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**Washington, DC 20548**

August 4, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
United States House of Representatives

Subject: *World Trade Center Health Program: Potential Effects of Implementation Options*

The James Zadroga 9/11 Health and Compensation Act of 2010 became law on January 2, 2011, and established a World Trade Center Health Program (WTCHP) to assume the functions of the World Trade Center (WTC) responder health programs beginning on July 1, 2011.[1,2] From September 11, 2001, through fiscal year 2010, approximately $475 million in federal funds was made available for screening, monitoring, and treating WTC responders for illnesses and conditions related to the WTC disaster.[3,4] These include asthma, persistent coughing, and

[1]Pub. L. No. 111-347, § 101, 124 Stat. 3623, 3624 (adding title XXXIII, §§ 3301 et seq., to the Public Health Service Act (PHSA), codified at 42 U.S.C. §§ 300mm et seq.). In this report, a "responder" refers to anyone involved in rescue, recovery, or cleanup activities at or near the vicinity of the WTC or the Staten Island site, the landfill that was the off-site location of the WTC recovery operation. Responders include New York City Fire Department (FDNY) personnel; federal government personnel; and other government and private-sector workers and volunteers from New York and elsewhere. Other populations that may receive WTCHP services include community members (referred to as "survivors") and persons who are not eligible responders or survivors but who are diagnosed with a WTC-related health condition by the WTCHP.

[2]For a list of the abbreviations used in this report, see encl. I.

[3]See Congressional Research Service, *Comparison of the World Trade Center Medical Monitoring and Treatment Program and the World Trade Center Health Program Created by Title I of P.L. 111-347, the James Zadroga 9/11 Health and Compensation Act of 2010*, R41292 (Washington D.C.: Jan. 25, 2011).

[4]In this report, "screening" refers to initial physical and mental health examinations of responders. "Monitoring" refers to tracking the health of responders over time through follow-up physical and mental health examinations.

other respiratory conditions and mental health conditions such as depression, anxiety, and post-traumatic stress disorder (PTSD). The three federal programs that provided screening, monitoring, and treatment services to responders prior to July 1, 2011, which we refer to here as the WTC responder health programs, were the New York City Fire Department's (FDNY) WTC Medical Monitoring and Treatment Program, the New York/New Jersey (NY/NJ) WTC Consortium,[5] and the WTC National Responder Health Program. The FDNY WTC program and the NY/NJ WTC Consortium provided services to WTC responders in the New York City (NYC) metropolitan area and each had a Data and Coordination Center (DCC) that was responsible for, among other things, collecting and analyzing clinical data for research on WTC-related health conditions. The WTC National Responder Health Program provided services to WTC responders outside the NYC area and did not have a DCC. The federal agency that was responsible for oversight of the three WTC responder health programs was the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) in the Department of Health and Human Services (HHS). According to NIOSH, as of March 31, 2011, the WTC responder health programs had identified about 55,000 WTC responders who were eligible for health services.

The WTCHP is administered by HHS and provides screening, monitoring, and treatment services through contracted clinical centers in the NYC area for responders in that area and through a nationwide network of providers for responders outside the NYC area. In addition to these health services, the WTCHP is required to establish a program to pay for prescription drugs prescribed under the program and to contract with one or more data centers to coordinate patient outreach and, by analyzing claims data, conduct research on WTC-related health conditions. Although the Zadroga Act generally provides that the WTCHP is the primary payer for benefits for responders under the WTCHP, the act establishes the WTCHP as a secondary payer in certain circumstances.[6] In May 2011, HHS delegated authority to the Centers for Medicare & Medicaid Services to provide payment services for the WTCHP. All other WTCHP activities will be administered by NIOSH. In April 2011, NIOSH issued a solicitation for clinical centers to provide health services to responders and a solicitation for one or more data centers to provide case management and increased capacity for analysis of responder health conditions; on July 1, 2011, NIOSH awarded contracts to six clinical centers and two

[5]The NY/NJ WTC Consortium consisted of five clinical centers in the NY/NJ area. The five clinical centers were operated by (1) Mount Sinai School of Medicine, (2) Long Island Occupational and Environmental Health Center at SUNY, Stony Book, (3) New York University School of Medicine/Bellevue Hospital Center, (4) Center for the Biology of Natural Systems at CUNY, Queens College, and (5) University of Medicine and Dentistry of New Jersey Robert Wood Johnson Medical School, Environmental and Occupational Health Sciences Institute.

