section 1128A of the Social Security Act, authorizes HHS-OIG to impose civil penalties for violations of the Anti-Kickback Statute as well as a range of other violations. Penalties range from $10,000 to $50,000 per violation. These violations include, but are not limited to, the following: 42 U.S.C. § 1320a-7a. Each suspected case of FWA is reviewed to categorize the allegation as Fraud, Waste, or Abuse. Intent is the key distinction between Fraud and Abuse. An allegation of waste and abuse can escalate into a fraud investigation if a pattern of intent is determined. Fraud is defined as an intentional deception, false statement, or misrepresentation made by a person with the knowledge that the deception could result in unauthorized benefit to oneself or another person. It includes any act that constitutes fraud under applicable federal or state law.

It is a crime to defraud the Federal Government and its programs. 18 U.S.C. § 1001. Punishment may involve imprisonment, significant fines, or both. Criminal penalties for health care fraud reflect the serious harms associated with health care fraud and the need for aggressive and appropriate fraud prevention. In some states, providers and health care organizations may lose their licenses. Convictions also may result in exclusion from participation for a specified length of time. Fraud may also result in civil liability. Examples of Fraud Could Include: Waste is defined as failure to control costs or regulated payment associated with federal program funding. Furthermore, waste results in taxpayers not receiving reasonable value for their money. Waste relates primarily to mismanagement, inappropriate actions, or inadequate oversight. Examples of Waste Could Include: Abuse is defined as practices that are inconsistent with professional standards of care; medical necessity; or sound fiscal, business, or medical practices. Examples of Abuse Could Include: Detecting, preventing, and reporting FWA are the responsibilities of everyone associated with the WTC Health Program including employees, members, providers, and contractors. The WTC Health Program will closely monitor program activities to detect or prevent any FWA. The WTC Health Program will report fraudulent conduct to federal law enforcement agencies and violators may be subject to criminal, civil, or administrative penalties. Information concerning suspected fraud related to the WTC Health Program by contractors, grantees, health care providers, or individual recipients will be reported to the Department of Health and Human Services Office of Inspector General (OIG) by phone at 1-800-HHS-TIPS (1-800-447-8477); online at oig.hhs.gov/report-fraud; or in writing to the following address: U.S. Department of Health and Human Services, Office of Inspector General, ATTN: OIG HOTLINE OPERATIONS, P.O. Box 23489, Washington, DC 20026. The WTC Health Program has instituted FWA activities including: The following areas of the WTC Health Program incorporate measures and activities to protect against FWA: The full application and enrollment process is described in the WTC Health Program Policy and

Procedure Manual (PPM, Chapter 2). Using an online portal or by submitting a paper application, applicants apply to the program and submit supporting documentation related to their activities, location, and time periods of exposure. Applications are reviewed for completeness and compliance with the relevant eligibility criteria established in Title XXXIII of the PHS Act and 42 C.F.R. part 88. Quality Control checks are built into the workflow and there is an appeals process for denials of enrollment (see 42 C.F.R. § 88.14). Internal audits of enrollment are conducted on a quarterly basis. Performance metrics are used to monitor the completeness and timeliness of the application/enrollment process, and outreach and communication services. These Quality Control checks facilitate the identification of potential instances of FWA. Outreach and education materials, including the Member Handbook, incorporate information on member FWA responsibilities, such as avoiding potential fraudulent enrollment. Various Program activities also help to ensure that resources are used efficiently and waste is avoided. The WTC Health Program works strategically with the Responder and Survivor Steering Committees, Clinical Centers of Excellence (CCEs), the Nationwide Provider Network (NPN), and the Data Centers (DCs) to evaluate program participation and client satisfaction. The program seeks to maintain contact with currently enrolled members and to increase participation for those who have been inactive in program follow-up. Together with CCEs, NPN, DCs, and Steering Committees, the WTC Health Program identifies and reduces barriers that affect member participation. The tools employed include surveys, newsletters, websites, key informant feedback, and scheduling reminders. The CCEs/NPN have primary responsibility for safeguarding against fraudulent providers. The CCEs/NPN vary in how they provide medical services; some do most of the services in-house while others refer many services to outside providers. External providers affiliated with the CCEs are credentialed and enrolled in the Program through a third party provider management sub-contractor under a WTC Health Program Support (HPS) contract. This provider

management sub-contractor screens CCE-affiliated external providers against the OIG/GSA exclusion lists and/or the CMS Fraud Investigation Database, conducts criminal background checks, establishes business agreements which include a provision that the agreement with the WTC Health Program may be terminated immediately for fraudulent billing, gives guidance to the providers on the limited nature of the WTC Health Program and what costs may be appropriately paid, and informs the network providers of the authorization and billing requirements for member care including the following: External providers affiliated with the NPN are credentialed and enrolled through a separate third party administrator under United Health Care (UHC). NPN authorizes provider bills in the same manner as the CCEs. Once CCEs/NPN request registration of a provider in the program, the HPS contractor registers the provider in the claims system so that they can be paid. As part of this registration process, the HPS contractor verifies the validity of the provider's National Provider Identification (NPI) number. The WTC Health Program provides a limited health care coverage for qualifying certified WTC-related and medically associated conditions. Treatment benefits are controlled through administrative certification of health conditions on an individual member basis (see PPM Chapter 3 for full details). This process, outlined in Title XXXIII of the PHS Act and in 42 C.F.R. part 88, enables the mandatory requirements for coverage to be determined through a two-step process that first entails a clinical diagnostic evaluation which is subsequently reviewed by a federal official for certification. The process has data quality and control checks built into the workflow, including an administrative appeals procedure (see 42 C.F.R. § 88.21), a decertification procedure (see 42 C.F.R. § 88.19), member communication regarding health condition certification denials, and a procedure for the Administrator's discretionary reopening of decisions (see 42 C.F.R. § 88.25). The HPS contractor and CCE/NPN exchange certification data to ensure alignment of member information for benefit management. The two-step process consisting of an initial CCE/NPN physician determination, followed

