



Report to the Ranking Member,
Committee on Homeland Security and
Governmental Affairs, U.S. Senate

July 2014

WORLD TRADE CENTER HEALTH PROGRAM

Approach Used to
Add Cancers to List of
Covered Conditions
Was Reasonable, but
Could Be Improved

GAO Highlights

Highlights of [GAO-14-606](#), a report to the Ranking Member, Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

The WTCHP provides health benefits to eligible responders and survivors of the September 11, 2001, attacks. In September 2012, the WTCHP added 60 types of cancer to the list of covered conditions. The VCF—which provides financial compensation to eligible individuals—uses the WTCHP list as a basis for eligibility. GAO was asked to review the WTCHP Administrator's approach to add cancers and the effects of the additions on the WTCHP and VCF. This report (1) describes and assesses the approach for adding cancers to the list of covered conditions, (2) describes the effects the addition has had on the WTCHP, and (3) describes the effects the addition has had on the VCF. GAO reviewed relevant laws and documents, interviewed WTCHP officials, and convened a meeting of experts with the assistance of the Institute of Medicine. GAO examined data for services paid by the WTCHP from October 2012 through March 2014, and VCF claims data as of March 31, 2014.

What GAO Recommends

GAO recommends that, to help ensure future decisions are equitable and credible, HHS direct the WTCHP Administrator to communicate clearly the approach used for determining whether to add conditions to its list, and include an independent peer review in the approach, seeking authority to extend time frames if necessary. HHS supports these recommendations, but noted concerns with including a peer review given statutory time frames. GAO acknowledges the time constraints by recommending HHS seek authority to extend the time frames if necessary.

View [GAO-14-606](#). For more information, contact Debra Draper at (202) 512-7114 or draperd@gao.gov.

July 2014

WORLD TRADE CENTER HEALTH PROGRAM

Approach Used to Add Cancers to List of Covered Conditions Was Reasonable, but Could Be Improved

What GAO Found

The Administrator of the World Trade Center Health Program (WTCHP)—a program of the Department of Health and Human Services (HHS)—used a hazard-based, multiple-method approach to determine whether to add cancers to the WTCHP list of covered conditions for which treatment may be provided at no cost to an enrollee. Experts who participated in a meeting held by GAO indicated that the Administrator's approach was reasonable but could be improved.

- According to these experts, a hazard-based approach focuses on identifying whether particular “hazards”—sources of potential harm—are associated with certain health conditions, and does not attempt to quantify the risks of developing those health conditions. The Administrator's approach used four methods to determine whether there was an association between a September 11 exposure and a specific cancer, and thus, whether to add that cancer to the list.
- The experts considered the approach reasonable given the WTCHP certification process for enrollees to obtain coverage for treatment for a condition on the list, the lack of data related to exposure levels and risks, and the use of similar approaches by previous federal compensation programs.
- The experts indicated the approach could have been communicated more clearly. For example, the description of the approach in rulemaking did not clearly articulate how decisions would be made when evidence under one method supported adding a cancer type to the list, and evidence under a different method did not. The Administrator noted that this omission was an oversight. Since the Administrator plans to use the same approach in future cancer-related decision making, the absence of a clear description can lead to questions about the credibility and equity of the program.
- According to the experts, an independent peer review process similar to that used in other federal compensation programs could improve the approach. According to the Administrator, this was not feasible due to time constraints imposed by law. A process through which an independent party assesses the validity of the information upon which decisions are being made and that rationales for decisions are clearly described could help ensure the credibility of the Administrator's approach.

WTCHP spending (claims paid) directly attributable to the addition of cancers to the list of covered conditions accounted for 6.5 percent of its total spending on services from October 2012 (when cancers were added) through March 2014. The addition of cancers to the list led to the need for a third-party administrator to help the program provide uninterrupted cancer-related services to enrollees who had been receiving care outside of the program. WTCHP and other officials reported that the addition of cancers has helped ensure enrollees have access to high-quality cancer care, which may contribute to better health outcomes, but required increased WTCHP staff to accommodate the program's growing scope.

The effects on the Department of Justice's September 11th Victim Compensation Fund (VCF) of adding cancers to the list of covered conditions are not yet known because there have been a small number of compensation decisions. Of the 502 compensation decisions made as of March 31, 2014, only 39 were for claimants with cancer, either alone or in combination with other conditions.

Contents

Letter		1
	Background	8
	Experts Indicated That the WTCHP Administrator's Hazard-Based Approach Was Reasonable, but Could Be Improved	13
	Addition of Cancers to the List of Covered Conditions Accounted for a Small Portion of Spending and Led to the Need for a Third-Party Administrator	24
	The Effects on the VCF of Adding Cancers to the List of Covered Conditions Are Not Yet Known	30
	Conclusions	33
	Recommendations for Executive Action	33
	Agency Comments and Our Evaluation	34
Appendix I	Composition of the World Trade Center Health Program Scientific/Technical Advisory Committee	36
Appendix II	List of Participants in GAO's Expert Meeting Hosted by the Institute of Medicine, October 21, 2013	37
Appendix III	Cancers Added to the WTCHP List of Covered Conditions	38
Appendix IV	Comments from the Department of Health and Human Services	42
Appendix V	GAO Contact and Staff Acknowledgments	45
Tables		
	Table 1: World Trade Center Health Program (WTCHP) Contracts for the Provision of Services	11
	Table 2: World Trade Center Health Program (WTCHP) Claims Paid, from October 2012 through March 2014	25

Table 3: Spending for World Trade Center Health Program (WTCHP) Clinical Center of Excellence (CCE) Subcontracts with HealthSmart to Provide Cancer-Related Services, from October 2012 through March 2014	27
Table 4: Status of September 11th Victim Compensation Fund (VCF) Claimant Submissions and Compensation Decisions as of March 31, 2014	31

Figure

Figure 1: World Trade Center Health Program (WTCHP) Administrator's Stated Approach to Determining Whether to Add Cancers to the Program's List of Covered Conditions, as Published in the September 12, 2012, Final Rule	16
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Abbreviations

CCE	Clinical Center of Excellence
CDC	Centers for Disease Control and Prevention
DOJ	Department of Justice
HHS	Department of Health and Human Services
IOM	Institute of Medicine
NPN	Nationwide Provider Network
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
STAC	Scientific/Technical Advisory Committee
VCF	September 11th Victim Compensation Fund
WTC	World Trade Center
WTCHP	World Trade Center Health Program
Zadroga Act	James Zadroga 9/11 Health and Compensation Act of 2010

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July 23, 2014

The Honorable Tom Coburn, M.D.
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

Dear Dr. Coburn:

The September 11, 2001, attacks caused great loss of life and directly affected the long-term physical and mental health of many exposed to the event. In particular, in the New York City area, the collapse of the World Trade Center (WTC) and the burning of adjacent buildings produced a dense dust and smoke cloud containing toxic compounds. Responders and survivors¹ exposed to these and other hazards experienced a wide range of physical and emotional trauma following the attacks, and many continue to experience problems or have been newly diagnosed.² However, determining the exact relationships between exposure to

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

²See for example, GAO, *September 11: HHS Needs to Develop a Plan That Incorporates Lessons from the Responder Health Programs*, [GAO-08-610](#) (Washington, D.C.: May 30, 2008), p. 9, for details on some of the problems responders and survivors experienced following the attacks. In addition, research findings related to September 11 health effects are listed at <http://www.cdc.gov/wtc/wtcresearch.html> (accessed Mar. 17, 2014).

specific substances from the attacks and particular health conditions has been challenging.³

In light of health problems among responders and survivors following the September 11 attacks, the President signed the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) on January 2, 2011.⁴ The act (1) established the World Trade Center Health Program (WTCHP) to provide, beginning July 1, 2011, medical monitoring and treatment benefits to responders and survivors enrolled in the program,⁵ and (2) reactivated the September 11th Victim Compensation Fund (VCF) to provide expanded compensation to individuals who suffered physical harm as a result of the attacks.⁶ The act appropriated amounts not to exceed about \$1.6 billion to support the WTCHP for the last quarter of fiscal year 2011 and for fiscal years 2012 through 2016,⁷ and about \$2.8 billion for the VCF's period of reactivation (Oct. 3, 2011, through Oct. 3, 2016).⁸ The WTCHP is administered by the Centers for Disease Control and Prevention (CDC), an agency within the Department of Health and Human Services (HHS); specifically, the WTCHP Administrator is the director of CDC's National Institute for Occupational

³For example, challenges to conducting definitive scientific analysis on the relationship between exposure to the attacks and particular health conditions include: (1) lack of exposure measurements for individuals, especially during the early stages of the September 11 attacks, when exposures were most intense, and (2) the length of time between exposure and detection (sometimes years or decades) of some conditions, including certain types of cancer. The latency (time between exposure and detection) of some conditions may mean that those conditions may not be captured in epidemiologic studies of the affected population, even when they could be related to exposure to the attacks.

⁴Pub. L. No. 111-347, 124 Stat. 3623.

⁵Pub. L. No. 111-347, tit. I, 124 Stat. 3624 (adding Title XXXIII to the Public Health Service Act) (codified at 42 U.S.C. §§ 300mm et seq.).

⁶Pub. L. No. 111-347, tit. II, 124 Stat. 3659 (amending various provisions of the Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, 115 Stat. 230 (2001)) (codified at 49 U.S.C. § 40101 note). The VCF previously provided compensation to eligible claimants from December 21, 2001, through December 21, 2003. See Pub. L. No. 107-42, § 405(a)(3), 115 Stat. 238 (codified at 49 U.S.C. § 40101 note).

⁷Pub. L. No. 111-347, 124 Stat. 3657 (adding § 3351 to the Public Health Service Act) (codified at 42 U.S.C. 300mm-61).

⁸Pub. L. No. 111-347, §205, 124 Stat. 3664 (amending Pub. L. No. 107-42 § 406) (codified at 49 U.S.C. § 40101 note). The fund will be open through October 3, 2017 to process and pay claims.

Safety and Health (NIOSH). The Department of Justice (DOJ) administers the VCF.

The Zadroga Act established a WTCHP list of covered conditions for which treatment may be provided at no cost to a WTCHP enrollee if the program determines that exposure to the September 11 attacks was “substantially likely to be a significant factor in aggravating, contributing to, or causing” the enrollee’s condition.⁹ The list included certain aerodigestive disorders,¹⁰ musculoskeletal disorders, and mental health conditions. The WTCHP Administrator is authorized to consider the addition of other conditions to the list and must respond to petitions that request the addition of conditions to the list.¹¹ The Special Master of the VCF decided to rely on the medical judgment of the WTCHP and use its list of covered conditions as the basis for determining eligibility for VCF compensation.¹²

In response to a September 2011 petition from members of Congress to consider the addition of cancer to the list of covered conditions, the

⁹Pub. L. No. 111-347, 124 Stat. 3639, 3652 (adding §§ 3312 and 3322 to the Public Health Service Act) (codified at 42 U.S.C. §§ 300mm-22 and 300mm-32).

¹⁰Aerodigestive disorders include, but are not limited to, asthma, chronic cough syndrome, and gastroesophageal reflux disorder.