[6]The WTCHP is a secondary payer when a responder has a WTC-related health condition that is work related and the enrollee has filed an applicable workers' compensation claim or a WTC-related health condition that is not work related and the enrollee is covered by a public or private health insurance plan (with the exception of Medicare). Pub. L. No. 111-347, 124 Stat. 3653 (adding PHSA § 3331). The workers' compensation exception does not apply when responders are covered under a workers' compensation plan administered by New York City.

data centers.[7] The Zadroga Act established the WTCHP Fund and provided appropriations for the federal share of expenditures for each of fiscal years 2012 through 2016, as well as the last calendar quarter of fiscal year 2011, totaling a maximum of $1.6 billion.[8]

The Zadroga Act requires us to study feasibility, efficiency, and effectiveness issues related to the WTCHP established by the act, including the WTCHP's potential use of one consolidated data center rather than multiple data centers, the potential use of Department of Veterans Affairs (VA) health care facilities to serve WTC responders outside the NYC area, and the potential use of an existing federal prescription drug purchasing program to provide prescription drugs for all WTC responders.[9] The act expressly authorizes (but does not require) the WTCHP to enter into an agreement with VA to provide WTCHP services to responders living outside the NYC area through VA facilities. However, the act does not expressly authorize an agreement with a federal prescription drug purchasing program to provide prescription drugs to WTC responders. In this report, we identify potential effects of (1) creating a consolidated data center for the WTCHP, (2) using VA facilities to provide WTCHP services to responders living outside the NYC area, and (3) using an existing federal prescription drug purchasing program for the WTCHP.

To identify potential effects of creating a consolidated data center for the WTCHP, we interviewed DCC, NIOSH, and WTC Steering Committee officials who were involved with managing or overseeing the DCCs.[10] To obtain additional information

[7]With one exception, the entities that were awarded contracts for operating clinical centers for the WTCHP are the same as those that served as clinical centers for the FDNY WTC program and the NY/NJ WTC Consortium. NIOSH awarded a contract to the Long Island Jewish Medical Center, which did not previously have a contract as a clinical center. According to a CDC official, Long Island Jewish Medical Center will have a partnership with Queens College, which was a clinical center for the NY/NJ WTC Consortium prior to July 1, 2011. The entities awarded contracts to operate the data centers for the WTCHP are the same as those that served as the DCCs for the FDNY WTC program and the NY/NJ WTC Consortium. In addition, NIOSH awarded a task order not to exceed $79,830,170 to Computer Sciences Corporation for overall program administration, business communications, and information systems implementation of the WTCHP. This task order includes the services of a pharmacy benefit manager—an entity that negotiates rebates and payments with manufacturers, negotiates prices with retail pharmacies, and can provide other related administrative and clinical services—for the WTCHP's prescription drug plan.

[8]Pub. L. No. 111-347, 124 Stat. 3657 (adding PHSA § 3351). The act specifies that the federal share of the funding for the WTCHP will be the lesser of either 90 percent of the actual expenditures each year or an amount specified for each year. The act also provides that a 10 percent NYC share shall be deposited into the WTCHP Fund and that disbursements from the WTCHP Fund are conditioned on NYC contracting to contribute a 10 percent share of actual expenditures.