by a review and certification by the Administrator or designee provides distinct exercise of independent judgement of the relatedness of the medical diagnosis with exposure information to effect certification of conditions, thus further safeguarding certification against FWA. The medical benefits available under the program are detailed in Chapter 4 of the PPM. This chapter of the PPM includes FWA mitigation procedures that help prevent unnecessary or unauthorized services being paid under the program. The WTC Health Program maintains a Code Book of the allowable billing codes by specific benefit plans. The Code Book categorizes the benefit plans for the initial health evaluation, periodic medical monitoring, cancer screening, diagnostic evaluation, and treatment of specific certified conditions (through "care suites"). Further details about benefit control can be found in Chapter 4. There is an administrative medical change control process that ensures oversight for any requested change to the Code Book; and quality control checks are built into the workflow. The Code Book is also subject to modification based on evaluation of reasons for denied service claims, updates to medical guidelines or policy, coding updates from source organizations, and when new health conditions are added for program coverage. The CCEs, DCs, and NPN must adhere to an operations manual that specifies how they are implementing the tasks in their performance work statement. The elements are addressed in Chapters 6, 7, and 8 of the PPM. These operations include quality assurance metrics for scheduling, completion of all components of the examination and testing, notification and counseling about results and providing professional referrals for further evaluation or treatment compliant with program policy and standards of medical practice. The WTC Health Program meets with the clinical directors and administrators of the CCEs, DCs, and NPN on a regular basis to calibrate and clarify medical and administrative policies and procedures. Minutes of these meetings are taken and sent out to all participants. Practice guidelines following principles of medical necessity and community standards of care are produced by the DCs in consultation with the CCEs and approved for

implementation by the WTC Health Program. Prescription medications are a significant expenditure for member treatment under the WTC Health Program. Significant controls are in place to prevent FWA and ensure that only those drugs in a specific formulary are authorized and paid by the program. WTC Health Program members receive outpatient medication to control certified conditions and medically associated conditions arising from the 9/11 terror attacks. Members with certified health conditions are assigned a specific pharmacy benefit plan. Each pharmacy benefit plan has a closed formulary, authorization controls for certain medications, and provides the pharmacist with safety messaging and real-time claims processing at the point of sale. Chapter 12 provides details regarding these benefit plans and the formulary change control process that ensures oversight for requested changes to program formularies. The plan formularies undergo periodic review by the Medical Benefits Team. The WTCHP medical and pharmacy teams work with the CCEs and NPN to determine prescribing patterns, medical necessity criteria, safety concerns, and make cost assessments. The pharmacy team analyzes paid claims and conducts on site audits of the CCE's to ensure prescriptions are used for certified conditions. New drugs and drug requests get reviewed monthly to determine if they should be added to the formulary. The pharmacy team reviews most frequently prescribed medications, brand vs generic, single source brand use, overrides, DEF costs, coordination of benefits for survivors, opioid use, pharmacy overrides such as prior authorizations, prescription not covered, and refill too soon. Claims processing and payment is a critical area in the protection against FWA in the WTC Health Program. The WTC Health Program uses a fee-for-service reimbursement strategy for health care services (see Chapter 5). The only exception is a capitated fee for a group of services constituting the standardized initial health and annual medical monitoring examination for eligible members (see Chapter 4). The WTC Health Program pays the approved rates to an enrolled provider, for covered, correctly coded and correctly billed services, provided to an eligible beneficiary (see 42 C.F.R. §

88.22). The claims processing system has been designed to guard against FWA by reducing payment errors by preventing the initial payment of claims that do not comply with the WTC Health Program coverage, coding, payment and billing policies. To maintain or improve provider compliance and lower the error rate, the WTC Health Program follows these parallel strategies: The CCEs, the NPN, and the HPS contractors analyze provider compliance with WTC Health Program coverage and coding rules and take appropriate corrective action when providers are found to be non-compliant. For example, some errors are the result of provider misunderstanding or failure to pay adequate attention to Program policy. Other errors may represent calculated plans to knowingly acquire unwarranted payment. The CCEs/NPN evaluate the circumstances surrounding the errors and proceed with the appropriate plan of correction. If errors continue to be repeated, or if the errors suggest potential fraud or a pattern of abuse, then more severe administrative action is initiated. The HPS contractor consults with industry experts to identify medical practice and technology changes that may result in improper billing or program abuse to propose areas for data analysis and remedial action as needed. Types of service claims are routinely assessed for patterns of waste or abuse include, but are not limited to: While automation is the preferred mode of operation for the claims processing system to minimize error from human touch, based on program findings, the following types of claims are routinely handled through manual processing: Metrics are monitored that assess electronic claims submission accuracy, claims processing time, auto-adjudication success and accuracy, claims volume and payment adjustments, volume and reasons for claims being denied or pended for further resolution, and compliance with the Prompt Payment Act. All points of sale are connected to the program’s contracted pharmacy benefit manager through software transmitting claims processing rules and safety notices to the pharmacist at the point of sale. The rules require verification of member, pharmacy plan assignment, an authorized prescriber, a supply limit and prevent early refills, off-formulary product