¹¹See Pub. L. No. 111-347, 124 Stat. 3642, 3652 (adding Public Health Service Act §§ 3312(a)(6) and 3322(b)(3)) (codified at 42 U.S.C. §§ 300mm-22(a)(6) and 300mm-32(b)(3)). In addition, the Administrator was required to conduct an initial review of available scientific and medical evidence within 180 days of enactment to determine if cancer or types of cancer should be added to the list. For the initial review, the Administrator gathered information from peer-reviewed studies on exposure and cancer resulting from the September 11 attacks, findings and recommendations from various programs that gathered information from WTC responders, and information obtained from the public. In July 2011, the Administrator published a report stating there was insufficient evidence available to propose a rule to add any type of cancer to the list. He noted that he would consider any emerging findings about exposures and cancer in responders and survivors in subsequent periodic reviews. See Department of Health and Human Services (National Institute for Occupational Safety and Health), *First Periodic Review of Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program*, Publication Number 2011-197 (Washington, D.C.: July 2011).

¹²76 Fed. Reg. 54112, 54114 (Aug. 31, 2011) (preamble, I.(b).) (discussion of presumptively covered conditions). The VCF’s use of the WTCHP list of covered conditions became effective October 3, 2011. The VCF does not provide compensation for mental health conditions because it is authorized only to provide compensation related to physical conditions. See Pub. L. No. 111-347, § 202(c)(2), 124 Stat. 3661 (amending 49 U.S.C. § 40101 note).

WTCHP Administrator created an approach for determining whether conditions should be added.¹³ Although the Zadroga Act required the Administrator to respond to petitions to add conditions to the list within a specific time frame, it did not prescribe a particular approach for determining whether conditions should be added.¹⁴ As a result of his review of evidence, in September 2012, the Administrator expanded the list to include 60 types of cancer.¹⁵ Coverage for these cancer types became effective October 12, 2012; treatment received after that date has been covered for enrollees with these types of cancers so long as the WTCHP determines that exposure to the September 11 attacks is “substantially likely” to be a significant factor in the development of their cancers. Furthermore, prospective VCF claimants with a cancer added to the list and associated with exposure to the September 11 attack sites have been eligible, since October 12, 2012, to seek VCF compensation for related financial loss.

In light of the WTCHP Administrator’s decision in September 2012 to add 60 types of cancer to the list, you asked us to review the Administrator’s approach, and the potential effects of the additions on the WTCHP and VCF. In this report, we (1) describe and assess the Administrator’s approach to determining whether to add certain cancers to the list of covered conditions; (2) describe effects that the addition of cancers to the list has had on the WTCHP; and (3) describe effects that the addition of cancers to the list has had on the VCF.

¹³NIOSH published the petition on its website: <http://www.cdc.gov/wtc/received.html> (accessed July 9, 2014).

¹⁴See Pub. L. No. 111-347, 124 Stat. 3642 (adding Public Health Service Act § 3312(a)(6)) (codified at 42 U.S.C. § 300mm-22(a)(6)).

¹⁵World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions (Final Rule), 77 Fed. Reg. 56138, 56158 (Sept. 12, 2012) (codified at 42 C.F.R. § 88.1 (2013)). In subsequent rulemaking, the Administrator expanded the list of covered conditions to include prostate cancer effective October 21, 2013, and amended the definition of “rare cancers” and reversed a policy pertaining to certain rare cancers, resulting in four specific types of cancers becoming eligible for coverage effective February 18, 2014: malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis. The Administrator grouped the types of cancers that were added to the list into 24 broad categories. See 78 Fed. Reg. 57505, 57522 (Sept. 19, 2013) (prostate cancer); 79 Fed. Reg. 9100, 9117 (Feb. 18, 2014) (malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis) (both rules codified at 42 C.F.R. 88.1).

To describe and assess the Administrator's approach, we analyzed the Zadroga Act and 2012 proposed and final rulemaking adding cancers to the list of covered conditions,¹⁶ and reviewed federal standards for internal controls.¹⁷ Among other things, the proposed and final rulemaking described the Administrator's approach and his decision to expand the list to include 60 types of cancer in 2012. We reviewed HHS documents such as correspondence between the Administrator and members of the WTCHP Scientific/Technical Advisory Committee (STAC)—an advisory committee established by the Zadroga Act.¹⁸ To clarify the Administrator's approach, we interviewed HHS officials, including the WTCHP Administrator, and the STAC chairperson. We also reviewed reports from Institute of Medicine (IOM) committees charged with assisting other federal compensation programs similarly assess whether specific exposures were associated with certain health outcomes that may have been experienced by those programs' targeted populations.¹⁹ We reviewed these IOM reports to identify approaches commonly used to assess available evidence, and interviewed IOM officials responsible for directing these committees to clarify these approaches. In addition, we convened a meeting of relevant experts, with the assistance of IOM, to

¹⁶See World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions (Notice of Proposed Rulemaking), 77 Fed Reg. 33574 (June 13, 2012); and 77 Fed Reg. 56138 (Sept. 12, 2012).

¹⁷See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999), and its supplemental guide, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

¹⁸The WTCHP STAC is an advisory committee established by the Administrator to, among other things, review scientific and medical evidence and make recommendations on the addition of eligibility criteria and covered health conditions. Members of the STAC include scientific and medical professionals with expertise in occupational medicine and environmental health (among other specialties), and at least two WTC responder representatives and two WTC survivor representatives. See Pub. L. No. 111-347, 124 Stat. 3627 (adding Public Health Service Act § 3302) (codified at 42 U.S.C. § 300mm-1). (For additional information on the STAC, see appendix I.)

¹⁹IOM is a component of the National Academy of Sciences, a private, nonprofit organization charged by Congress with providing independent, objective advice on matters related to science and technology. Statutes directed agencies administering certain federal compensation programs, including those for veterans of the Vietnam War and Gulf War, to use the National Academy of Sciences to create study committees of experts to assess whether specific exposures are associated with certain health outcomes. IOM is the arm of the National Academy of Sciences that directs such study committees. The committees publish their results in reports provided to the agency administering the federal compensation program, and to the general public.

help us characterize and assess the Administrator's approach, including any potential areas for improvement. As we did not seek to achieve consensus among experts participating in this meeting, statements from these experts do not reflect the opinions of all meeting participants, unless otherwise noted. We worked with staff at IOM to identify experts and a moderator to participate; generally, selecting experts based on their areas of expertise, which included environmental medicine, epidemiology, occupational health, and other areas.²⁰ (See appendix II for a list of experts who participated.) We also conducted follow-up interviews with some of the participating experts to clarify points discussed during the meeting.

To describe effects that the addition of cancers to the list has had on the WTCHP, we analyzed WTCHP enrollment and spending data (based on paid claims) for services for cancer and noncancer conditions for four groups of enrollees: (1) those with coverage for treatment for cancer conditions only, (2) those with coverage for treatment for noncancer conditions only, (3) those with coverage for treatment for both cancer and noncancer conditions, and (4) those being monitored, but who had not received coverage for treatment for any condition.²¹ The WTCHP spending data captured claims for services paid by the program from October 2012 through March 2014. To identify program spending that resulted from the addition of cancers to the list, we analyzed the spending data for each of the four groups of enrollees based on (1) the types of services they received—specifically, monitoring or treatment for cancer and noncancer conditions; and (2) the date of enrollment for individual enrollees (before or after October 12, 2012, the date the addition of cancers to the list became effective). For purposes of this report, monitoring includes initial health and diagnostic evaluations, screening tests, and monitoring exams. We reviewed the Zadroga Act, including funding appropriated by the act. We also reviewed 2012 proposed and final rulemaking that added 60 cancers to the list and included estimates of future costs and benefits resulting from these additions. In addition, we conducted interviews with officials associated with the program, including

²⁰To ensure that experts represented a broad range of views and interests and that we fully understood those interests, we required that experts complete conflict-of-interest forms, which we reviewed before the expert meeting.

²¹WTCHP enrollees who joined the program after October 12, 2012, may have joined as a result of the addition of cancers to the list regardless of whether they received coverage for the treatment of cancer.

members of the WTCHP Responder and Survivor Steering committees.²² We also reviewed previous GAO reports for background on the WTCHP and earlier programs for WTC responders and survivors.²³

To describe effects on the VCF of the addition of cancers to the list, we reviewed data obtained from VCF officials for three claimant groups: (1) claimants with cancer only, (2) claimants with noncancer conditions only, and (3) claimants with both cancer and noncancer conditions. The VCF data captured registrations, submitted claims (including eligibility and compensation forms), eligibility decisions, and VCF compensation decisions and calculations as of March 31, 2014. We reviewed the Zadroga Act, including VCF requirements and funding for the program, and applicable rulemaking, which describes the VCF program and potential effects resulting from the addition of cancers.²⁴ We also interviewed VCF officials and reviewed VCF documents that describe program eligibility, processes for submitting claims, and key deadlines.²⁵

We assessed the reliability of WTCHP and VCF data we received by reviewing related documentation, performing data reliability checks (such as examining the data for missing values), and interviewing WTCHP and VCF officials. After taking these steps, we determined that the data we used were sufficiently reliable for the purposes of our report.

We conducted this performance audit from May 2013 to July 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

²²The steering committees were intended for the purpose of receiving input from affected stakeholders and facilitating the coordination of monitoring and treatment programs for enrolled WTC responders and survivors.

²³See, for example, [GAO-08-610](#) and GAO, *September 11: HHS Needs to Ensure the Availability of Health Screening and Monitoring for All Responders*, [GAO-07-892](#) (Washington, D.C.: July 23, 2007).

²⁴See 76 Fed. Reg. 36027 (June 21, 2011) and 76 Fed. Reg. 54112 (Aug. 31, 2011) (codified at 28 C.F.R. part 104).

²⁵The VCF publishes such documents on its website: <http://www.vcf.gov>. (accessed May 6, 2014).

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The Zadroga Act established the WTCHP to provide medical monitoring and treatment benefits, and reactivated the VCF to provide financial compensation to eligible individuals.

WTCHP

As of March 31, 2014, there were 67,783 WTCHP enrollees, including responders and survivors from the WTC attack site and responders from the Pentagon and Shanksville, Pennsylvania, attack sites.²⁶ Monitoring, for the purposes of this report, includes initial health and diagnostic evaluations, screening tests, and monitoring exams.²⁷ Treatment provided by the WTCHP must be deemed medically necessary, and in accordance with the WTCHP's medical treatment protocols.²⁸ WTCHP services are provided to enrollees at no cost, through contracts with Clinical Centers of Excellence (CCE) in the New York metropolitan area and the Nationwide Provider Network (NPN) for those who reside outside of the New York metropolitan area.²⁹

Under the Zadroga Act, the Administrator may publish a rule to add conditions to the list of covered conditions at his discretion. If the Administrator receives a written petition requesting the addition of a

²⁶Although the name of the program refers specifically to the WTC, responders from all three September 11, 2001, attack sites may be eligible to join the program. The vast majority of enrollees are responders from the WTC site.

²⁷Responders enrolled in the WTCHP are automatically eligible to receive periodic monitoring exams for conditions on the list, and to determine whether a condition should be attributed to the September 11 attacks and, as such, may be the basis for WTCHP treatment benefits. Survivors are eligible to receive an initial health evaluation from the program to determine treatment and monitoring benefits.

²⁸Treatment could include services of physicians and other health-care providers, diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other medically necessary treatment.