[9]Pub. L. No. 111-347, 124 Stat. 3631, 3646-48 (adding PHSA §§ 3305(a)(5), 3312(c)(B)(iv), and 3313(d)(2)). The Zadroga Act includes an additional GAO mandate requiring an analysis of whether the Clinical Centers of Excellence (CCE) with which the WTCHP enters into a contract have financial systems that will allow for the timely submission of claims data as envisioned by the act. Pub. L. No. 111-347, 124 Stat. 3633 (adding PHSA § 3305(d)). See GAO, *World Trade Center Health Program: Administrator's Plans for Evaluating Clinics' Capability to Provide Required Data*, GAO-11-793R (Washington, D.C.: Jul. 15, 2011).

[10]The WTC Steering Committee consists of the principal investigators from each WTC clinical center, the principal investigators from each DCC, an external advisory committee representative, a chairperson appointed by NIOSH, and other, nonvoting members. The WTC Steering Committee was intended to develop and ensure compliance with clinical policies and procedures, evaluate protocols proposed by the clinical centers, and ensure that studies were properly conducted and study results were reported and disseminated to the scientific community, including physicians involved in the care of WTC responders, in a timely manner.

about the two DCCs and the potential effects of consolidation, we also reviewed documents related to the DCCs, including progress reports and clinical instruments used for data collection, relevant provisions of the Zadroga Act, our prior reports, and documents describing initiatives for consolidating federal data centers.

To identify potential effects of using VA facilities to provide WTCHP services to responders living outside the NYC area, we interviewed officials involved in implementing or overseeing the WTC National Responder Health Program, including officials from Logistics Health, Incorporated (LHI), the contractor that has been responsible for implementing the program.[11] We also interviewed VA officials knowledgeable about the provision of health services for individuals served by VA. We reviewed relevant documents related to WTC National Responder Health Program operations and to the provision of VA health services, such as VA directives.

In addition, we calculated the percentages of WTC responders living outside the NYC area who resided within certain designated distances of a VA facility by analyzing ZIP code data on the locations of WTC responders' residences and the locations of relevant VA facilities, including VA medical centers (VAMC), community-based outpatient clinics (CBOC), and independent outpatient clinics (IOC).[12] The data for WTC responders' residential locations were provided by the NY/NJ WTC Consortium DCC, the entity that managed recruitment for the WTC National Responder Health Program. According to the DCC's database, as of March 19, 2011, 4,621 of the approximately 53,000 WTC responders are known to reside outside the NYC area, including in locations outside the country. The data for the locations of VA facilities were provided by VA and included ZIP codes for 150 VAMCs, 739 CBOCs, and 5 IOCs in the United States. Our analysis has several limitations. First, there was no way to determine whether the VA facilities in the ZIP codes nearest the responders' ZIP codes would have the appropriate expertise or space available to provide services in the future. Second, the analysis does not account for the precise residential location of a responder in a ZIP code; distances were calculated from the geographic center of a ZIP code in which a responder resides to the geographic center of a ZIP code in which a VA facility is located.[13] Finally, the accuracy of the ZIP code data was not verified. We assessed the reliability of the ZIP code level data by interviewing knowledgeable DCC and VA officials, and we determined that the data were sufficiently reliable for our purposes.

[11]LHI designs, implements, and manages occupational health services and medical and dental services for the U.S. military and HHS, as well as for commercial companies.

[12]VAMCs provide a wide range of services, including outpatient, mental health, and critical care; surgery; and pharmacy. In addition, most VAMCs offer additional medical and surgical specialty services, such as neurology. A CBOC is associated with, but geographically separate from, a parent VAMC, and can provide primary, specialty, subspecialty, and mental health care, or any combination of health care delivery services that can be appropriately provided in an outpatient setting. Other outpatient clinics in the VA health system include IOCs, which are freestanding ambulatory care clinics. In contrast to CBOCs, IOCs are not associated with VAMCs.

[13]We calculated the straight-line distance between ZIP codes and did not account for factors that might affect travel distances or travel time.