dispensing, and dispensing of duplicate ingredients or supplies. Higher tier drugs or select products that may be prone to misuse or abuse require additional authorization by the CCE/NPN in the system before the pharmacist can fill the prescription. Prescriptions are filled with generic formulations unless a brand is authorized. Brand availability on the formulary is subject to considerations of therapeutic efficacy, allergy to ingredients, side effect profile, patient adherence factors, safety, and cost. Continual monitoring to optimize pharmacy cost control strategies include the following: The following administrative improvements enhance controls for FWA. Title XXXIII of the PHS Act requires recoupment of treatment costs for WTC-related health conditions and medically associated health conditions if the condition is work-related (see also 42 C.F.R. § 88.24). The WTC Health Program determined that the CCEs and NPN did not have the resources to manage this requirement, so an alternative approach was implemented that utilizes the New York State Workers' Compensation Board Health Insurance Match Program (HIMP) that assists health insurers and health benefits plans to set up a system to identify claims that they have paid which may be the responsibility of the employer, workers' compensation insurance carrier, or special fund, and to obtain reimbursement therefore. The WTC Health Program awarded a contract to HMS Federal to implement the HIMP for our program in September, 2014. The WTC Health Program receives monthly reports on recoupment activities. Since HIMP is a comprehensive and efficient process that interacts directly with the New York State Workers' Compensation Board and insurers, more funds are recovered and verification of appropriate claims payment is increased. Additionally, the WTC Health Program is in the process of posting a solicitation to address the provider payments accounts receivables aging balances associated with overpayments made to providers in excess of amounts owed or payments made in error. All overpayments identified as un-recouped (all efforts to offset have been exhausted) will be turned over to the WTC Health Program's debt collection support services contractor to collect the debt owed

the Federal Government. The debt collection support services contract is expected to be awarded during second quarter of 2018. The WTC Health Program has created an online set of policies and procedures for transparency and consistency in program administration. In addition to this PPM chapter on FWA, there are requirements for the Health Insurance Portability and Accountability Act (HIPAA) and the Federal Information Security Management Act (FISMA).

Working with the HHS Program Integrity Initiative, the WTC Health Program is addressing data security and privacy (HIPAA and FISMA), resource alignment for performance requirements of CCEs/NPN to comply with benefit administration, streamlining the process of program application/processing, and program communication.

In addition, the WTC Health Program periodically reviews metrics that provide qualitative and quantitative measures to assess the Program's performance on customer service, pharmacy utilization, claims processing, and cost efficiency of managing the WTC Health Program. Review of these metrics facilitates the identification of potential instances of FWA.

The WTC Health Program has a Fraud Prevention Officer (FPO) and a Fraud Risk Assessment Team (FRAT) in place who adhere to established procedures for processing allegations pertaining to FWA when received. The FRAT includes the FPO, the WTC Health Program Deputy Division Director, the Office of the General Counsel (OGC), and any other relevant parties related to the specific allegation. The WTC Health Program provides stakeholders with information about the Program's FWA efforts and procedures through information included on the WTC Health Program website and in the Member Handbook. Allegations of FWA are to be reported to the FPO. In addition, the HHS OIG has a website dedicated to reporting possible FWA. (https://oig.hhs.gov/fraud/report-fraud/index.asp) If the allegation of FWA comes to the WTC Health Program from the OIG, the FPO will work with the OIG, as requested, to

assist with the OIG investigation. When an allegation of FWA is received from any source other than the OIG by the WTC Health Program, the allegation is immediately forwarded to the FPO. The FPO will record receipt of the allegation on the FWA Intake Form, enter the FWA allegation into the FWA Allegation Status Log, and begin an initial investigation to determine if the allegation should be categorized as fraud, waste, or abuse. As a result of the initial investigation, if the allegation is categorized as potential fraud, the FPO will gather any relevant information and forward the case to the OIG for investigation. The FPO will monitor the status of the OIG investigation and report the OIG's findings and resolution to the FRAT. If the allegation is determined to be either waste or abuse, the FPO will continue the WTC Health Program's internal investigation of the allegation with the assistance of any relevant personnel. Once the investigation is completed, the FPO will present the results of the investigation to the FRAT along with a recommended resolution. The FPO is responsible for ensuring the waste or abuse allegation is resolved based on the decision of the FRAT. The FPO is also responsible for ensuring the waste or abuse investigation and resolution are documented and reported to the appropriate HHS/CDC contact, as required. Last Revised – August, 2014 The purpose of this chapter is to describe the relationships and actions among the World Trade Center (WTC) Health Program, other parts of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS), and other government agencies. The WTC Health Program is responsible for providing health care benefits according to the provisions of the Zadroga Act, including those provisions related to WTC Health Program member eligibility, enrollment, benefits, and responsibility for determining the payment amounts to be disbursed. The Administrator, Centers for Medicare & Medicaid Services (CMS), is responsible for disbursing payment for the program. Administration of the WTC Health Program involves cooperation and coordination with HHS and other government agencies, some

of which are specified in the Zadroga Act. The WTC Health Program must also cooperate with, and respond to, program oversight evaluations and audits performed by the Government Accountability Office (GAO) and HHS Office of the Inspector General (IG). In addition, the WTC Health Program collaborates with other 9/11 programs such as the September 11th Victim Compensation Fund (VCF) administered by the Department of Justice. Office of the Inspector General (IG) (The Zadroga Act, 42 U.S.C. § 300mm(d))

Responsibility:

The Zadroga Act requires the HHS Office of the Inspector General (IG) to manage certain oversight responsibilities, including the review of the WTC Health Program health care expenditures to detect fraudulent or duplicate billing and payment for inappropriate services, as well as the review of the WTC Health Program for unreasonable administrative costs, including with respect to infrastructure, administration and claims processing. In addition, the IG can initiate a review, not specifically required by the Zadroga Act, of other components of the WTC Health Program.

Activity:

In August 2011, the HHS IG initiated an audit to review the WTC Health Program's controls for awarding and monitoring the Clinical Centers of Excellence (CCEs) and determine whether the CCEs' financial systems can provide reliable financial and performance data, including medical service claims data. As of July 2013, the results of this review had not yet been published.

