(B) Timing

(i) Currently identified responders

In accordance with subparagraph (A)(i), the WTC Program Administrator shall enroll an individual described in paragraph (1)(A) in the WTC Program not later than July 1, 2011.

(ii) Other responders

In accordance with subparagraph (A)(ii) and consistent with paragraph (4), the WTC Program Administrator shall enroll any other individual who is determined to be a WTC responder in the WTC Program at the time of such determination.

(4) Numerical limitation on eligible WTC responders

(A) In general

The total number of individuals not described in paragraph (1)(A) or (2)(A)(ii) who may be enrolled under paragraph (3)(A)(ii) shall not exceed 25,000 at any time, of which no more than 2,500 may be individuals enrolled based on modified eligibility criteria established under paragraph (1)(C).

(B) Process

In implementing subparagraph (A), the WTC Program Administrator shall—

(i) limit the number of enrollments made under paragraph (3)—

(I) in accordance with such subparagraph; and

(II) to such number, as determined by the Administrator based on the best available information and subject to amounts available under section 300mm-61 of this title, that will ensure sufficient funds will be available to provide treatment and monitoring benefits under this subchapter, with respect to all individuals who are enrolled; and

(ii) provide priority (subject to paragraph (3)(A)(i)) in such enrollments in the order in which individuals apply for enrollment under paragraph (3).

(5) Disqualification of individuals on terrorist watch list

No individual who is on the terrorist watch list maintained by the Department of Homeland Security shall qualify as an eligible WTC responder. Before enrolling any individual as a WTC responder in the WTC Program under paragraph (3), the Administrator, in consultation with the Secretary of Homeland Security, shall determine whether the individual is on such list.

(b) Monitoring benefits

(1) In general

In the case of an enrolled WTC responder (other than one described in subsection (a)(2)(A)(ii)), the WTC Program shall provide for monitoring benefits that include monitoring consistent with protocols approved by the WTC Program Administrator and including clinical examinations and long-term health monitoring and analysis. In the case of an enrolled WTC responder who is an active member of the Fire Department of New York City, the responder shall receive such benefits as part of the individual's periodic company medical exams.

(2) Provision of monitoring benefits

The monitoring benefits under paragraph (1) shall be provided through the Clinical Center of Excellence for the type of individual involved or, in the case of an individual residing outside the New York metropolitan area, under an arrangement under section 300mm-23 of this title.

(July 1, 1944, ch. 373, title XXXIII, §3311, as added Pub. L. 111-347, title I, §101, Jan. 2, 2011, 124 Stat. 3635; amended Pub. L. 114-113, div. O, title III, §302(d), Dec. 18, 2015, 129 Stat. 2999.)

Amendments

 $2015{\rm --Subsec.}$ (a)(4)(B)(i)(II). Pub. L. 114–113 struck out ''through the end of fiscal year 2020'' after ''who are enrolled''.

§ 300mm-22. Treatment of enrolled WTC responders for WTC-related health conditions

(a) WTC-related health condition defined

(1) In general

For purposes of this subchapter, the term "WTC-related health condition" means a condition that—

(A)(i) is an illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, as determined under paragraph (2); or

(ii) is a mental health condition for which such attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition, as determined under paragraph (2); and (B) is included in the applicable list of

(B) is included in the applicable list of WTC-related health conditions or—

(i) with respect to a WTC responder, is provided certification of coverage under subsection (b)(2)(B)(iii); or

(ii) with respect to a screening-eligible WTC survivor or certified-eligible WTC survivor, is provided certification of coverage under subsection (b)(2)(B)(iii), as applied under section 300mm-32(a) of this title.

In the case of a WTC responder described in section 300mm-21(a)(2)(A)(ii) of this title (relating to a surviving immediate family member of a firefighter), such term does not include an illness or health condition described in subparagraph (A)(i).

(2) Determination

The determination under paragraph (1) or subsection (b) of whether the September 11,

2001, terrorist attacks were substantially likely to be a significant factor in aggravating, contributing to, or causing an individual's illness or health condition shall be made based on an assessment of the following:

(A) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the terrorist attacks. Such exposure shall be—

(i) evaluated and characterized through the use of a standardized, population-appropriate questionnaire approved by the Director of the National Institute for Occupational Safety and Health; and

(ii) assessed and documented by a medical professional with experience in treating or diagnosing health conditions included on the list of WTC-related health conditions.