To identify potential effects of using an existing federal prescription drug purchasing program for the WTCHP, we interviewed officials from the WTC responder health programs and NIOSH who were involved in implementing or overseeing the programs' seven prescription drug plans.[14] We limited our scope to the following federal prescription drug purchasing programs: VA's drug purchasing program; TRICARE, the Department of Defense's (DOD) health care program; and HHS's 340B Drug Pricing Program.[15,16] We interviewed officials from VA; DOD; and HHS's Health Resources and Services Administration (HRSA), which administers the 340B Drug Pricing Program. We reviewed documents related to the WTC responder health programs' prescription drug plans and the federal drug purchasing programs, including drug plan information provided to beneficiaries and drug formularies.[17] In addition, we obtained from each of the WTC prescription drug plans the names of the 10 prescription drugs most frequently used by WTC responders covered by each plan in 2010. The top 10 lists for the seven plans yielded a total of 29 prescription drugs. We then determined which of the 29 drugs were on the formularies used by VA and TRICARE and were available through the 340B program.[18]

We conducted this performance audit from March 2011 to August 2011, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Results in Brief

Creating a consolidated data center could lead to cost savings and enhanced research opportunities; however, consolidation could require upfront expenditures. In addition, establishing a consolidated data center could result in a loss of responders' clinical data from the WTCHP because of the potential need to have responders sign new consent forms to enable use of their data for research. Responders provided consent to their respective clinical centers to send their clinical data to the center's DCC for research purposes, and existing consent might not authorize the use of such data by a consolidated data center. Responders might be unavailable or

[14]The seven prescription drug plans included those of the FDNY WTC program, each of the five clinical centers of the NY/NJ WTC Consortium, and the WTC National Responder Health Program.

[15]TRICARE is a regionally structured program that uses contractors to maintain provider networks to complement health care provided at military treatment facilities. The 340B Drug Pricing Program provides eligible entities, such as health centers and hospitals that provide comprehensive health care services for a high proportion of low-income patients, with access to discounted drug prices.

[16]We included the federal prescription drug purchasing programs for which an arrangement with HHS to provide prescription drugs to WTC responders seemed the most feasible.

[17]A formulary is a list of drugs that a health care organization has determined to be the most medically appropriate and cost-effective for its patient population.

[18]To identify the drugs that were on the formularies used by VA and TRICARE and were available through the 340B program, we used the VA National Formulary published on its Web site in January 2011 (accessed March 10, 2011), the TRICARE Formulary Search Tool available on DOD's Web site (accessed June 2, 2011), and the 340B Prime Vendor Program Catalog (accessed May 17, 2011). According to HRSA, the 340B Prime Vendor Program Catalog does not include all prescription drugs available through the 340B Drug Pricing Program.

unwilling to provide consent again. Although most WTC responders outside the NYC area live near a VA facility, the use of VA facilities for the WTCHP could affect access to health services for WTC responders because not all types of clinical expertise are available at all VA facilities, VA facilities do not always have space available to serve nonveterans, and it would take an undetermined length of time to implement an agreement between VA and HHS. The use of VA facilities for the WTCHP could also affect enrollment retention because WTC responders might need to change health care providers. Providing prescription drugs to WTC responders through an existing federal prescription drug purchasing program could reduce drug prices. It might also affect the availability of options for filling prescriptions and responders' access to certain prescription drugs. In addition, VA and DOD officials told us that use of their respective drug purchasing programs for WTC responders would require administrative changes to their programs. In written comments, DOD concurred with a draft of this report. HHS and VA provided technical comments, which we incorporated as appropriate.

## Background

Within HHS, NIOSH awarded funds to and oversaw the WTC responder health programs. Beginning in 2001, the FDNY WTC program and the NY/NJ WTC Consortium received federal funding to provide services to responders. The programs began as screening and monitoring programs, tracking the health status of WTC responders. In December 2005, the Congress first appropriated funds specifically for treatment programs for certain responders with health conditions related to the WTC disaster,[19] and in fall 2006 NIOSH began awarding funds for outpatient and inpatient treatment. NIOSH contracted with LHI in 2008 to implement the WTC National Responder Health Program.[20] According to NIOSH, of the almost 55,000 eligible responders, about 49,000 had been screened as of March 31, 2011, by the three WTC responder health programs;[21] from April 1, 2010, to March 31, 2011, about 27,000 were monitored and about 16,000 were treated.[22]

### DCCs

In 2004, NIOSH entered into cooperative agreements with two DCCs to provide data management and coordination for the two largest WTC responder health programs, which are located in the NYC area. The FDNY Bureau of Health Services operated the DCC for the FDNY WTC program, and the Mount Sinai School of Medicine

[19]See Department of Defense Appropriations Act, 2006, Pub. L. No. 109-148, § 5011(b), 119 Stat. 2680, 2814 (2005).