The Office of the General Counsel (OGC) provides representation and legal advice for the Department of Health and Human Services (HHS). OGC supports the development and implementation of the Department's programs by providing legal services to the Secretary of HHS and the organization's

various agencies and divisions. OGC provides legal support and assistance to the WTC Health Program to ensure the Program is administered in accordance with the Zadroga Act and other applicable Federal laws and regulations. Government Accountability Office (GAO) (Exhibit 1, 42 U.S.C. § 300mm-4 and § 300mm-22) Responsibility: The Zadroga Act required the Comptroller General to submit an analysis to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate no later than July 1, 2011 on whether the Centers for Clinical Excellence (CCEs) have financial systems that allow for the timely submission of claims data (Exhibit 1, 42 U.S.C. § 300mm-4(d)). In addition, the Zadroga Act requires the GAO to study feasibility, efficiency and effectiveness issues related to the WTC Health Program, including: The GAO, like the IG, can also initiate a review, not specifically required by the Zadroga Act, of other components of the WTC Health Program. Activity: The Zadroga Act required GAO to report by July 1, 2011, on whether the CCEs under contract with the WTC Program Administrator hadfinancial systems that would allow for the timely submission of health care claims data as envisioned by the act. According to the WTC Program Administrator's CCE contract awards schedule, the Administrator would not have awarded any contracts with the CCEs until at least June 30, 2011. Therefore, they could not perform a review of CCE contractors' financial systems because no CCE contractors were in place to assess by July 1, 2011. On July 15, 2011, GAO issued a briefing that focused on (1) the CDC/NIOSH schedule for awarding contracts to the CCEs, (2) health care claims data for the CCEs and planned procedures, and (3) the Administrator's plans for evaluating each CCE system's health care claims data capabilities during and after the award of the contracts. (Exhibit 3) The results of the briefing found that: On August 4, 2011, GAO issued its report regarding (1) the consolidated data center, (2) the use of VA health care facilities for members living outside the New York metropolitan area, and (3) the use of an existing federal prescription drug purchasing program. (Exhibit 2) While the

GAO report did not offer any formal recommendations, its analysis stated that: On July 23, 2014, the GAO completed an audit on the WTC Health Program's approach to add cancers to the list of WTC-covered conditions (See Exhibit 4). The main objectives of this audit were: The Director of CDC oversees CDC/NIOSH responsibilities under the WTC Health Program. CDC Office of the Director staff, as well as other CDC Offices as appropriate, are involved in reviewing performance plans, documenting progress, identifying risks, and interceding as necessary to ensure the highest standards of performance. The CDC Procurement and Grants Office provides assistance with acquisitionand related activities to enable the centers, institutes, and offices at CDC to implement health-related programs, initiatives, and acquisitions. PGO is the only entity within CDC which can obligate federal funds. PGO contributes to the implementation of initiatives and acquisitions related to the WTC Health Program through non-programmatic management for all Program financial assistance (grants and cooperative agreements) and contract activities. The NIOSH Office of Extramural Programs (OEP) facilitates the management of extramural grant and cooperative agreement portfolios. OEP is located within the NIOSH Office of the Director under the direction of the Associate Director for Research Integration and Extramural Performance. OEP manages the extramural portfolio of cooperative agreements for all NIOSH activities, including the WTC Health Program. OEP, in coordination with the WTC Health Program, facilitates the solicitation, review, and issuance of cooperative agreements related to the September 11th terrorist attacks. This portfolio includes the awards for the WTC Health Registry, research projects, and outreach and education activities (Exhibit 1, 42 U.S.C. §§ 300mm-2, 300mm-51, 300mm-52). Responsibility:
The Secretary of HHS delegated authority to the WTC Health Program to assume enrollment and eligibility functions (Exhibit 5). Required eligibility and enrollment activities that were delegated under the Zadroga Act include:
Activity: The procedures and protocols used to perform WTC Health Program eligibility

and enrollment functions are detailed in Chapter 2, Eligibility and Enrollment. The procedures and protocols used to perform Program oversight are detailed in

Chapter 12

, Quality Assurance and Program Evaluation.

Responsibility: The Zadroga Act mandates that any individual who is on the terrorist watch list maintained by the Department of Homeland Security (DHS) be disqualified for eligibility within the WTC Health Program. The Zadroga Act incorrectly states that DHS maintains the terrorist watch list. The Federal Bureau of Investigation (FBI), housed within the Department of Justice (DOJ), administers the Terrorist Screening Center (TSC). As such, the WTC Program Administrator collaborates with the TSC to meet the requirements of the Zadroga Act regarding qualification for enrollment in the WTC Health Program. Activity: The WTC Health Program established a process to share WTC Health Program member and applicant information with DOJ in order to meet the requirements of the Zadroga Act. The WTC Health Program Contractor prepares a list of new WTC Health Program applicants on a weekly basis and the list is transferred to the TSC. Based on the information provided by the TSC, the applicant is qualified or not qualified for enrollment into the WTC Health Program. Only qualified applicants will be considered for enrollment into the WTC Health Program based on the Program's eligibility criteria. (See Chapter 2, Eligibility and Enrollment) Responsibility: The Zadroga Act prohibits NIOSH from making payments for the provision of WTC Health Program health care benefits (Exhibit 1, 42 U.S.C. § 300mm-5(14)(B)). Activity: The Secretary, HHS, delegated authority for disbursing payments in the WTC Health Program to the Administrator, Centers for Medicare & Medicaid Services (CMS) in May 2011. (Exhibit 5, 76 Fed. Reg. 31337 (May 31, 2011)). The WTC Health Program and CMS established an interagency agreement for this activity. See Chapter 5, Claims Processing, for details regarding the CMS payment function. Responsibility: As required by the Zadroga Act,