(B) The type of symptoms and temporal sequence of symptoms. Such symptoms shall be—

(i) assessed through the use of a standardized, population-appropriate medical questionnaire approved by the Director of the National Institute for Occupational Safety and Health and a medical examination; and

(ii) diagnosed and documented by a medical professional described in subparagraph (A)(ii).

(3) List of health conditions for WTC responders

The list of health conditions for WTC responders consists of the following:

(A) Aerodigestive disorders

(i) Interstitial lung diseases.

(ii) Chronic respiratory disorder—fumes/ vapors.

(iii) Asthma.

(iv) Reactive airways dysfunction syndrome (RADS).

(v) WTC-exacerbated chronic obstructive pulmonary disease (COPD).

(vi) Chronic cough syndrome.

(vii) Upper airway hyperreactivity.

(viii) Chronic rhinosinusitis.

(ix) Chronic nasopharyngitis.

(x) Chronic laryngitis.

(xi) Gastroesophageal reflux disorder (GERD).

(xii) Sleep apnea exacerbated by or related to a condition described in a previous clause.

(B) Mental health conditions

(i) Posttraumatic stress disorder (PTSD).

(ii) Major depressive disorder.

(iii) Panic disorder.

(iv) Generalized anxiety disorder.

(v) Anxiety disorder (not otherwise specified).

(vi) Depression (not otherwise specified).

(vii) Acute stress disorder.

(viii) Dysthymic disorder.

(ix) Adjustment disorder.

(x) Substance abuse.

(C) Musculoskeletal disorders for certain WTC responders

In the case of a WTC responder described in paragraph (4), a condition described in such paragraph.

(D) Additional conditions

Any cancer (or type of cancer) or other condition added, pursuant to paragraph (5) or (6), to the list under this paragraph.

(4) Musculoskeletal disorders

(A) In general

For purposes of this subchapter, in the case of a WTC responder who received any treatment for a WTC-related musculo-skeletal disorder on or before September 11, 2003, the list of health conditions in paragraph (3) shall include:

(i) Low back pain.

(ii) Carpal tunnel syndrome (CTS).

(iii) Other musculoskeletal disorders.

(B) Definition

The term "WTC-related musculoskeletal disorder" means 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.

(5) Cancer

(A) In general

The WTC Program Administrator shall periodically conduct a review of all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related health conditions. The WTC Program Administrator shall conduct the first review under this subparagraph not later than 180 days after January 2, 2011.

(B) Proposed regulations and rulemaking

Based on the periodic reviews under subparagraph (A), if the WTC Program Administrator determines that cancer or a certain type of cancer should be added to such list of WTC-related health conditions, the WTC Program Administrator shall propose regulations, through rulemaking, to add cancer or the certain type of cancer to such list.

(C) Final regulations

Based on all the available evidence in the rulemaking record, the WTC Program Administrator shall make a final determination of whether cancer or a certain type of cancer should be added to such list of WTCrelated health conditions. If such a determination is made to make such an addition, the WTC Program Administrator shall by regulation add cancer or the certain type of cancer to such list.

(D) Determinations not to add cancer or certain types of cancer

In the case that the WTC Program Administrator determines under subparagraph (B) or (C) that cancer or a certain type of cancer should not be added to such list of WTC-related health conditions, the WTC Program Administrator shall publish an explanation for such determination in the Federal Register. Any such determination to not make such an addition shall not preclude the addition of cancer or the certain type of cancer to such list at a later date.

(6) Addition of health conditions to list for WTC responders

(A) In general

Whenever the WTC Program Administrator determines that a proposed rule should be promulgated to add a health condition to the list of health conditions in paragraph (3), the Administrator may request a recommendation of the Advisory Committee or may publish such a proposed rule in the Federal Register in accordance with subparagraph (D).

(B) Administrator's options after receipt of petition

In the case that the WTC Program Administrator receives a written petition by an interested party to add a health condition to the list of health conditions in paragraph (3), not later than 90 days after the date of receipt of such petition the Administrator shall-

(i) request a recommendation of the Advisory Committee;

(ii) publish a proposed rule in the Federal Register to add such health condition, in accordance with subparagraph (D);

(iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination: or

(iv) publish in the Federal Register a determination that insufficient evidence exists to take action under clauses (i) through (iii).