²⁹As of May 2014, the contracted CCEs were Icahn School of Medicine at Mount Sinai, New York University School of Medicine, North Shore Long Island Jewish Health System, State University of New York (Stony Brook), Rutgers University, the Fire Department of New York City, and the New York City Health and Hospitals Corporation. The NPN is operated by Logistics Health, Inc., which subcontracts with systems, such as UnitedHealthcare, to provide services to enrollees, according to WTCHP officials.

condition to the list, the law specifies certain time frames in which he must respond to that petition. Specifically, upon receipt of a petition to add a health condition to the list, the Administrator is required to respond within 60 days in one of four specified ways: (1) request a recommendation of the STAC; (2) publish a proposed rule in the Federal Register to add the condition; (3) publish in the Federal Register a determination not to publish such a rule; or (4) publish in the Federal Register a determination that insufficient evidence exists to take any such action.³⁰ If the Administrator chooses to request a recommendation of the STAC, the STAC has up to 180 days to provide it,³¹ and the Administrator has up to 60 days, following the receipt of the STAC's recommendation, to publish a decision on whether to add the condition in the Federal Register. Therefore, when a recommendation from the STAC is requested for a review based on a petition, up to 300 days may elapse from the time the Administrator receives the petition to when he publishes a response in the Federal Register. In response to the September 2011 written petition from members of Congress to add coverage for cancer, the Administrator requested a recommendation from the STAC,³² which, in March 2012, provided its recommendation to add certain types of cancers to the list.³³ The Administrator then conducted his own assessment of available scientific evidence, including an assessment of the STAC's recommendation.

³⁰See Pub. L. No. 111-347, 124 Stat. 3642 (adding § 3312(a)(6) to the Public Health Service Act) (codified at 42 U.S.C. § 300mm-22(a)(6)).

³¹The law requires the STAC to provide its recommendation no later than 60 days after the Administrator's request, or by a date specified by the Administrator, which may not exceed 180 days from the date of the request.

³²The Administrator requested that the STAC provide a scientific basis for any recommendations to add cancer, or a type of cancer, to the list of covered conditions. Specifically, he requested the STAC provide a description of the scientific or technical evidence it relied on, a description of the quality of the data supporting the recommendation, and a description of the methods used to formulate its recommendations. See *"Letter from John Howard, M.D., Administrator, World Trade Center Health Program, to Elizabeth Ward, Ph.D., Chair, World Trade Center Health Program Scientific/Technical Advisory Committee,"* October 5, 2011, accessed March 14, 2013, <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-100511-letter.pdf>.

³³See *"WTCHP STAC letter from Elizabeth Ward, Chair, to John Howard, MD, WTCHP Administrator,"* March 31, 2012, accessed April 8, 2013, <http://www.cdc.gov/niosh/topics/wtc/stacpetition001.html>.

To obtain coverage for treatment for a condition included on the list, a WTCHP enrollee must obtain a determination from a CCE or NPN physician, and a certification from the WTCHP. Specifically, a physician must determine that (1) the condition for which the enrollee seeks coverage is on the list; and (2) exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11 attacks is “substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.”³⁴ The WTCHP then reviews the physician’s determination and certifies that the enrollee satisfactorily meets the exposure assessment and symptom requirements. Once an enrollee’s condition has been certified for coverage, a WTCHP provider can be reimbursed for treatment services provided for that specific health condition.

The Zadroga Act established the WTCHP Fund and made appropriations to that fund for the federal share of expenditures for the last calendar quarter of fiscal year 2011, as well as for each of fiscal years 2012 through 2016, totaling a maximum of about \$1.6 billion.³⁵ As of March 31, 2014, cumulative WTCHP obligations totaled about \$0.8 billion. About one-half of that amount (\$450.9 million) was obligated to pay for claims from the CCEs and the NPN. The remaining amount (\$326.2 million) was obligated for CCE and NPN infrastructure, education and outreach, the STAC, data centers, and other activities. Claims paid from October 2012 (when cancers were added to the list) through March 2014 totaled about \$140.7 million. In addition, the estimated costs of the CCE and NPN contracts for the 5-year period ranged from about \$5.9 million to nearly \$55.0 million. (See table 1.)

³⁴Pub. L. No. 111-347, 124 Stat. 3643 (adding § 3312(b)(1)(A) to the Public Health Service Act) (codified at 42 U.S.C. § 300mm-22(b)(1)(A)).

³⁵The Zadroga Act specified that the federal share of funding for the WTCHP was to be the lesser of either 90 percent of expenditures for a year, or an amount specified for that year. The amount provided for fiscal year 2016 is limited to any unexpended funds remaining available from fiscal years 2011 through 2015. Federal payments are conditioned on New York City agreeing to contribute 10 percent of the program’s costs through fiscal year 2015 and one-ninth of any federal spending in fiscal year 2016.

Table 1: World Trade Center Health Program (WTCHP) Contracts for the Provision of Services

WTCHP contracted entity	Period of performance ^a	Estimated cost ^b (dollars)
Clinical Center of Excellence (CCE)		
Icahn School of Medicine at Mount Sinai	07/01/2011 - 06/30/2016	\$54,965,150
State University of New York (Stony Brook)	07/01/2011 - 06/30/2016	24,267,708
Fire Department of New York City	07/01/2011 - 06/30/2016	39,784,900
New York University School of Medicine	07/01/2011 - 06/30/2016	5,858,523
Rutgers University	07/01/2011 - 06/30/2016	7,751,271
North Shore Long Island Jewish Health System	07/01/2011 - 06/30/2016	8,545,829
New York City Health and Hospitals Corporation	09/29/2011 - 06/30/2016	14,569,904
Nationwide Provider Network (NPN)		
Logistics Health, Inc. ^c	09/30/2010 - 09/29/2015	25,544,423

Source: Centers for Disease Control and Prevention. | GAO-14-606

^aAccording to CDC officials, the CCE contracts were awarded for 1 year with 4 option years. While the end date for the last option year is June 30, 2016 (3 months before program funding expires), CDC officials stated that the contracts may be extended as long as the maximum amount of the awards have not been expended.

^bThe contract costs are estimated because the contracted entities are reimbursed by the WTCHP following service delivery.

^cThe NPN is operated by Logistics Health, Inc., which subcontracts with health systems, such as UnitedHealthcare, to provide services to enrollees, according to WTCHP officials.

VCF

Rules reactivating the VCF under the Zadroga Act became effective October 3, 2011.³⁶ The VCF provides compensation for personal injury or death resulting from traumatic physical injuries, physical health conditions, or diseases considered to have occurred as a result of the September 11 attacks or debris removal.

An individual must register with the VCF within 2 years of diagnosis with a covered condition, but not later than October 3, 2016.³⁷ Individuals with an existing condition have 2 years from the date the condition is added to

³⁶The VCF previously provided compensation to eligible claimants from December 21, 2001, through December 21, 2003. During its 2 years of operation, the VCF distributed over \$7.0 billion in compensation.

³⁷Claimants who, prior to October 3, 2011, had been diagnosed with conditions that were eligible for compensation by the VCF when the program was reactivated, were required to register by October 3, 2013.

the WTCHP list to register with the VCF; all registrations must be submitted by October 3, 2016. As such, individuals who were diagnosed with a cancer added to the list on October 12, 2012, are required to register by October 12, 2014. To file a VCF claim, an individual must submit completed eligibility and compensation claim forms, including information that demonstrates a physical health condition included in the WTCHP list resulted from the September 11 attacks, by October 3, 2016.³⁸ Although there had been over 60,000 individual registrations with the VCF as of March 31, 2014, most claimants had not submitted eligibility or compensation forms as of that date.

The Zadroga Act capped funding for VCF compensation at nearly \$2.8 billion, which covers both claims and administrative costs. Of that amount, \$875 million (31 percent) is available for payments during the VCF's first 5 years after its reactivation (from Oct. 3, 2011, through Oct. 3, 2016). The act required the VCF to set a rate for prorating payments during the first 5 years to ensure that every eligible claimant received a payment during that period. In January 2013, the VCF set a proration amount of 10 percent of total compensation calculations for those first 5 years. In the VCF's sixth year (from Oct. 3, 2016, through Oct. 3, 2017), the program will make payments based on the remaining funds. After all payments are made, the VCF shall be permanently closed.

³⁸A claimant may amend a submitted compensation form if the claimant is diagnosed with a covered health condition after the form was submitted. In addition, claimants may modify submitted claims under other circumstances. For example, if the covered health condition substantially worsened, resulting in damages or losses that were not previously compensated, the claimant may amend the claim. Thus, claimants who submitted claims prior to October 12, 2012, can amend their claims if they were diagnosed with a type of cancer that since has been added to the list.

Experts Indicated That the WTCHP Administrator’s Hazard-Based Approach Was Reasonable, but Could Be Improved

In determining whether to add cancers to the list of covered conditions, the Administrator used a hazard-based, multiple method approach. Experts who participated in our meeting indicated that this approach was reasonable. However, the approach could be improved, as it was not clearly communicated and did not include an independent peer review.

The Administrator Used a Hazard-Based, Multiple-Method Approach to Determine Whether to Add Cancers to the List

The WTCHP Administrator used a hazard-based, multiple-method approach—rather than a risk-based approach—to determine whether to add certain types of cancer to the list. The Zadroga Act does not prescribe a specific methodology for assessing evidence to determine whether to add new conditions to the list. According to experts who participated in our meeting,³⁹ a hazard-based approach focuses on identifying whether particular “hazards”—sources of potential harm—are associated with certain health conditions, and does not attempt to quantify the risks or likelihood of developing those health conditions as would a risk-based approach. Under the Administrator’s hazard-based approach, types of cancer found to be associated with exposures to the September 11 attack sites were added to the list. In contrast, a risk-based approach would have involved determining whether the risk of a specific type of cancer from the September 11 exposures was high or low as a result of quantified levels and durations of exposure, and would have added only those cancers where risk was determined to be high.

The Administrator’s hazard-based approach used four methods to determine whether there was an association between a September 11 exposure and a particular cancer that warranted adding that cancer to the

³⁹As we did not seek to achieve consensus among experts participating in the meeting we convened, statements from these experts do not reflect the opinions of all meeting participants, unless otherwise noted.

list. According to the approach described in rulemaking,⁴⁰ the Administrator may have added a cancer to the list in the following circumstances:

- **Method 1:** Data from published, peer-reviewed epidemiologic studies in the September 11 exposed population supported a causal association between September 11 exposures and the cancer type.
- **Method 2:** Multiple published epidemiologic studies supported a causal association between the cancer and a condition already on the list (such as esophageal cancer and gastroesophageal reflux disease).⁴¹
- **Method 3:** A hazard identified at the September 11 attack sites in peer-reviewed studies was identified by the National Toxicology Program to be (or reasonably anticipated to be) a human carcinogen,⁴² and the International Agency for Research on Cancer

⁴⁰See 77 Fed. Reg. 35580 (June 13, 2012) (preamble, III.D.3.); 77 Fed. Reg. 56142 (Sept. 12, 2012) (preamble, IV.). The approach was also described in a WTCHP policy memorandum. See World Trade Center Health Program, *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions*, May 14, 2014, accessed May 19, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPAAddingCancerConditions14May2014.pdf>.

⁴¹To evaluate whether the epidemiologic studies reviewed under Methods 1 and 2 supported causal associations between particular cancer types and either September 11 exposures or another condition already on the list, the Administrator used criteria established by epidemiologist Austin Bradford Hill (known as the Bradford Hill criteria), commonly used to assess relationships between exposure and health outcomes. See Austin Bradford Hill, "The Environment and Disease: Association or Causation?" *Proceedings of the Royal Society of Medicine*, 58: 295-300 (1965). The Administrator described the use of specific Bradford Hill criteria under certain circumstances in his approach (for example, when only one epidemiologic study was available) in 2012 rulemaking. See 77 Fed. Reg. 35578, 35580 (June 13, 2012) (preamble, III.D.2. and III.D.3.).