the WTC Health program reimburses costs for medically necessary treatment for WTC-related health conditions according to the payment rates that would apply to the provision of such treatment and services by the facility under the Federal Employees Compensation Act (FECA). For treatment for which FECA rates are not available, the WTC Health Program administrator is required to establish a treatment reimbursement rate (Exhibit 6, 42 C.F.R. § 88.16). In no case are the payments for WTC Health Program products or services made at a rate higher than the Office of Worker's Compensation Programs (OWCP) in DOL would pay for such products or services rendered at the time such products or services were provided. Activity: The WTC Health Program consulted with DOL to determine the best policies and procedures to reimburse for the provision of health care under the WTC Health Program. Based on those policies and procedures, the WTC Health Program established a system to process WTC Health Program claims, ensuring claims are paid in accordance with the Zadroga Act. In addition to establishing audits to ensure compliance, the WTC Health Program performs periodic retrospective reviews and analyses of claims to audit the Program's performance. More detailed information regarding claims processing can be found in Chapter 5. Responsibility: Title II of the Zadroga Act reactivates the September 11th Victim Compensation Fund of 2001 (VCF) that operated from 2001-2004 and requires a Special Master, appointed by the Attorney General, to provide compensation for any individual (or a personal representative of a deceased individual) who suffered physical harm or was killed as a result of the terrorist-related aircraft crashes of September 11, 2001 or the debris removal efforts that took place in the immediate aftermath of those crashes. On August 31, 2011, DOJ published a Final Rule regarding the operation of the VCF, as revised by the Zadroga Act, in the Federal Register (76 Fed. Reg. 54112).

The VCF only provides compensation for losses due to personal physical injury or death. An individual who elects compensation from the VCF waives his or her rights to

pursue litigation to seek damages for the physical injury or death resulting from the September 11, 2001 attacks.

Activity: The WTC Health Program assists DOJ as outlined by a Memorandum of Understanding (MOU) between the VCF and the WTC Health Program. With the specific authorization and consent of an individual VCF claimant, the MOU facilitates: 1) for those VCF claimants participating in both the WTC Health Program and the VCF, transmission of the individual's WTC Health Program medical information, including the WTC Health Program's decisions regarding certification and authorization for treatment, to the VCF for purposes of facilitating the VCF's evaluation of the individual's VCF claims; and 2) for those VCF claimants who do not receive care within the WTC Health Program, review by the WTC Health Program of VCF claimants' exposure and health information to assist the VCF, for the purposes of making compensation determination, in verifying whether claimants' health conditions are related to their 9/11 exposures.

The VCF only provides compensation for losses due to personal physical injury or death. An individual who elects compensation from the VCF waives his or her rights to pursue litigation to seek damages for the physical injury or death resulting from the September 11, 2001 attacks.

Activity: The WTC Health Program assists DOJ as outlined by a Memorandum of Understanding (MOU) between the VCF and the WTC Health Program. With the specific authorization and consent of an individual VCF claimant, the MOU facilitates: 1) for those VCF claimants participating in both the WTC Health Program and the VCF, transmission of the individual's WTC Health Program medical information, including the WTC Health Program's decisions regarding certification and authorization for treatment, to the VCF for purposes of facilitating the VCF's evaluation of the individual's VCF claims; and 2) for those VCF claimants who do not receive care within the WTC Health Program, review by the WTC Health Program of VCF claimants' exposure and health

information to assist the VCF, for the purposes of making compensation determination, in verifying whether claimants' health conditions are related to their 9/11 exposures.

The VCF only provides compensation for losses due to personal physical injury or death. An individual who elects compensation from the VCF waives his or her rights to pursue litigation to seek damages for the physical injury or death resulting from the September 11, 2001 attacks.

Activity: The WTC Health Program assists DOJ as outlined by a Memorandum of Understanding (MOU) between the VCF and the WTC Health Program. With the specific authorization and consent of an individual VCF claimant, the MOU facilitates: 1) for those VCF claimants participating in both the WTC Health Program and the VCF, transmission of the individual's WTC Health Program medical information, including the WTC Health Program's decisions regarding certification and authorization for treatment, to the VCF for purposes of facilitating the VCF's evaluation of the individual's VCF claims; and 2) for those VCF claimants who do not receive care within the WTC Health Program, review by the WTC Health Program of VCF claimants' exposure and health information to assist the VCF, for the purposes of making compensation determination, in verifying whether claimants' health conditions are related to their 9/11 exposures.

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guidelines, James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) and James Zadroga 9/11 Health and Compensation Reauthorization Act (Reauthorization) requirements and intent, and prevent fraud, waste, and abuse. Measure: 100% compliance with Appropriations Law, HHS guidelines, and Zadroga Act and Reauthorization requirements. Spend Plan Development and Management Scope: Coordinate the planning and development of Spend Plans with appropriate staff. Review prior fiscal year(s) actual results; assess impact of known program and budget issues/decisions; and set priorities based on Program's goals and mission. Measure: Spend Plan developed and submitted to Office and Management and Budget (OMB) for approval 30 days prior to new fiscal year. Budget Execution and Performance Scope: Track, monitor, and report on use of Spend Plan funds; and track, monitor, and report on Program performance (i.e., Clinical Center of Excellence (CCE) and Nationwide Provider Network (NPN) claims submission and contract invoice submissions). Measure: Review, approve, and process CCE and NPN invoices within 5 business days of receipt; and 2.) Review and monitor expenditure trends and produce monthly reports. Analysis and Budget Forecasting Scope: Conduct regular burn rate reviews of expenditures to determine if current budgets are adequate for balance of performance period. Measure: Establish notification triggers at 75% and 90% expenditure levels and assess the details at each level to determine if Program action(s) is required. Quality Assurance Scope: Quality assurance encompasses all of the above activities and enables the Program to achieve and maintain high performance levels. Our goals are to develop Standard Operating Procedures (SOPs) for each step of the invoice reimbursement process and closely monitor other performance measures to ensure Program is performing according to statutory requirements. Measure: No deviation from Program's goals without Core Management Team (CMT) approval. The WTC Health Program financial controls and policy and procedures guidance was developed to assist Program and financial management in accomplishing fiscal year fund control objectives. This