(C) Action by Advisory Committee

In the case that the Administrator requests a recommendation of the Advisory Committee under this paragraph, with respect to adding a health condition to the list in paragraph (3), the Advisory Committee shall submit to the Administrator such recommendation not later than 90 days after the date of such request or by such date (not to exceed 180 days after such date of request) as specified by the Administrator. Not later than 90 days after the date of receipt of such recommendation, the Administrator shall, in accordance with subparagraph (D), publish in the Federal Register a proposed rule with respect to such recommendation or a determination not to propose such a proposed rule and the basis for such determination.

(D) Publication

The WTC Program Administrator shall, with respect to any proposed rule under this paragraph-

(i) publish such proposed rule in accordance with section 553 of title 5; and

(ii) provide interested parties a period of 30 days after such publication to submit written comments on the proposed rule.

The WTC Program Administrator may extend the period described in clause (ii) upon a finding of good cause. In the case of such an extension, the Administrator shall publish such extension in the Federal Register.

(E) Interested party defined

For purposes of this paragraph, the term "interested party" includes a representative of any organization representing WTC responders, a nationally recognized medical association, a Clinical or Data Center, a State or political subdivision, or any other interested person.

(F) Independent peer reviews

Prior to issuing a final rule to add a health condition to the list in paragraph (3), the WTC Program Administrator shall provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.

(G) Additional advisory committee recommendations

(i) Program policies

(I) Existing policies

Not later than 1 year after December 18, 2015, the WTC Program Administrator shall request the Advisory Committee to review and evaluate the policies and procedures, in effect at the time of the review and evaluation, that are used to determine whether sufficient evidence exists to support adding a health condition to the list in paragraph (3).

(II) Subsequent policies

Prior to establishing any substantive new policy or procedure used to make the determination described in subclause (I) or prior to making any substantive amendment to any policy or procedure described in such subclause, the WTC Program Administrator shall request the Advisory Committee to review and evaluate such substantive policy, procedure, or amendment.

(ii) Identification of individuals conducting independent peer reviews

Not later than 1 year after December 18, 2015, and not less than every 2 years thereafter, the WTC Program Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct the independent peer reviews under subparagraph (F).

(b) Coverage of treatment for WTC-related health conditions

(1) Determination for enrolled WTC responders based on a WTC-related health condition (A) In general

If a physician at a Clinical Center of Excellence that is providing monitoring benefits under section 300mm-21 of this title for an enrolled WTC responder makes a determination that the responder has a WTC-related health condition that is in the list in subsection (a)(3) and that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the medical facts supporting such determination; and

(ii) on and after the date of such transmittal and subject to subparagraph (B), the WTC Program shall provide for payment under subsection (c) for medically necessary treatment for such condition.

(B) Review; certification; appeals

(i) Review

A Federal employee designated by the WTC Program Administrator shall review determinations made under subparagraph (A).

(ii) Certification

The Administrator shall provide a certification of such condition based upon reviews conducted under clause (i). Such a certification shall be provided unless the Administrator determines that the responder's condition is not a WTC-related health condition in the list in subsection (a)(3) or that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is not substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.

(iii) Appeal process

The Administrator shall establish, by rule, a process for the appeal of determinations under clause (ii).

(2) Determination based on medically associated WTC-related health conditions

(A) In general

If a physician at a Clinical Center of Excellence determines pursuant to subsection (a) that the enrolled WTC responder has a health condition described in subsection (a)(1)(A) that is not in the list in subsection (a)(3) but which is medically associated with a WTC-related health condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the facts supporting such determination; and

(ii) the Administrator shall make a determination under subparagraph (B) with respect to such physician's determination.

(B) Procedures for review, certification, and appeal

The WTC Program Administrator shall, by rule, establish procedures for the review and certification of physician determinations under subparagraph (A). Such rule shall provide for—

(i) the timely review of such a determination by a physician panel with appropriate expertise for the condition and recommendations to the WTC Program Administrator; (ii) not later than 60 days after the date of the transmittal under subparagraph (A)(i), a determination by the WTC Program Administrator on whether or not the condition involved is described in subsection (a)(1)(A) and is medically associated with a WTC-related health condition;

(iii) certification in accordance with paragraph (1)(B)(ii) of coverage of such condition if determined to be described in subsection (a)(1)(A) and medically associated with a WTC-related health condition; and

(iv) a process for appeals of determinations relating to such conditions.

(C) Inclusion in list of health conditions

If the WTC Program Administrator provides certification under subparagraph (B)(iii) for coverage of a condition, the Administrator may, pursuant to subsection (a)(6), add the condition to the list in subsection (a)(3).