⁴²The National Toxicology Program is an interagency program of HHS established to provide information to health regulatory and research agencies, scientific and medical communities, and the public, about potentially toxic substances. For additional information on its classifications of carcinogenicity, see National Toxicology Program, *Listing Criteria*, accessed April 25, 2014, <http://ntp.niehs.nih.gov/?objectid=47B37760-F1F6-975E-7C15022B9C93B5A6>.

determined that there was at least limited evidence that the hazard causes the cancer.⁴³

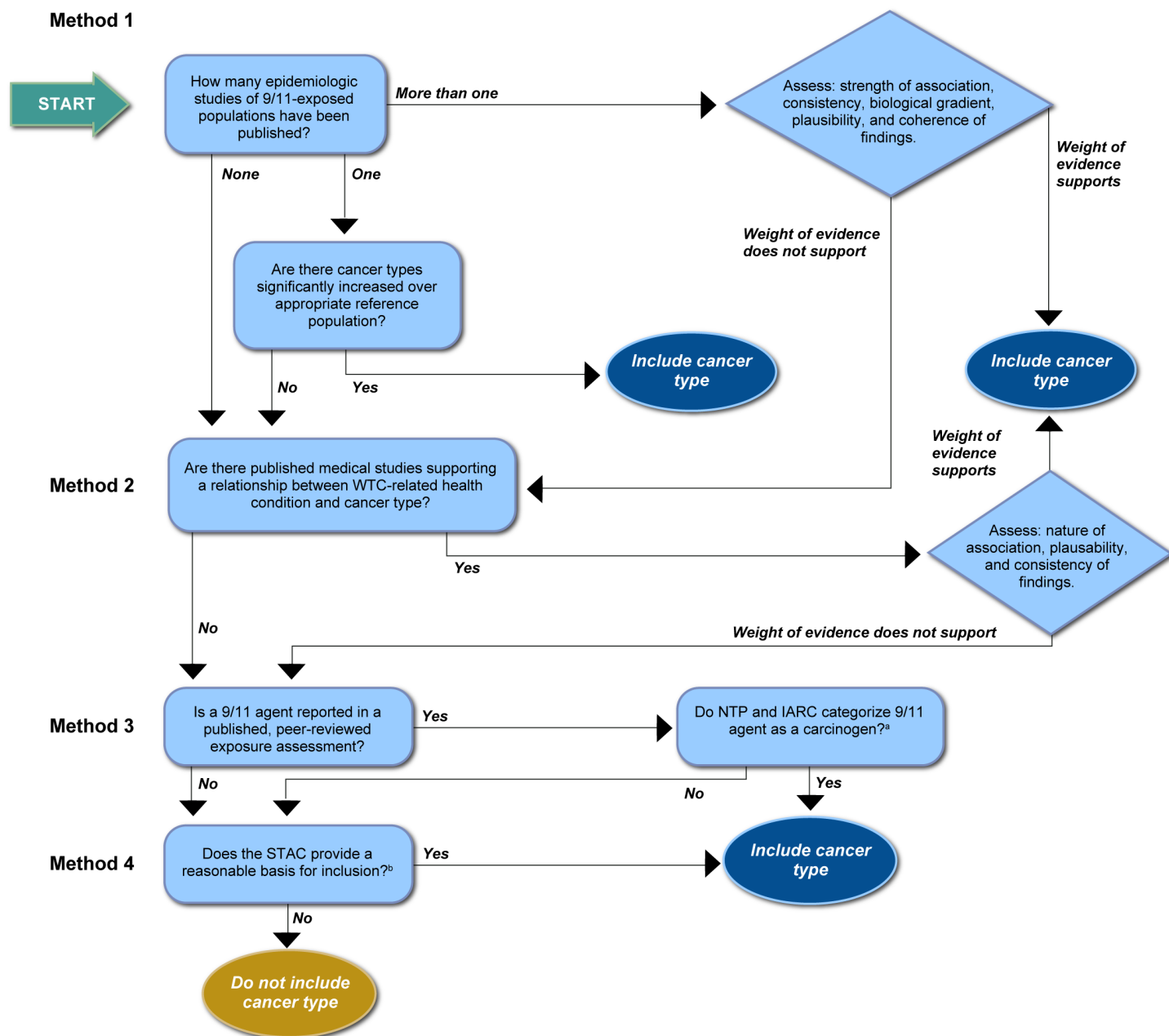
- **Method 4:** The STAC provided a reasonable basis to add a cancer to the list based on its review of scientific and medical evidence.⁴⁴

The Administrator characterized his hazard-based, multiple-method approach as a hierarchy in 2012 rulemaking. To determine whether to add a particular type of cancer, the Administrator said he began his review by assessing evidence under Method 1, which he considered to be the strongest type of evidence. If a cancer did not meet the criteria to be added to the list under Method 1, the Administrator considered evidence under Methods 2, 3, or 4, which he considered to be less rigorous forms of evidence. The Administrator told us that when evidence that supported the addition of a cancer was available under a method higher in the hierarchy, he did not consider evidence under the methods lower in the hierarchy. (See fig. 1 for a flowchart of the approach presented in the 2012 rulemaking adding cancers to the list.)

⁴³The International Agency for Research on Cancer is the World Health Organization's agency that promotes international collaboration in cancer research. For additional information on its classifications, see International Agency for Research on Cancer, *Agents Classified by the IARC Monographs, Volumes 1-109*, accessed April 25, 2014, <http://monographs.iarc.fr/ENG/Classification/index.php>.

⁴⁴To make its recommendation regarding the addition of cancers to the list, the STAC reviewed the same types of sources used by the Administrator—that is, epidemiologic studies, studies on causal associations between a cancer type and a condition on the list, and information from the International Agency for Research on Cancer and the National Toxicology Program. The STAC, however, did not report using specific criteria to assess whether the epidemiologic evidence reviewed supported a causal association between September 11 exposures and a cancer type, but did document its rationale for adding certain types of cancer in a letter to the Administrator.

Figure 1: World Trade Center Health Program (WTCHP) Administrator's Stated Approach to Determining Whether to Add Cancers to the Program's List of Covered Conditions, as Published in the September 12, 2012, Final Rule



Source: Federal Register and GAO. | GAO-14-606

Notes: This figure, with the exception of the figure notes, has been taken in its entirety from the World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions (Final Rule) published on September 12, 2012. See 77 Fed Reg. 56143 (Sept. 12, 2012).

To evaluate whether the epidemiologic studies reviewed under Methods 1 and 2 supported a causal association between the cancer type and either September 11 exposures or another condition on the list, the Administrator used criteria established by epidemiologist Austin Bradford Hill (known as the Bradford Hill criteria), commonly used to assess relationships between exposure and health outcomes. The Administrator described the use of specific Bradford Hill criteria under certain circumstances in his approach (for example, when only one epidemiologic study was available) in World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions (Notice of Proposed Rulemaking). See 77 Fed. Reg. 35578, 35580 (June 13, 2012) (preamble, III.D.2. and III.D.3.).

^aNTP refers to the National Toxicology Program, which is an interagency program of the Department of Health and Human Services established to provide information about potentially toxic substances. IARC refers to the International Agency for Research on Cancer, which is the World Health Organization's agency that promotes international collaboration in cancer research.

^bSTAC refers to the WTCHP Scientific/Technical Advisory Committee, an advisory committee established by the Administrator to, among other things, review scientific and medical evidence and make recommendations on the addition of eligibility criteria and covered health conditions.

Of the 60 types of cancers that the Administrator added to the list, 53 were added using Method 3, 6 using Method 4, and 1 using Method 2. No cancers were added based on Method 1. (See text box, below, for examples of how two cancers were added to the list and appendix III for a list of cancers added to the list by method.)

Examples of the World Trade Center Health Program (WTCHP) Administrator's Application of the Hazard-Based, Multiple-Method Approach:

Example 1: Esophageal Cancer

Method 1: The Administrator considered adding the cancer to the WTCHP list of covered conditions under Method 1; however, no evidence was available under this method to support its addition.

Method 2: The Administrator then assessed scientific information that supported a causal relationship between esophageal cancer and gastroesophageal reflux disease—the latter, a condition already on the WTCHP list—and determined that the information was sufficient to add the cancer.

Methods 3 and 4: According to the Administrator, the consideration of these less rigorous methods was not needed given the evidence available under Method 2.

Decision: Add esophageal cancer based on evidence considered under Method 2.

Example 2: Thyroid Cancer

Method 1: Epidemiologic evidence demonstrated an association between September 11 exposures for New York City firefighters and thyroid cancer. However, the Administrator reported in proposed rulemaking that he would not add the cancer under Method 1 as that association was not significantly higher than for firefighters with the cancer who were not exposed to the September 11 attack site.

Methods 2 and 3: No evidence was available under these methods to support adding the cancer.

Method 4: The Administrator found that the WTCHP Scientific/Technical Advisory Committee (STAC) provided a “reasonable basis” for including thyroid cancer; the STAC reviewed the same evidence the Administrator reviewed under Method 1.

Decision: Add thyroid cancer based on evidence considered under Method 4.

Source: GAO summary of information from the Federal Register and WTCHP officials. | GAO-14-606

In deciding on the approach to use, the Administrator reported trying to strike a balance between the program's need to provide timely health care services to affected September 11 responders and survivors, and the limited availability of scientific information. He reported considering an alternative approach that would have presumed September 11 exposures could have resulted in the development of any and all types of cancer. However, he decided against such an approach because it would not require any scientific evidence as a basis for determinations. Alternatively, the Administrator considered an approach that would have relied only on epidemiologic studies that demonstrated an association between September 11 exposure and the development of a type of cancer. He ultimately decided against such an approach because epidemiological studies linking conditions with September 11 exposure may not yet have been published, due to the long latency period for certain cancers. Waiting for such studies could prevent coverage for some responders and survivors with conditions that may have been related to September 11 exposures, according to the Administrator.

Experts at our meeting indicated that the Administrator's decision to use a hazard-based, multiple-method approach resulted in a high degree of inclusivity, allowing more types of cancers to be added to the list than other approaches might have allowed. According to these experts, this high degree of inclusivity could result in individuals with cancers not related to September 11 exposures seeking coverage from the WTCHP program for these cancers, while a lower degree of inclusivity, which would have resulted from using a risk-based approach, could have meant some individuals with cancers related to September 11 exposures would not have been able to obtain coverage.

Experts Indicated That the Administrator's Approach Was Reasonable

According to experts participating in our meeting, the Administrator's approach was reasonable. Both hazard-based and risk-based approaches can be used for determining associations between exposures and health outcomes, according to these experts. They indicated that the Administrator's use of a hazard-based, multiple-method approach was reasonable given the certification process and data constraints for the WTCHP, and the use of similar approaches by other federal compensation programs. Specifically, they indicated the following:

- *Certification process.* Experts highlighted the fact that an applicant must obtain certification to receive coverage for treatment, and as part of this process provide information comparable to that used in a risk-based approach, adding some of the benefit of that type of approach.⁴⁵ The Administrator explained that the information reviewed during the certification process includes assessing WTCHP enrollees' time period of exposure, duration of exposure, temporal sequence of symptoms, and activities that caused the exposure. In addition, qualitative exposure assessments are performed to determine whether enrollees have met the requirements needed for certification that their condition be covered.
- *Data Constraints.* Experts told us that developing a risk-based approach would have been less feasible than developing a hazard-based approach. Specifically, a risk-based approach would have required data on levels of exposures to specific hazards among

⁴⁵Specifically, the WTCHP certification process calls for physicians to use information about individuals' specific exposures to the September 11 sites, and duration of those exposures, to determine whether those individuals' cancers are substantially likely to be related to the September 11 attacks.

individuals, but such data (for example, epidemiologic studies regarding cancer risk in the exposed population) was lacking. This point was confirmed by the Administrator who told us that using a risk-based approach would have been challenging due to the lack of data on individual exposures following the attacks, especially in the immediate aftermath of the attacks when exposures were at their highest. According to experts, the multiple-method approach was reasonable because of limitations in available data due to the length of cancer latency and the relatively short period of time that had elapsed between the attacks and the Administrator's review.