guidance provides fund control procedures and contract clauses for applicable activities for each fiscal year. The WTC Health Program works with its contractors, the CCEs and the NPN, to provide quality care to WTC Health Program members. As the Federal entity, the WTC Health Program's governing role is to ensure that the resources dedicated are properly managed and performance is measured against the Program's goals and mission to improve financial efficiency. Statutory Authority Title I of the Zadroga Act amended the Public Health Service Act to add Title XXXIII and established the WTC Health Program within the HHS. In December 2015, Title XXXIII of the Public Health Act was amended by the Reauthorization. The Reauthorization authorized the WTC Health Program through FY 2090. Fiscal Year Spend Plan/Apportionment Each Fiscal Year's Spend plan requires the approval of the OMB before execution. Responsibility: Centers for Disease Control and Prevention (CDC)/National Institute for Occupational Safety and Health (NIOSH)/WTC Health Program Awards Once the Spend Plan is approved by OMB, the Grants Management Officer (GMO) and Contracting Officer (CO) can begin the process of issuing awards. Responsibility: OFR/WTC Health Program Personnel Personnel projections are based on program priorities and are also subject to the availability of funds. Responsibility: NIOSH/WTC Health Program Governance NIOSH is the responsible Federal entity and must exercise sound stewardship of appropriated funds. Responsibility: NIOSH/WTC Health Program/OFR Performance The WTC Health Program's overall performance is measured by how effectively and efficiently the Zadroga Act's and Reauthorization's requirements were executed. Responsibility: NIOSH/WTC Health Program Reports The Zadroga Act requires the WTC Health Program to submit annual reports to Congress. OMB requires monthly report submissions. Responsibility: NIOSH/WTC Health Program Close out All awards must be closed out at the end of their performance period. Responsibility: NIOSH/WTC Health Program Note:The World Trade Center Health Program has a new Pharmacy Benefit Manager (PBM), Express Scripts, as of June 1, 2022, and some of the PBM

policies have updated with this change. This section is currently being updated. In the meantime, please visit the Program Pharmacy Page, the Coordination of Benefits page, and our FAQ page for current information about WTC Health Program pharmacy benefits. For more detailed questions, please call our help line at 1-888-982-4748. Last Revised – January 9, 2024 This chapter describes the pharmacy benefits that are available through the WTC Health Program under the James Zadroga 9/11 Health and Compensation Act of 2010 (the Act) and its reauthorization. Program regulations relating to pharmacy benefits are established in the following sections of 42 C.F.R. Part 88: The parties involved in providing WTC Health Program pharmacy benefits and their responsibilities are detailed below: The WTC Health Program does not have restrictions on retail pharmacy access. Any pharmacy contracted with the PBM may submit a claim to the Program. This includes most major chains and many community pharmacies. Members can talk to their respective CCE/NPN or contact the PBM to find a pharmacy. Members may also visit https://www.cdc.gov/wtc/pharmacy.html. The PBM offers home delivery and specialty pharmacy services to all members that would like to participate. Home delivery and specialty pharmacy services provide medications at a reduced cost to the Program. They can also help improve health outcomes for members through increased medication compliance. The home delivery and specialty pharmacy provides maintenance medications to the member by mail. Maintenance medications are prescription drugs taken on a regular or on-going basis. Specialty medications are defined as high-cost prescription medications used to treat complex, chronic conditions like cancer and often require special handling (such as refrigeration during shipping) and administration (such as infusions). Home delivery and specialty pharmacy services provide many benefits to members. Prescriptions can be conveniently mailed to the member’s home or location of choice, with no need to travel to or wait at the pharmacy. Home delivery and specialty pharmacy services also reduce the risk of running out of medication or missing a medication dose, while allowing for synchronization of

medication refills. Members also have access to expert pharmacist advice 24/7. The HPS contractor is also responsible for enrolling and maintaining the WTC Health Program prescriber networks (See Chapter 6, Section 6: Provider Networks). The HPS contactor transfers data on prescribers to the PBM. If pharmacy claims are submitted to the PBM by a provider who is not enrolled in the appropriate CCE's prescriber network for the member (See Section 2.3: Prescriber Networks), the claim will be rejected at the point of sale with a message to the pharmacy stating "Prescribing Physician Not in Member Network." If this occurs, the CCE may override the rejection for up to 90 days when appropriate to treat the member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. This does not apply to the NPN/WSC. CCEs may override rejections when: The following exceptions apply to the prescriber not-in-network edit: The PBM system performs a drug utilization review (DUR) on each claim by screening the drug against previously submitted claims. The purpose of DUR is to improve patient safety and prevent waste. DUR rules are utilized by all federal pharmacy programs and managed by the dispensing pharmacy. If the prescription does not meet the Program's rules, then the claim will be rejected at the point of sale. The pharmacy has the ability to override DUR rules based on their professional judgment. DUR rules enforced by the PBM system include: Refill too soon (RTS) point of sale rejections mitigate waste by preventing a member from receiving more medication than is medically necessary. Seventy-five percent of the previous refill must be exhausted based on days' supply prior to the adjudication of another fill (e.g., ≥23 days of a 30-day supply, ≥68 days of a 90 day supply). If the refill is submitted prior to the 75% threshold, the prescription will reject at the point of sale. The pharmacist may call the PBM for an override in the following circumstances: Certain select medications may have limitations on quantities based on Program rules outlined in the formulary. These quantity limits are enforced through point of sale rules and restrictions. The Program has placed limits on the number of