(D) Conditions already declined for inclusion in list

If the WTC Program Administrator publishes a determination under subsection (a)(6)(B) not to include a condition in the list in subsection (a)(3), the WTC Program Administrator shall not provide certification under subparagraph (B)(ii) for coverage of the condition. In the case of an individual who is certified under subparagraph (B)(ii) with respect to such condition before the date of the publication of such determination the previous sentence shall not apply.

(3) Requirement of medical necessity (A) In general

In providing treatment for a WTC-related health condition, a physician or other provider shall provide treatment that is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) Regulations relating to medical necessity

For the purpose of this subchapter, the WTC Program Administrator shall issue regulations specifying a standard for determining medical necessity with respect to health care services and prescription pharmaceuticals, a process for determining whether treatment furnished and pharmaceuticals prescribed under this subchapter meet such standard (including any prior authorization requirement), and a process for appeal of a determination under subsection (c)(3).

(4) Scope of treatment covered

(A) In general

The scope of treatment covered under this subsection 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.

(B) Pharmaceutical coverage

With respect to ensuring coverage of medically necessary outpatient prescription drugs, such drugs shall be provided, under arrangements made by the WTC Program Administrator, directly through participating Clinical Centers of Excellence or through one or more outside vendors.

(C) Transportation expenses for nationwide network

The WTC Program Administrator may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide network under section 300mm-23 of this title involving travel of more than 250 miles and for which payment is made under this section in the same manner in which individuals may be furnished necessary and reasonable transportation and expenses incident to services involving travel of more than 250 miles under regulations implementing section 7384t(c) of this title.

(5) Provision of treatment pending certification

With respect to an enrolled WTC responder for whom a determination is made by an examining physician under paragraph (1) or (2), but for whom the WTC Program Administrator has not yet determined whether to certify the determination, the WTC Program Administrator may establish by rule a process through which the Administrator may approve the provision of medical treatment under this subsection (and payment under subsection (c)) with respect to such responder and such responder's WTC-related health condition (under such terms and conditions as the Administrator may provide) until the Administrator makes a decision on whether to certify the determination.

(c) Payment for initial health evaluation, monitoring, and treatment of WTC-related health conditions

(1) Medical treatment

(A) Use of FECA payment rates

(i) In general

Subject to clause (ii):

(I) Subject to subparagraphs (B) and (C), the WTC Program Administrator shall reimburse costs for medically necessary treatment under this subchapter 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.

(II) For treatment not covered under subclause (i) or subparagraph (B), the WTC Program Administrator shall establish by regulation a reimbursement rate for such treatment.

(ii) Exception

In no case shall payments for products or services under clause (i) be made at a rate higher than the Office of Worker's Compensation Programs in the Department¹ Labor would pay for such products or services rendered at the time such products or services were provided.

(B) Pharmaceuticals

(i) In general

The WTC Program Administrator shall establish a program for paying for the medically necessary outpatient prescription pharmaceuticals prescribed under this subchapter for WTC-related health conditions through one or more contracts with outside vendors.

(ii) Competitive bidding

Under such program the Administrator shall—

(I) select one or more appropriate vendors through a Federal competitive bid process; and

(II) select the lowest bidder (or bidders) meeting the requirements for providing pharmaceutical benefits for participants in the WTC Program.

(iii) Treatment of FDNY participants

Under such program the Administrator may enter into an agreement with a separate vendor to provide pharmaceutical benefits to enrolled WTC responders for whom the Clinical Center of Excellence is described in section 300mm—4 of this title if such an arrangement is deemed necessary and beneficial to the program by the WTC Program Administrator.

(iv) Pharmaceuticals

Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether existing Federal pharmaceutical purchasing programs can provide pharmaceutical benefits more efficiently and effectively than through the WTC program.

(C) Improving quality and efficiency through modification of payment amounts and methodologies

The WTC Program Administrator may modify the amounts and methodologies for making payments for initial health evaluations, monitoring, or treatment, if, taking into account utilization and quality data furnished by the Clinical Centers of Excellence under section 300mm-4(b)(1)(B)(iii) of this title, the Administrator determines that a bundling, capitation, pay for performance, or other payment methodology would better ensure high quality and efficient delivery of initial health evaluations, monitoring, or treatment to an enrolled WTC responder, screening-eligible WTC survivor, or certified-eligible WTC survivor.