- *Use of Similar Approaches.* Other federal compensation programs, such as those for Gulf War Veterans, used a similar hazard-based or multiple-method approach to assess the available, often limited, data about relationships between exposures and health outcomes, according to the experts. For example, under the Persian Gulf War Veterans Act, the Secretary of Veterans Affairs was required to use the National Academy of Sciences to determine whether certain health conditions had a relationship with specific war-related exposures;⁴⁶ the Academy performed this task through committees convened by its IOM. The IOM committees used a similar hazard-based approach as the Administrator, and did not consider the magnitude of the risk as would have been done with a risk-based approach.⁴⁷ IOM officials responsible for directing these committees also told us that the Administrator's approach was reasonable given the limitations of the available evidence, due in part to cancer latency.

Administrator's Approach Was Not Communicated Clearly and Did Not Include Independent Peer Review

Although experts participating in our meeting considered the Administrator's approach reasonable, they indicated that the approach could have been communicated more clearly to strengthen the credibility of the process. According to these experts, the approach was not clearly described in 2012 proposed and final rulemaking. Specifically, the Administrator did not clearly communicate the approach when there was negative evidence (information that supported not adding a cancer) under one method and positive evidence (information that supported adding a cancer) under a different method. The approach described in the

⁴⁶Pub. L. No. 105-277, title XVI, 112 Stat. 2681, 2681-742 (1998).

⁴⁷See Institute of Medicine of the National Academies, *Gulf War and Health, Volume 8: Update of Health Effects of Servicing in the Gulf War* (Washington, D.C., 2010).

flowchart and text in 2012 rulemaking (see fig. 1) suggested that if there was positive evidence under a given method (for example, Method 3), the Administrator would add the cancer to the list and cease assessing evidence; he would not consider negative evidence found under methods higher in the hierarchy (Methods 1 or 2), or any evidence under methods lower in the hierarchy (Method 4) in making his decision of whether to add that cancer to the list. The Administrator told us, however, that in the case of prostate cancer, negative evidence under Methods 1 and 4 led to his decision not to add prostate cancer during rulemaking in 2012,⁴⁸ even though there was positive evidence under Method 3.⁴⁹ He agreed that the process for decision making when there was negative evidence under a method higher in the hierarchy and positive evidence under a method lower in the hierarchy was not expressed in the flowchart or text included in 2012 proposed and final rulemaking. He acknowledged that it was an oversight not to have included this information. Further, according to the Administrator, decisions to add a condition to the list could be reconsidered with new evidence;⁵⁰ however, the approach outlined in 2012 rulemaking did not clearly communicate how he would assess such new evidence, for example from future studies, against existing evidence.

Information about decision making should be adequately communicated to external stakeholders, such as Congress and the public, according to *Standards for Internal Control in the Federal Government*.⁵¹ Additionally,

⁴⁸The STAC voted not to recommend adding prostate cancer to the list following its review of evidence in 2012, which we considered to be a form of negative evidence.

⁴⁹Subsequently, in 2013, the Administrator received a petition from the Patrolmen's Benevolent Association—a union representing New York City police officers—requesting the addition of prostate cancers to the list. In response to this petition, the Administrator reviewed available evidence using his four-method approach, including additional evidence under Method 1 and the same existing evidence under Method 3 that he had reviewed before. While the additional evidence under Method 1 was inconclusive, the Administrator ultimately determined that, based on evidence under Method 3, prostate cancer would be added to the list. See 78 Fed. Reg. 57506 (Sept. 19, 2013) (preamble.IV.).

⁵⁰The Administrator noted in the 2012 proposed rule that he would review any future studies with epidemiologic evidence on site-specific cancers, such as thyroid and melanoma cancers, implying that decisions may be reconsidered in the future. Thyroid and melanoma cancers were added to the list in 2012 under Method 4.

⁵¹*Standards for Internal Control* also states that government processes, including administrative decisions, such as those made during rulemaking, should be clearly documented. See [GAO/AIMD-00-21.3.1](#) and [GAO-01-1008G](#).

clear communication is particularly important as the Administrator plans to use the same approach to make future determinations on potential additions of cancer to the list.⁵² In the absence of a clearly communicated description, the approach may not be consistently applied during such future decision making, which could raise questions not only about the approach's credibility, but also equity for program enrollees.

In addition to improvements regarding communication, the Administrator's approach could be improved by the use of an independent peer review process, according to experts who participated in the meeting we convened. This peer review process would include, for example, an evaluation of scientific and technical evidence by independent experts to assess the validity and credibility of the information upon which decisions are being made. Experts participating in our meeting noted that independent peer review has been used to review conclusions made by IOM committees assessing scientific evidence related to exposures and health outcomes for other federal compensation programs. In these instances, peer reviewers independent of the IOM committee provided feedback on matters such as whether the specific evidence assessed by the committee was appropriate, what additional evidence should be assessed, and if aspects of the committee's report could be more clearly described.⁵³ According to IOM officials responsible for directing these committees, independent peer review helps ensure that a committee's assessment of scientific evidence is accurate and as effective in relaying its conclusions as possible. This assurance enhances the credibility of the final product by ensuring that the conclusions are scientifically based and appropriately portrayed, according to IOM officials.⁵⁴

⁵²See World Trade Center Health Program, *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions*, May 14, 2014, accessed May 19, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPPAddingCancerConditions14May2014.pdf>.

⁵³According to IOM officials, independent peer reviewers are selected based on their familiarity with the subject(s) addressed by the committee and conduct their evaluation of the report independent of the committee; however, the reviewers themselves may be stakeholders or those with known opinions on the subject.

⁵⁴The National Academies. "Consensus Reports," *Report Review Committee Guidelines for Review*, accessed February 7, 2014, http://www.nationalacademies.org/xpeditio/groups/nasite/documents/webpage/na_067076.pdf.

While the Administrator agreed that independent peer review was important, he told us that, due to time constraints, he did not use it in his approach for the 2012 decisions.⁵⁵ Specifically, he told us that although he supported the use of independent peer review in all NIOSH programs, he did not consider implementing such a process feasible given the time limitations in place under the Zadroga Act for responding to petitions and receiving a recommendation from the STAC. According to the act, when a recommendation from the STAC is requested for a review based on a petition, up to 300 days may elapse from the time the Administrator receives the petition to when he publishes a response in the Federal Register. The Administrator told us that the time limits imposed by the Zadroga Act for the review of petitions and responses to STAC recommendations, in addition to the time needed for administrative processes, are very restrictive and provide little time for scientific analysis and decision-making processes. However, without an independent peer review process through which an independent party has determined that the evidence assessed was appropriate and that the rationales for decisions made were clearly described, there may be questions around the transparency of the process and whether the decisions made were appropriate.

⁵⁵The Administrator told us that, at HHS's request, officials from the National Institutes of Health (NIH) reviewed the proposed rule, which describes the Administrator's approach and decision to add cancer to the list. While the Administrator told us that he viewed NIH's review as a form of independent peer review, he indicated that he did not know what NIH's review consisted of, because the request for the review was handled by HHS. NIH's input to the Administrator was limited to a memo, in which it commented on the approach's appropriateness as a policy decision. NIH did not comment on whether it assessed the appropriateness of specific evidence, or ways in which the Administrator could more clearly describe his assessment in rulemaking documents, key items that would be included in an independent peer review process.

Addition of Cancers to the List of Covered Conditions Accounted for a Small Portion of Spending and Led to the Need for a Third-Party Administrator

WTCHP spending on services (claims paid) directly attributable to the addition of cancers to the list of covered conditions accounted for 6.5 percent of total spending on services from October 2012 (the month when cancers were added) through March 2014. The addition of cancers also led to the need for a third-party administrator to facilitate uninterrupted care for enrollees with cancer. WTCHP officials and others reported that the addition of cancers has helped ensure access to high-quality cancer care for enrollees, but also required increased staff to accommodate the program's growing scope.

WTCHP Spending on Services Directly Attributable to the Addition of Cancers Totaled 6.5 Percent of Spending on Services from October 2012 through March 2014

WTCHP spending on services provided to enrollees that was directly attributable to the addition of cancers to the list totaled \$9.1 million, 6.5 percent of the \$140.7 million in total spending on services from October 2012 through March 2014. The \$9.1 million in spending included: about \$1.9 million on cancer monitoring for enrollees, regardless of whether they were diagnosed with any of the conditions on the list; and \$7.2 million on cancer treatment for enrollees who had cancer certifications.⁵⁶ Enrollees who received these cancer monitoring and treatment services may have joined the program before or after cancer coverage became effective (Oct. 12, 2012).

In addition to the spending directly attributable to the addition of cancers, an additional \$2.2 million spent on enrollees who joined the program on or after October 12, 2012 (1.5 percent of total spending on services from October 2012 through March 2014) also may have resulted from the addition of cancers. Enrollees who joined the program after October 12, 2012, may have joined as a result of the addition of cancers to the list, even if they only received services for noncancer conditions. The \$2.2 million in spending included about \$1.6 million on noncancer monitoring for these enrollees. It also included about \$0.6 million on noncancer treatment for enrollees who had certifications for noncancer conditions only. (See table 2.)

⁵⁶The WTCHP issued these certifications to enrollees when the program determined that September 11 exposure was substantially likely to be a significant factor in aggravating, contributing to, or causing cancer.

Table 2: World Trade Center Health Program (WTCHP) Claims Paid, from October 2012 through March 2014

	Service type	Enrollment date	Certification ^a	Number of Enrollees ^b	Spending ^c (dollars)	Average per enrollee (dollars)	Percentage of total spending ^d
WTCHP spending resulting from addition of cancers	Monitoring for cancer	Any	None or any	1,880 to 1,949 ^e	\$1,932,217	\$991 to \$1,028 ^f	1.37
	Treatment for cancer	Any	Cancer	581	7,169,097	12,339	5.09
	Total			\$9,101,314	Total	6.47	
WTCHP spending possibly resulting from addition of cancers ^g	Monitoring for noncancer condition	On or after 10/12/12	None or any	1,314 to 2,088 ^e	1,584,635	759 to \$1,206 ^f	1.13
	Treatment for noncancer condition	On or after 10/12/12	Noncancer	455	566,646	1,245	0.40
	Total			\$2,151,281	Total	1.53	
WTCHP spending not resulting from addition of cancers	Monitoring for noncancer condition	Before 10/12/12	None or any	30,202 to 47,844 ^e	33,097,436	692 to \$1,096 ^f	23.52
	Treatment for noncancer condition	Before 10/12/12	Noncancer	20,420	96,371,096	4,719	68.48
	Total			\$129,468,532	Total	92.00	
Overall spending from October 2012 through March 2014					\$140,721,127	Overall total	100.00

Source: GAO analysis of data from the Centers for Disease Control and Prevention. | GAO-14-606

Notes: The data in this table represent WTCHP claims paid from October 2012 (the month when cancers were added to the WTCHP list of covered conditions) through March 2014. Monitoring includes initial health and diagnostic evaluations, screening tests, and monitoring exams.