days’ supply allowed for certain medications, with a maximum days’ supply of 90 days for all medications allowed by the Program. Starting October 1st, 2019, the WTC Health Program will only allow up to a 30-day supply of medication for each fill at retail or community pharmacies. For any medication fills over 30 days and up to 90 days, the member must use home delivery service. For information on home delivery, please visit https://wtchomedelivery.optum.com/. Certain select medications on the formulary are subject to Level 2 Prior Authorization (PA) requirements and must be authorized by the member’s CCE/NPN. If the medication requires a Level 2 PA, the prescription will be rejected at the point of sale and require review by the CCE/NPN. The CCE/NPN can authorize the medication based on medical necessity and prior authorization criteria outlined in the formulary. As with all prescriptions, members should contact the pharmacy to make sure a prescription has been processed prior to picking up the medication. Medications that are not on the formulary will be rejected at the point of sale and require a Level 3 Prior Authorization (PA). To obtain approval, the CCE/NPN must submit a Request for a Level 3 PA to the WTC Health Program. Once the request is received, the WTC Health Program will decide whether to approve the Level 3 PA based on specific criteria outlined in the formulary and/or Program policy. The WTC Health Program reviews Requests for a Level 3 PA for the following: The NPN has more Level 2 and Level 3 Prior Authorization requirements, restrictions, and point of sale rules on medications than the CCEs. These restrictions apply to all members assigned to the NPN and the William Street Clinic (WSC); WSC pharmacy benefits are administered by the NPN and have the same rules and restrictions applied as the NPN for pharmacy claims. These additional restrictions are in place to permit the proactive review of medications prior to claim adjudication since the NPN/WSC does not have a closed prescriber network (See Section 2.3: Prescriber Networks). All prescriptions dispensed under the WTC Health Program must be medically necessary to manage, ameliorate, or cure a certified WTC-related health condition or health condition medically associated

with a certified WTC-related health condition. Please see Chapter 4, Section 4.0 for more detail on covered conditions. All treatments, including prescriptions, covered by the Program must have documentation of medical necessity. Documentation should include: In some cases, the member's certification may be a form of documentation of medical necessity. For example, if the member is certified for asthma and is receiving a Food and Drug Administration (FDA) approved asthma inhaler, the certification alone can be used as documentation of medical necessity. If the clinical use of the drug cannot be determined by reviewing the member's certified condition(s), then the CCE/NPN should document the certified condition being treated and the rationale for medical necessity. For example, the CCE/NPN should document when a drug has multiple indications, some of which are not WTC-related health conditions, or if the member is using the drug to treat a side effect or ancillary condition related to the certified condition. (See Chapter 4, Section 2.4: Treatment Benefit Plan). All documentation related to medical necessity for medication should be easily retrievable and available in the event of audits or drug utilization reviews. All authorizations performed in the PBM pharmacy claims processing system must have documentation in the system. The CCE/NPN must also document medical necessity of a medication in the electronic medical record, and/or other files as determined by the CCE/NPN. Decisions made by the CCE/NPN for transactions that require Level 2 Prior Authorization and other point of sale rules and restrictions must be documented in the pharmacy adjudication system provided by the PBM. This documentation must include: The WTC Health Program uses benefit plans to determine what kind of treatment a member is eligible to receive. Benefit plans are groupings developed by the WTC Health Program that define the acceptable scope of treatment for specific categories of covered health conditions. For more on benefit plans, please refer to Chapter 4, Section 2.0: Approved Benefit Plans. The WTC Health Program assigns members to the appropriate Pharmacy Formulary based on the member's certified health conditions, benefit plan, and

membership type (e.g., responder, screening-eligible or certified-eligible survivor, or immediate family of deceased FDNY firefighters). This section summarizes the current Pharmacy Formularies and provides highlights regarding formulary eligibility criteria and content. Medications are selected and reviewed on a quarterly basis by the WTC Health Program. The WTC Health Program selects classes of drugs to be reviewed for the quarter using the process described in Section 4.0: Medical Necessity Documentation Requirements. At the end of each quarter, the WTC Health Program presents the findings and formulary changes for the CCE/NPN at the Pharmacy and Therapeutics (P&T) Forum. Changes in the formulary are implemented 30 days after the P&T Forum and the new formulary is then distributed to the CCE/NPN. If restrictions are added for drugs that did not previously have restrictions, members are given a 3-month grandfathering period to fill the medication to allow time for the CCE/NPN to perform a clinical review. The WTC Health Program Pharmacy and Therapeutics (P&T) Forum meets quarterly to present clinical information researched during the formulary review process and inform the CCEs/NPN of changes to WTC Health Program pharmacy benefits. These changes could include formulary changes, point of sale rules and restriction changes, policy and/or procedure changes. The WTC Health Program makes all decisions related to formulary additions, deletions, or restrictions. The formulary is updated quarterly to coincide with the P&T Forum. Generally, formulary changes will be presented at the P&T Forum prior to being enacted by the Program. The Program will follow the timeline below. In the event of an exception, the CCEs/NPN will be notified accordingly.

The WTC Health Program evaluates all drugs to determine if they are eligible for coverage. Once a drug is approved as eligible for coverage, it is added to the WTC Health Program Pharmacy Formulary. In some limited circumstances, a drug that has not met the criteria for inclusion in the WTC Health Program Pharmacy Formulary may be eligible for coverage by the Program if certain other criteria are met.

Full details can be found in the Policy and Procedures for Coverage of Drugs.

Policy and Procedures for Coverage of Drugs [PDF, 9 pages, 320 KB]

Prescription drugs marketed in the United States must be approved by the U.S. FDA. FDA approval is based on the drug's demonstrated safety and effectiveness according to criteria specified by FDA regulations. When a provider prescribes a drug for a use other than the use specified in the FDA-approved drug label it is considered an "off-label drug use" (OLDU) or an "unapproved use." The WTC Health Program may provide coverage of OLDU if such use is considered medically necessary for the member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. OLDU must be prescribed by a WTC Health Program provider when certain criteria are met. Full details can be found in the Medical Coverage Determination for the Coverage of Off-Label Use of FDA-Approved Drugs.