(2) Monitoring and initial health evaluation

The WTC Program Administrator shall reimburse the costs of monitoring and the costs of an initial health evaluation provided under this subchapter at a rate set by the Administrator by regulation.

¹So in original. The word "of" probably should appear.

(3) Determination of medical necessity

(A) Review of medical necessity and protocols

As part of the process for reimbursement or payment under this subsection, the WTC Program Administrator shall provide for the review of claims for reimbursement or payment for the provision of medical treatment to determine if such treatment is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) Withholding of payment for medically unnecessary treatment

The Administrator shall withhold such reimbursement or payment for treatment that the Administrator determines is not medically necessary or is not in accordance with such medical treatment protocols.

(d) Medical treatment protocols

(1) Development

The Data Centers shall develop medical treatment protocols for the treatment of enrolled WTC responders and certified-eligible WTC survivors for health conditions included in the applicable list of WTC-related health conditions.

(2) Approval

The medical treatment protocols developed under paragraph (1) shall be subject to approval by the WTC Program Administrator.

(July 1, 1944, ch. 373, title XXXIII, §3312, as added Pub. L. 111-347, title I, §101, Jan. 2, 2011, 124 Stat. 3639; amended Pub. L. 114-113, div. O, title III, §302(e), Dec. 18, 2015, 129 Stat. 2999.)

References in Text

The Federal Employees Compensation Act, referred to in subsec. (c)(1)(A)(i)(I), is act Sept. 7, 1916, ch. 458, 39 Stat. 742. The act was repealed, and the provisions thereof were reenacted as subchapter I (§8101 et seq.) of chapter 81 of Title 5, Government Organization and Employees, by Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 378.

AMENDMENTS

2015—Subsec. (a)(6)(B). Pub. L. 114–113, 302(e)(1)(A), substituted "90 days" for "60 days" in introductory provisions.

Subsec. (a)(6)(C). Pub. L. 114-113, §302(e)(1)(B), substituted "90 days" for "60 days" in two places.

Subsec. (a)(6)(F), (G). Pub. L. 114–113, 302(e)(2), added subpars. (F) and (G).

§ 300mm-23. National arrangement for benefits for eligible individuals outside New York

(a) In general

In order to ensure reasonable access to benefits under this part for individuals who are enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors and who reside in any State, as defined in section 201(f) of this title, outside the New York metropolitan area, the WTC Program Administrator shall establish a nationwide network of health care providers to provide monitoring and treatment benefits and initial health evaluations near such individuals' areas of residence in such States. Nothing in this subsection shall be construed as preventing such individuals from being provided such monitoring and treatment benefits or initial health evaluation through any Clinical Center of Excellence.

(b) Network requirements

Any health care provider participating in the network under subsection (a) shall—

(1) meet criteria for credentialing established by the Data Centers;

(2) follow the monitoring, initial health evaluation, and treatment protocols developed under section 300 mm-4(a)(2)(A)(ii) of this title;

(3) collect and report data in accordance with section 300mm-3 of this title; and

(4) meet such fraud, quality assurance, and other requirements as the WTC Program Administrator establishes, including sections 1320a-7 through 1320a-7e of this title, as applied by section 300mm(d) of this title.

(c) Training and technical assistance

The WTC Program Administer¹ may provide, including through contract, for the provision of training and technical assistance to health care providers participating in the network under subsection (a).

(d) Provision of services through the VA (1) In general

The WTC Program Administrator may enter to an agreement with the Secretary of Vet-

into an agreement with the Secretary of Veterans Affairs for the Secretary to provide services under this section through facilities of the Department of Veterans Affairs.

(2) National program

Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether the Department of Veterans Affairs can provide monitoring and treatment services to individuals under this section more efficiently and effectively than through the nationwide network to be established under subsection (a).

(July 1, 1944, ch. 373, title XXXIII, §3313, as added Pub. L. 111-347, title I, §101, Jan. 2, 2011, 124 Stat. 3647.)

SUBPART 2-WTC SURVIVORS

§ 300mm–31. Identification and initial health evaluation of screening-eligible and certifiedeligible WTC survivors

(a) Identification of screening-eligible WTC survivors and certified-eligible WTC survivors

(1) Screening-eligible WTC survivors

(A) Definition

In this subchapter, the term "screening-eligible WTC survivor" means, subject to subparagraph (C) and paragraph (3), an individual who is described in any of the following clauses:

(i) Currently identified survivor

An individual, including a WTC responder, who has been identified as eligible

¹So in original. Probably should be "Administrator".