^aTo obtain coverage for treatment for a condition included on the list, a WTCHP enrollee must obtain a determination from a WTCHP-affiliated physician and a certification from the WTCHP. Specifically, a physician must first determine that (1) the condition for which the enrollee seeks coverage is on the list; and (2) exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11 attacks is "substantially likely to be a significant factor in aggravating, contributing to, or causing the condition." The WTCHP then must review the physician's determination and certify that the enrollee satisfactorily meets the exposure assessment and symptom requirements. In some cases, an enrollee may receive coverage for treatment without having a certification. This may occur when the enrollee is transitioning into the program and requires immediate care for a condition that a physician believes will result in a certification.

^bThe number of enrollees represents individuals that received the specified type of service. While most enrollees had certifications for the treatment services received, some enrollees who required immediate care received treatment without having certifications. In addition, enrollees may receive multiple types of services, so the number of enrollees who received services cannot be added to determine the total number of enrollees in the WTCHP who received services. For example, an enrollee with a certification for cancer only may have received monitoring for cancer, monitoring for noncancer conditions, and treatment for cancer, and as a result, the enrollee is represented in the enrollee counts for all three types of services.

^cWhile most spending for treatment was provided to enrollees who had certifications for such treatment, some spending for treatment was for enrollees who required immediate care, and thus did not have certifications for that treatment.

^dPercentages for spending on each type of service were calculated based on the WTCHP's total spending on services after cancers were added to the list, which totaled about \$140.7 million.

^eEnrollees may have received multiple types of monitoring services, and the data we received did not provide an unduplicated count of enrollees who received any monitoring service. Therefore, this range represents the minimum and maximum number of enrollees who received monitoring services.

^fEnrollees may have received multiple types of monitoring services and the data we received did not provide an unduplicated count of enrollees who received any monitoring service. Thus, these figures represent the possible range of average spending per enrollee based on the minimum and maximum numbers of enrollees who received monitoring services.

^gBecause this group of enrollees joined the WTHCP on or after October 12, 2012, it is possible that they sought services as a result of the addition of cancers to the list of covered conditions.

Addition of Cancers to the List Led to the Need for a Third-Party Administrator

WTCHP officials reported that the addition of cancers to the list led to the need for a third-party administrator to help the program provide uninterrupted cancer-related services to enrollees who had been receiving care outside of the program. Cancer care for any individual (regardless of WTCHP enrollment) requires the provision of services by multiple physicians, such as oncologists, surgeons, infectious disease specialists, and nephrologists, according to a WTCHP Responder Steering Committee member and a CCE official. Initially, to ensure uninterrupted access to services for enrollees already receiving cancer services from physicians outside the CCEs or NPN, the CCEs and NPN credentialed such physicians on a case-by-case basis, which, according to a WTCHP Responder Steering Committee member, was an unwieldy process and risked delaying the certification and treatment of enrollees.⁵⁷ Furthermore, the program needed to establish a separate billing arrangement for each physician, and doing so risked delaying the payment of claims.

To facilitate uninterrupted care for its enrollees with cancer, each of the WTCHP's seven CCEs subcontracted with HealthSmart—a third-party administrator that could provide enrollees with access to cancer services by developing a broad network of providers.⁵⁸ WTCHP spending for these subcontracts totaled \$2.2 million from October 2012 through March 2014,

⁵⁷Credentialing is the process of reviewing a health professional's credentials, training, experience, demonstrated ability, practice history, and medical certification or license, to determine if clinical privileges to practice in a particular setting are to be granted.

⁵⁸According to WTCHP officials, CDC did not establish a single contract between the agency and a third-party administrator because of time constraints. They said that to meet the immediate need of program enrollees with cancer, each CCE needed to establish a separate subcontract.

which fell well below the combined maximum amounts negotiated for each contract.⁵⁹ (See table 3.) According to a WTCHP Responder Steering Committee member and a CCE official, HealthSmart recruits providers to join a network, or makes other case-by-case arrangements with providers, so that WTCHP enrollees have the option of continuing to receive cancer services from physicians outside of the CCEs without interruption. In addition to providing access to providers, HealthSmart also provides enrollees with case management services and access to a 24/7 nurse triage line. Additionally, it processes claims for services provided through its network, and performs network credentialing and contracting as needed. WTCHP officials told us they were not aware of any enrollees who were unable to receive needed cancer-related services through the WTCHP.

Table 3: Spending for World Trade Center Health Program (WTCHP) Clinical Center of Excellence (CCE) Subcontracts with HealthSmart to Provide Cancer-Related Services, from October 2012 through March 2014

CCE	Negotiated maximum annual cost for subcontract (dollars)	Spending (dollars)
Icahn School of Medicine at Mount Sinai	\$1,639,450	\$1,031,757
State University of New York (Stony Brook)	1,857,462	172,100
Fire Department of New York City	1,574,662	373,648
New York University School of Medicine	279,289	48,498
Rutgers University	1,096,945	158,788
North Shore Long Island Jewish Health System	984,498	60,671
New York City Health and Hospitals Corporation	1,328,571	338,309
Total	\$8,760,877	\$2,183,771

Source: GAO summary of information from the Centers for Disease Control and Prevention. | GAO-14-606

Notes: WTCHP benefits are provided at no cost to WTCHP enrollees in the New York metropolitan area through contracts with CCEs. To facilitate uninterrupted care for its enrollees with cancer, each of the CCEs subcontracted with HealthSmart—a third-party administrator that could provide enrollees with access to cancer services by developing a broad network of providers. The dollar amounts shown in the table represent the maximum annual cost for these subcontracts and actual spending for the first year-and-a-half of the WTCHP's coverage of certain types of cancer. According to WTCHP officials, the subcontracts include fixed costs that may be related to both cancer and noncancer services and cannot be attributed specifically to cancer.

⁵⁹Each CCE negotiated a maximum dollar amount for subcontracted services that could be billed by the third-party administrator for the first year of cancer coverage. According to WTCHP officials, the subcontracts include fixed costs that may be related to both cancer and noncancer services and cannot be attributed specifically to cancer.

The Addition of Cancers Has Helped Ensure Access to High-Quality Cancer Care, but Required Increased Staff to Implement Program Changes

Officials we spoke with reported that the addition of cancers to the list has helped ensure that enrollees have access to high-quality cancer care, which may contribute to better health outcomes. In particular, the WTCHP has provided access to high-quality cancer care because providers affiliated with the CCEs have experience treating cancer patients and are well suited for monitoring recurrences and complications, according to officials associated with the WTCHP. In addition, officials noted that the network established by HealthSmart on behalf of the CCEs includes physicians that specialize in cancer care and provide high-quality services.

WTCHP officials and others also reported that the addition of cancers has helped ensure access to high-quality cancer care because the program developed cancer-related policies and procedures using appropriate guidance. The WTCHP implemented a cancer treatment plan,⁶⁰ and prescription drug formulary,⁶¹ allowing providers who participate in the WTCHP the ability to provide medically necessary treatment, including medications, according to the National Comprehensive Cancer Network's Clinical Practice Guidelines in Oncology.⁶² In addition, physicians have provided colon and breast cancer screenings for members who meet certain criteria as recommended by the U.S. Preventive Services Task Force.⁶³ According to officials associated with the WTCHP, access to high-quality care, including cancer-related monitoring that could result in

⁶⁰According to WTCHP officials, a cancer treatment plan is used for claims adjudication, and allows an enrollee with a cancer certification to receive certain prescription drugs and other benefits.

⁶¹A formulary is a list of medications, grouped by therapeutic class, that a health care system's providers are expected to use when prescribing medications.

⁶²The National Comprehensive Cancer Network is a nonprofit alliance of 25 cancer centers that develops resources for stakeholders in the health care delivery system, including the Clinical Practice Guidelines in Oncology, which document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes.

⁶³The U.S. Preventive Services Task Force is an independent panel of nonfederal experts in prevention and evidence-based medicine that makes recommendations to primary care clinicians on clinical preventive services. The task force reviews evidence from randomized control trials and other studies documenting the effectiveness of clinical preventive services. It then issues recommendations for providers and may include guidance on the sex and age groups most likely to benefit from the service, as well as the interval of the service.

early detection of the disease, may contribute to better health outcomes for enrollees who otherwise would not have had access to such services.

Although WTCHP officials and others reported that the addition of cancers has helped ensure access to high-quality care, they reported that these additions also led to the need for dedicating significant amounts of staff time, and for hiring new staff. According to WTCHP officials, a CCE official, and a WTCHP Responder Steering Committee member, after cancers were added to the list, NIOSH and the CCEs needed to dedicate a large amount of staff time to develop and implement policies and procedures that would address the needs of enrollees seeking cancer services. For example, NIOSH had to hire a consultant to help evaluate whether certain procedures were medically necessary for cancer treatment and the CCEs had to increase the amount of staff time dedicated to:

- providing case management services to enrollees;
- educating affiliated physicians regarding WTCHP coverage rules;
- facilitating cancer diagnostic services for enrollees immediately after “red flag” symptoms are identified, particularly for cancer types that need frequent follow-up services (such as colon cancer and thyroid cancer);
- responding to end of life issues affecting enrollees and their families; and
- reviewing the most up-to-date guidelines on screening for certain cancer types (such as colon cancer and breast cancer), and working with NIOSH to develop WTCHP screening protocols.

A WTCHP Responder Steering Committee member told us the program may encounter future challenges as enrollment increases as a result of the addition of cancers, including increased wait times and an increased rate of spending. The member said that program enrollment is likely to increase significantly, which could result in extended wait times to obtain appointments for enrollees seeking non-urgent services. The member added that there had been no observable effects yet, but that wait times may soon increase as the program anticipates a large influx of enrollees as responders and survivors seek certifications from the WTCHP in order

to document their VCF eligibility.⁶⁴ The member also expressed concern about the finite funding for the WTCHP, and said that the cost of treating cancer is expected to be higher than the cost of treating other serious conditions such as certain lung diseases. CDC forecast that the annual cost of adding cancers to the list could range from about \$12.5 million to \$33.3 million; however, this estimate was made before verifiable data on the cancer status of WTCHP enrollees were available.⁶⁵ As of January 2014, CDC had yet to revise the estimate to include fiscal year 2013 spending and enrollment data.

The Effects on the VCF of Adding Cancers to the List of Covered Conditions Are Not Yet Known

The effects on the VCF of adding cancers to the WTCHP list of covered conditions are not yet known because there have been only a small number of compensation decisions. As of March 31, 2014, there were 502 VCF compensation decisions, totaling \$194.6 million, while 5,587 claimants had been found eligible to receive compensation.⁶⁶ The number of compensation decisions is limited in part because many of the forms submitted by claimants did not contain sufficient information. Specifically, as of March 31, 2014, only 1,237 claimants (22.1 percent of the 5,587 eligible claimants) had submitted both eligibility and compensation forms that VCF determined to be actionable for compensation decisions.