Medical Coverage Determination for the Coverage of Off-Label Use of FDA-Approved Drugs [PDF, 4 pages, 230 KB] The WTC Health Program requires that generic medications be used when available and clinically appropriate in order to reduce costs. Multisource medications, or brand medications with an FDA-approved generic, are subject to Level 2 Prior Authorization (PA) rules and restrictions at the point of sale. The following criteria must be met and rationale should be documented in the medical record for approval of a multisource brand medication: The WTC Health Program implements step therapy for certain classes of medications. Often drugs used to treat the same condition, with similar efficacy, have significant variations in cost. The Program performs cost-effective analysis and clinical and market research to determine if certain medications should be subject to step therapy rules. Step therapy requires the member to try less expensive drugs that are equally efficacious before starting higher cost drugs. Compounded prescription drugs are a subset of prescription drugs used to

meet a member's unique health needs that cannot be met by an FDA-approved medication. For example, compounded drugs may be prescribed if a member has an allergy and needs a medication to be made without a certain dye, or if a member cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available. Active ingredients in a compound medication that are not on the formulary will require a Level 3 Prior Authorization (PA). An "active ingredient" is any ingredient in a medication that has a pharmacologic effect. Most compound medications also contain "inactive ingredients" that have no pharmacological effect. Compound medications may only be prescribed and approved for use in the Program when: The WTC Health Program covers compound medications based on the member's assigned treatment plan. Only FDA approved ingredients may be used in a compound medication. Bulk powders (i.e., active ingredients for compounding) are not covered by the WTC Health Program, as bulk chemicals do not have FDA approval.1 Pharmacies are reimbursed for compound medications based on their contracted rate of reimbursement with the WTC Health Program PBM for each ingredient billed in the compound claim. The WTC Health Program does not manage contracts with individual pharmacies and does not manage reimbursement rates. If a member has difficulty finding a compounding pharmacy to fill their prescription, they should contact their CCE/NPN or the pharmacy customer service line. The FDA has specified that any drug that is not a prescription drug is an over-the-counter (OTC) or non-prescription drug. An OTC drug is considered safe and effective for use by the general public without a physician's prescription. An OTC health care product is a non-drug, non-durable equipment item that is used to aid in the diagnosis or treatment of a health condition and which can be purchased without a prescription from a physician (e.g., blood glucose self-testing equipment supplies). The WTC Health Program provides limited coverage of OTC drugs and healthcare products to treat certified WTC-related health conditions, or health conditions medically associated with a certified WTC-related health conditions, for medically accepted

indications. OTC drugs must be prescribed by a WTC Health Program provider and dispensed in conjunction with the quantity and dosing limitations specified in the Pharmacy Formulary, along with any requirements for prior authorization.2 Only the following categories of OTC drugs are available for coverage: Only the following categories of OTC healthcare products are available for coverage: Pharmacies submit claims for prescription medications. Claims must be submitted electronically and in compliance with the National Council of Prescription Drug Programs (NCPDP) standards. Eligibility for claim payment is determined by carrier code and matching member record. When a match is found, the claim will process. If a match is not found, the claim will reject for “Member Not Eligible.” All claims submitted by the pharmacy will be subject to point of sale rules and restrictions (See Section 3.0, Point of Sale Adjudication Rules and Restrictions). Pharmacists have authority to fill and dispense prescriptions and submit claims based on their professional judgement and discretion. If a member has issues filling a prescription, they should contact their CCE/NPN provider or the PBM pharmacy customer service line. Pharmacy claims must be submitted within 90 days of the fill date; all claims older than 90 days will be rejected. The pharmacy should contact the PBM pharmacy customer service line if a prescription is rejected due to the submission date being more than 90 days after the fill date. Pharmacies are reimbursed for claims billed to the WTC Health Program based on their contracted rate of reimbursement with the WTC Health Program PBM. The WTC Health Program does not directly manage contracts with individual pharmacies or reimbursement rates. Neither the WTC Health Program nor the CCE/NPN nor the PBM can directly reimburse members for medications that were paid for out of pocket. All medications must be billed to the Program at the point of sale. If a medication rejects at the point of sale, the member should resolve the issue with the CCE/NPN or PBM customer service line to determine if coverage is available prior to paying for the medication out of pocket (See https://www.cdc.gov/wtc/pharmacy.html). The Program cannot reimburse members for

other types of services related to prescription medications that are not billed with the prescription (e.g., delivery charges, additional tax or fees, mailing charges, etc.). Please contact the CCE/NPN prior to paying for these services out of pocket. Each pharmacy has policies and procedures to determine when they will be willing and able to rebill a medication that has already been dispensed. The WTC Health Program, the CCE/NPN, and the PBM are unable to facilitate rebilling of prescriptions at the pharmacy. Furthermore, if a medication is rebilled to the WTC Health Program after dispensing, there is no guarantee of coverage. In accordance with statutory requirements, the WTC Health Program must distinguish between how responder and survivor health care claims are billed. The WTC Health Program is the primary payer for responder health care claims, unless the health condition being treated is the subject of certain workers' compensation claims.3 The WTC Health Program is the secondary payer on claims for survivors. Survivor claims require coordination with the member's primary health insurance. This means that a member's primary insurance (e.g., private group health insurance, Medicare, Medicaid, etc.) must be billed first and only the remaining balance on the claim will be paid by the Program, if appropriate. In order to perform coordination of benefits (COB) for a pharmacy claim for a survivor, the pharmacy must have the both survivor's primary insurance billing information and their WTC Health Program billing information on file. The pharmacy then submits the claim to process automatically with primary and secondary payers. The primary payer will be adjudicated first, and any point of sale rules and restrictions that are applicable to the plan of the member's primary payer will be activated. Each CCE must perform quality assurance prescription claim reviews (PCR) to ensure prescriptions are being administered according to Program policy for certified WTC Health Conditions. There are two requirements for each CCE: Review Requirements:

Source URL: https://www.cdc.gov/wtc/ppm.html