Further adding to the challenge of determining the effects on the VCF of adding cancers to the list, few of the compensation decisions to date have been for claimants with cancer, either alone or in combination with other conditions. Specifically, of the 502 compensation decisions, only 39 were

⁶⁴In addition, a WTCHP Responder Steering Committee member noted that a large influx of enrollees due to the addition of cancers could result in the program reaching WTCHP enrollment limits established by the Zadroga Act (85,000 responders and 30,000 survivors), but it is too early to determine the likelihood of this occurring. Reaching enrollment limits could exacerbate any existing delays in wait times for WTCHP enrollees and it could leave responders and survivors who are not enrolled in the program without access to needed services.

⁶⁵CDC included the estimated range in September 2012 final rulemaking and identified important limitations. CDC did not have data on the cancer status of responders and survivors who had not yet enrolled in the WTCHP. A WTCHP Responder Steering Committee member noted that information using actual WTCHP data to estimate the range would be needed for CDC to produce a useful forecast.

⁶⁶The \$194.6 million in VCF compensation calculations represents about 22.2 percent of the \$875 million in VCF funding available for the first 5 years after the program's reactivation.

for claimants with cancer; compensation calculations for these individuals totaled \$15.6 million (8.0 percent of the \$194.6 million calculated for all compensation decisions).⁶⁷ The remaining 463 compensation decisions were for claimants who had a noncancer condition only, and totaled \$179.0 million (92.0 percent of the total \$194.6 million). (See table 4.)

Table 4: Status of September 11th Victim Compensation Fund (VCF) Claimant Submissions and Compensation Decisions as of March 31, 2014

	Claimants who submitted both eligibility and compensation forms ^b			Compensation decisions ^c	Compensation calculations ^c (dollars)	Average calculated compensation per claimant ^c (dollars)
	Eligible claimants ^a	Incomplete	Actionable for compensation decision			
Claimants with cancer only	161	84	31	39	\$15,564,797	\$399,097
Claimants with both cancer and noncancer conditions	461	242	138			
Claimants with noncancer conditions only	4,965	2,017	1,068	463	179,043,919	386,704
Total	5,587	2,343	1,237	502	\$194,608,716	\$387,667

Source: GAO analysis of data from the Department of Justice (DOJ). | GAO-14-606

Notes: The VCF is a federally funded program, administered by DOJ, that provides compensation to individuals who suffered physical harm, or relatives of individuals who were killed, as a result of the September 11 attacks.

^aTo be considered eligible for compensation, an individual must register with the VCF and submit a completed eligibility form that includes information demonstrating that his or her physical health condition resulted from the September 11 attacks. The numbers of claimants in this column represent claimants for whom VCF had approved eligibility as of March 31, 2014.

^bTo be considered for compensation from the VCF, claimants must submit eligibility forms that show their conditions were related to or affected by the September 11 attacks, and compensation forms that document expenses related to their condition(s). Claimants' eligibility and compensation forms are considered incomplete, and require follow up, if they are missing information. VCF officials consider forms to be actionable for compensation decisions when forms contain sufficient information to make a decision about the claimant's eligibility, and to calculate compensation. For example, the eligibility forms must demonstrate that the claimant has a physical health condition covered by the

⁶⁷Due to the limited number of decisions made, we combined data on compensation decisions for claimants with both cancer and noncancer conditions, and claimants with cancer only, to protect claimants' privacy. As of March 31, 2014, VCF had made more compensation decisions for claimants with both cancer and noncancer conditions than decisions for claimants with cancer only. Similarly, the total amount of compensation calculations was higher for claimants with both cancer and noncancer conditions than for claimants with cancer only.

VCF that resulted from exposure to the September 11 attacks, and the compensation forms must include documentation (such as a W-2 form) to substantiate lost income.

^cDue to the limited number of decisions made, we combined data on compensation decisions for claimants with both cancer and noncancer conditions, and claimants with cancer only, to protect claimants' privacy. As of March 31, 2014, VCF had made more compensation decisions for claimants with both cancer and noncancer conditions than decisions for claimants with cancer only. Similarly, the total amount of compensation calculations was higher for claimants with both cancer and noncancer conditions than for claimants with cancer only.

VCF officials indicated that the amount set for prorating initial VCF payments accounted for the cancers that have been added to the list. The Zadroga Act required VCF to set a proration amount to ensure that every eligible claimant received a payment during the first 5 years of the program's reactivation. VCF officials told us that in setting this proration amount at 10 percent, the program took into account all September 11-related physical injuries covered by the VCF, including the 60 cancers added to the list.⁶⁸ As of March 31, 2014, VCF had issued initial prorated payments to 310 of the 502 claimants who received compensation decisions from the VCF, totaling \$13.0 million.⁶⁹ Final payments will be sent to claimants in Year 6 of the program based on remaining funds.⁷⁰

Officials stated that no significant administrative changes to the VCF resulted specifically from the addition of cancers to the list. Although the VCF added 44 new staff members in fiscal year 2013, VCF officials reported that these staff members were hired as a result of the overall increase in eligibility and compensation forms, and related documentation submitted by claimants. As of March 31, 2014, the number of claimants who had submitted eligibility and compensation forms for which cancer was the only condition was low (3.2 percent), and had not required the need for additional staff. They said the remaining claims that included cancer were from claimants who also had noncancer conditions that likely would have led to a claim regardless of the addition of cancer coverage.

⁶⁸Because prostate cancer was added to the list on October 21, 2013, this cancer was not included in the proration analysis; however, the VCF determined that the addition of prostate cancer likely would not have a material effect on the proration percentage.

⁶⁹Specifically, VCF issued prorated payments to 21 of the 39 claimants with cancer (for a total of \$871,442, or \$41,497 per claimant) and 289 of the 463 claimants with only noncancer conditions (for a total of \$12,154,569, or \$42,057 per claimant).

⁷⁰In light of the uncertainty of the number of potential claimants, the VCF must prorate the initial payments to ensure that all eligible claimants receive an equal percentage of their calculated compensation as an initial payment within the first 5 years of the program's reactivation.

Conclusions

For responders and survivors who suffered serious health problems as a result of September 11 exposures, the WTCHP and VCF may be important sources of needed health-care services or financial assistance, respectively. Among other factors, eligibility for these programs is contingent on an individual having a covered health condition for which exposure to the September 11 attacks was “substantially likely to be a significant factor in aggravating, contributing to, or causing.” Consequently, it is important to ensure that additions to the list of covered conditions are made in a transparent and credible manner. Although experts participating in the meeting we convened indicated that the WTCHP Administrator’s approach to determining whether to add cancers to the list was reasonable, they also indicated that the approach was not communicated clearly and lacked an independent peer review. Standards for internal control also state that administrative decisions should be clearly communicated. The lack of a clearly communicated approach could result in difficulty replicating the approach during future decision making, which may affect the equity and credibility of the overall process. In addition, the WTCHP missed an important opportunity to validate its approach by not using an independent peer review process to, among other things, assess the validity and credibility of the information upon which decisions were being made, as has been used by other federal compensation programs making similar coverage decisions. The time constraints imposed by the Zadroga Act may preclude the inclusion of such a process; however, the addition of an independent peer review process may help ensure the credibility of the Administrator’s approach, which is especially important to the extent that he plans to use the same or a similar approach for future coverage decisions.

Recommendations for Executive Action

To help ensure that future decisions related to adding conditions to the WTCHP list of covered conditions are equitable and credible, we recommend that the Secretary of HHS direct the WTCHP Administrator to take the following actions:

- communicate clearly, through rulemaking or other means, the approach for decision making related to the addition of covered conditions to the list, including a clear delineation of the relationship between methods when conflicting evidence is available.
- include an independent peer review in the approach for adding to the list of covered conditions, seeking authority to extend time frames if necessary.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS and DOJ for their review, and HHS provided written comments (see app. IV). HHS supports our recommendation to clearly communicate the WTCHP's approach for decision making related to the addition of covered conditions to the list. In its written comments, HHS indicated that, since the publication of rulemaking on the decision to add cancers, the WTCHP published a policy document on its website that further clarified the approach. However, neither the policy document nor the 2012 proposed and final rulemaking fully describe the approach used by the Administrator. Specifically, these documents indicate that if any of the methods provide evidence to support adding a cancer to the list, the cancer will be added. As noted in the report, the Administrator told us that, despite having evidence under Method 3 supporting the addition of prostate cancer to the list, he decided not to add this cancer during 2012 rulemaking because of negative evidence under Methods 1 and 4. Thus, we continue to believe that a complete description of the process is needed to ensure that the approach is consistently applied during future decision making.

In regard to our recommendation on the inclusion of an independent peer review process, HHS indicated that it supports the intent of the recommendation, but noted concerns about the implementation of such a process given statutory time restrictions. Specifically, HHS explained that if the WTCHP Administrator receives a petition to add a health condition to the list, the Administrator must take one of four actions within 60 days of receipt of the petition. Our report provides a detailed description of the time frames imposed by the Zadroga Act when responding to a petition requesting the addition of a condition to the list. The report also acknowledges that these statutory time frames may preclude the inclusion of a peer review process in the approach. However, we continue to believe that the inclusion of an independent peer review process is important to ensure that future decisions related to the addition of conditions to the list are equitable and credible, which is why our recommendation accounts for the possibility that HHS may need to seek a legislative change—namely, to extend these time frames—to include a peer review process in the approach.

HHS and DOJ both provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and the Attorney General of the Department of Justice, and other interested parties. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

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

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Debra A. Draper', with a stylized flourish at the end.

Debra A. Draper
Director, Health Care

Appendix I: Composition of the World Trade Center Health Program Scientific/Technical Advisory Committee

The World Trade Center Health Program (WTCHP) Scientific/Technical Advisory Committee (STAC) is an advisory committee established pursuant to the law¹ to, among other things, review scientific and medical evidence and make recommendations to the program Administrator on eligibility criteria, and the addition of covered health conditions. The law required the Administrator to appoint the members of the STAC and include at least:

- four occupational physicians, at least two of whom have experience treating World Trade Center (WTC) rescue and recovery workers;
- one physician with expertise in pulmonary medicine;
- two environmental medicine or environmental health specialists;
- one industrial hygienist;
- one toxicologist;
- one epidemiologist;
- one mental health professional;
- two representatives of WTC responders; and
- two representatives of certified-eligible WTC survivors.

The WTCHP Administrator first solicited nominations to serve on the STAC in June 2011 through an announcement in the Federal Register.² According to the Administrator, since this primarily resulted in responses from individuals in the New York City region, WTCHP and other officials from the Centers for Disease Control and Prevention also contacted additional individuals outside of the New York City region to expand the geographic diversity of the STAC membership. The Administrator also told us that he added a third representative of WTC responders to ensure that the different types of responder groups were represented on the committee. The Administrator also added a third representative for the survivors to ensure equal representation between the responder and survivor groups.

¹Pub. L. No. 111-347, 124 Stat. 3627 (adding Public Health Service Act § 3302) (codified at 42 U.S.C. 300mm-1). This provision of law provides that the STAC shall be established subject to the Federal Advisory Committee Act, which contains broad requirements for balance, independence, and transparency. See 5 U.S.C. App. 2.

²76 Fed. Reg. 36926 (June 23, 2011).

Appendix II: List of Participants in GAO's Expert Meeting Hosted by the Institute of Medicine, October 21, 2013

Name	Title and Affiliation
A. John Bailer, PhD	University Distinguished Professor and Chair, Department of Statistics Miami University; Oxford, OH
David H. Garabrant, MD, MPH	Professor Emeritus, Environmental Health Sciences; Emeritus Professor of Occupational Medicine and Epidemiology The University of Michigan School of Public Health; Ann Arbor, MI
Jack R. Harkema, DVM, PhD, DACVP	University Distinguished Professor, College of Veterinary Medicine Michigan State University; East Lansing, MI
Rogene Henderson, PhD, DABT <i>Moderator</i>	Senior Scientist Emeritus Lovelace Respiratory Research Institute; Albuquerque, NM
Petros Koutrakis, PhD	Professor of Environmental Sciences; Director of the Environmental Chemistry Lab, Exposure, Epidemiology & Risk Program Harvard School of Public Health; Boston, MA
Daniel Kreswki, PhD, MHA	NSERC Chair in Risk Science; Professor and Director, McLaughlin Centre for Population Health and Risk Assessment University of Ottawa; Ottawa, Ontario, Canada
Dorothy E. Patton, PhD, JD	(Retired) Former Director, Office of Science Policy U.S. Environmental Protection Agency; Washington, DC
Charles Poole, ScD, MPH	Associate Professor, Department of Epidemiology Gillings School of Global Public Health, University of North Carolina; Chapel Hill, NC
Alvaro Puga, PhD	Professor of Molecular Biology and Environmental Health; Associate Director, Superfund Basic Research Program University of Cincinnati Medical Center; Cincinnati, OH
Kenneth S. Ramos, MD, PhD, PharmB	Distinguished University Professor University of Louisville Health Sciences Center; Louisville, KY
Carrie A. Redlich, MD, MPH	Professor of Medicine, Pulmonary Section & Occupational and Environmental Medicine; Program Director, Yale Occupational and Environmental Medicine Program Yale University School of Medicine; New Haven, CT
Steven D. Stellman, PhD, MPH	Professor of Clinical Epidemiology Mailman School of Public Health, Columbia University; New York, NY

Source: GAO. | GAO-14-606

Appendix III: Cancers Added to the WTCHP List of Covered Conditions

In determining whether to add cancer to the WTCHP list of covered conditions, in September 2012, the WTCHP Administrator developed a four-method approach. Following that approach, the Administrator may have added a cancer to the list in the following circumstances:

- **Method 1:** epidemiologic studies in the September 11-exposed population supported a causal association between September 11 exposures and the cancer type;
- **Method 2:** there were established causal associations between the cancer and a condition already on the list;
- **Method 3:** a hazard identified at the September 11 attack sites was identified by the National Toxicology Program to be (or reasonably anticipated to be) a human carcinogen, and the International Agency for Research on Cancer determined that there is at least limited evidence that the hazard causes the cancer; and
- **Method 4:** The STAC provided a reasonable basis to add a cancer to the list based on its review of scientific and medical evidence.

Of the 60 types of cancers that the WTCHP Administrator added to the list in September 2012,¹ 53 were added using Method 3, 6 using Method 4, and 1 using Method 2. No cancers were added based on Method 1.

Method 1:

No cancer types added under method

¹Coverage for the treatment and monitoring of these 60 cancers added to the list went into effect on October 12, 2012. See World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions (Final Rule), 77 Fed. Reg. 56158 (Sept. 12, 2012) (codified at 42 C.F.R. § 88.1 (2013)). In subsequent rulemaking the Administrator expanded the list of covered conditions to include prostate cancer effective October 21, 2013, and amended the definition of “rare cancers” and reversed a policy pertaining to certain rare cancers, resulting in four specific types of cancers becoming eligible for coverage effective February 18, 2014: malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis. The Administrator grouped the types of cancers that were added to the list into 24 broad categories. See 78 Fed. Reg. 57505, 57522 (Sept. 19, 2013) (prostate cancer); 79 Fed. Reg. 9100, 9117 (Feb. 18, 2014) (malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis) (both rules codified at 42 C.F.R. 88.1).

Method 2:

1. Malignant neoplasm of the esophagus

Method 3:

1. Malignant neoplasm of lip
2. Malignant neoplasm of base of tongue
3. Malignant neoplasms of other and unspecified parts of tongue
4. Malignant neoplasm of parotid gland
5. Malignant neoplasm of other and unspecified major salivary glands
6. Malignant neoplasm of floor of mouth
7. Malignant neoplasm of gum
8. Malignant neoplasm of palate
9. Malignant neoplasm of other and unspecified parts of mouth
10. Malignant neoplasm of tonsil
11. Malignant neoplasm of oropharynx
12. Malignant neoplasm of nasopharynx
13. Malignant neoplasm of piriform sinus
14. Malignant neoplasm of hypopharynx
15. Malignant neoplasms of other and ill-defined conditions in the lip, oral cavity, and pharynx
16. Malignant neoplasm of nasal cavity
17. Malignant neoplasm of accessory sinuses
18. Malignant neoplasm of larynx
19. Malignant neoplasm of the stomach
20. Malignant neoplasm of colon
21. Malignant neoplasm of rectosigmoid junction
22. Malignant neoplasm of rectum
23. Malignant neoplasm of other and ill-defined digestive organs
24. Malignant neoplasm of liver and intrahepatic bile duct
25. Malignant neoplasm of retroperitoneum and peritoneum

26. Malignant neoplasm of trachea
27. Malignant neoplasm of the bronchus and lung
28. Malignant neoplasm of heart, mediastinum and pleura
29. Malignant neoplasm of other ill-defined sites in the respiratory system and intrathoracic organs
30. Mesothelioma
31. Malignant neoplasm of peripheral nerves and autonomic nervous system
32. Malignant neoplasm of other connective and soft tissue
33. Other malignant neoplasms of skin
34. Malignant neoplasm of scrotum
35. Malignant neoplasm of ovary
36. Malignant neoplasm of bladder
37. Malignant neoplasm of the kidney
38. Malignant neoplasm of the renal pelvis
39. Malignant neoplasm of ureter
40. Malignant neoplasm of other and unspecified urinary organs
41. Hodgkin's disease
42. Follicular [nodular] non-Hodgkin lymphoma
43. Diffuse non-Hodgkin lymphoma
44. Peripheral and cutaneous T-cell lymphomas
45. Other and unspecified types of non-Hodgkin lymphoma
46. Malignant immunoproliferative diseases
47. Multiple myeloma and malignant plasma cell neoplasms
48. Lymphoid leukemia
49. Myeloid leukemia
50. Monocytic leukemia
51. Other leukemias of specified cell type
52. Leukemia of unspecified cell type
53. Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue

Method 4:

1. Malignant melanoma of skin
2. Malignant neoplasm of the breast²
3. Malignant neoplasm of eye and orbit
4. Malignant neoplasm of thyroid gland
5. Childhood Cancers
6. Rare Cancers³

²The basis for adding malignant neoplasm of the breast was changed to Method 3 in April 2013 (See 78 Fed Reg. 22794, 22795 (Apr. 17, 2013)).

³The Administrator amended the definition of “rare cancers” and reversed a policy pertaining to certain rare cancers, resulting in four specific types of cancers becoming eligible for coverage effective February 18, 2014: malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis. See 79 Fed. Reg. 9100, 9117 (Feb. 18, 2014) (malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis) (codified at 42 C.F.R. 88.1).

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUL 9, 2014

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

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "World Trade Center Health Program: Approach Used to Add Cancers to List of Covered Conditions Was Reasonable, but Could Be Improved" (GAO-14-606).

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

Sincerely,

A handwritten signature in black ink, reading "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: WORLD TRADE CENTER HEALTH PROGRAM: APPROACH USED TO ADD CANCERS TO LIST OF COVERED CONDITIONS WAS REASONABLE, BUT COULD BE IMPROVED (GAO-14-606)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

Communicate clearly, through rulemaking or other means, the approach for decisionmaking related to the addition of covered conditions to the list, including a clear delineation of the relationship between methods when conflicting evidence is available.

HHS Response

HHS supports this recommendation. Since the publication of the rule, which added certain types of cancers to the List of World Trade Center (WTC)-Related Health Conditions (List), the World Trade Center Health Program (WTCHP) has published a policy on its website, and disseminated the policy to stakeholders, which clarifies the Program's decisionmaking. The *Policy and Procedures for Adding Types of Cancer To the List of WTC-Related Health Conditions* clearly states, "If a review of the evidence demonstrates fulfillment of at least one of the four methods...the Administrator will publish in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) to add the type of cancer to the List." The policy also clearly states, "If a review of the evidence does not demonstrate fulfillment of at least one of the four methods described in IV.A. above and does demonstrate that 9/11 exposures are not causally related to the type of cancer, the Administrator will publish in the *Federal Register* a determination not to propose a rule and the basis for such determination." This policy is consistent with how the WTCHP made its decisions in the cancer rule and with how it will do so in the event of future decisions regarding cancer conditions. The *Policy and Procedures for Adding Types of Cancer To the List of WTC-Related Health Conditions* is available at: <http://www.cdc.gov/wtc/policies.html>

GAO Recommendation

Include and independent peer review in the approach for adding to the list of covered conditions, seeking authority to extend time frames if necessary.

HHS Response

HHS supports the intent of the recommendation, but has concerns about the implementation of such an action given the statutory time restrictions placed on the WTCHP Administrator with regard to publishing a NPRM. HHS does not think the draft report provides enough detail about the statutory time restrictions that are specified for the petition process nor does it acknowledge that "seeking authority to extend time frames" is not a simple administrative action but would require Congress to amend the statute. If the WTCHP Administrator decides to add a health condition to the List at his own discretion, there are no statutory time restrictions for the publication of a NPRM. However, if the WTCHP receives a petition to add a health condition to the List, the

Administrator must take one of the following four actions *within 60 days* of receipt of the petition:

1. Request a recommendation from the WTCHP Scientific/Technical Advisory Committee (STAC);
2. Publish a NPRM in the *Federal Register* to add a health condition;
3. Publish in the *Federal Register* the determination not to publish a NPRM and the basis for the determination; or
4. Publish in the *Federal Register* a determination that insufficient evidence exists to take one of actions (1) – (3).

If the Administrator requests a recommendation from the STAC, the WTCHP has only 60 days from the date it receives the STAC's recommendation to publish a determination in the *Federal Register*. Therefore, the 60 days would have to include the consideration and review of the STAC's recommendation and, if the Administrator determines to propose the addition of a health condition, the writing, revision, clearance, and publication of a NPRM. Due to the administrative requirements for clearance and publication of a NPRM, a 60-day time frame mandated by the statute is already quite limiting, without the added time needed to organize, hold, and consider the input from an independent peer review.

If the Administrator does not request a recommendation from the STAC, but determines to publish a NPRM for the petitioned health condition, the WTCHP has only 60 days from the date the petition was received to publish the NPRM. Therefore, the 60 days would have to include the Administrator's own review of the evidence for adding the health condition to the List, as well as the writing, revision, clearance, and publication of a NPRM. As mentioned above, due to the administrative requirements for clearance and publication of a NPRM, a 60-day time frame mandated by the statute is already quite limiting without the added time needed to organize, hold, and consider the input from an independent peer review.

In summary, CDC concurs with GAO's recommendation for clear communication of the WTC Health Program's approach for decisionmaking related to the addition of health conditions to the List. However, while CDC understands the potential value input from an independent peer review would provide, CDC does not think that the statutory time restrictions related to the petition process allow for such a review.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Helene Toiv, Assistant Director; Michelle B. Rosenberg, Assistant Director; Jennie Apter; Hernán Bozzolo; Toni Harrison; Emily Ryan; Walter Vance; and George Bogart made key contributions to this report.

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