[20]Since November 2002, NIOSH has implemented various forms of a national program for responders outside the NYC area, although no program existed from August 2004 until June 2005. See GAO, *September 11: HHS Needs to Ensure the Availability of Health Screening and Monitoring for All Responders*, GAO-07-892 (Washington, D.C.: Jul. 23, 2007).

[21]According to NIOSH, responders who meet eligibility criteria can be enrolled in the program; however, not all individuals participate in their respective programs after enrolling.

[22]NIOSH reports current data on the numbers of responders screened, monitored, and treated on its Web site: http://www.cdc.gov/niosh/topics/wtc/census.html (accessed June 17, 2011).

operated the DCC for the NY/NJ WTC Consortium.[23] According to NIOSH's original request for applications in 2003, the two DCCs were to be responsible for monitoring the quality and quantity of data received from their respective clinical centers, maintaining an electronic clinical data entry tool, analyzing clinical data, providing reports to NIOSH, and coordinating outreach and patient follow-up. The FDNY DCC provided services to active duty FDNY firefighters, emergency medical services personnel, civilian volunteers, and retired nonactive duty FDNY firefighters; the Consortium DCC provided services to a more heterogeneous group of WTC responders, including police officers, sanitation workers, construction workers, transit workers, a wide range of volunteers, and active duty and retired firefighters who responded from locations outside the NYC area. The cooperative agreements between NIOSH and the DCCs ended on June 30, 2011.

Under the Zadroga Act, the WTCHP is required to contract with one or more data centers to collaborate with the clinical centers that will be providing services to WTC responders in the NYC metropolitan area,[24] and on July 1, 2011, NIOSH awarded contracts to two data centers; the two data centers are the same entities that served as the DCCs for the FDNY WTC program and the NY/NJ WTC Consortium. The WTCHP data centers will continue the activities of the WTC responder health programs' DCCs in addition to new activities. The responsibilities for each WTCHP data center include analyzing and reporting on claims data; coordinating with corresponding clinical centers to obtain input on the analysis and reporting of data collected; developing protocols for screening, monitoring, and treatment; coordinating outreach activities; and establishing criteria for the credentialing of medical providers.

We have previously reported on the data collection efforts of WTC responder health programs[25] and on federal data centers in general, including the opportunity to increase government efficiency through consolidating such centers.[26] In February 2010, the Office of Management and Budget launched the Federal Data Center Consolidation Initiative (FDCCI) to increase government efficiency.[27] The FDCCI is a governmentwide effort to consolidate more than 2,000 federal government data centers. We have identified challenges or potential effects of consolidation in ongoing reviews of this initiative.[28]

[23]FDNY's Bureau of Health Services provides health services for all FDNY employees and also provided screening, monitoring, and treatment services for the FDNY WTC program.

[24]Pub. L. No. 111-347, 124 Stat. 3630 (adding PHSA § 3305(a)(2)).

[25]GAO, *September 11: World Trade Center Health Programs Business Process Center Proposal and Subsequent Data Collection*, GAO-11-243R (Washington, D.C.: Dec. 3, 2010).

[26]GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, GAO-11-318SP (Washington, D.C.: Mar. 1, 2011) and GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, GAO-11-441T (Washington D.C.: Mar. 3, 2011).

[27]Office of Management and Budget, *Memorandum for Chief Information Officers: Update on the Federal Data Center Consolidation Initiative* (Washington, D.C.: October 2010).

[28]GAO-11-318SP.

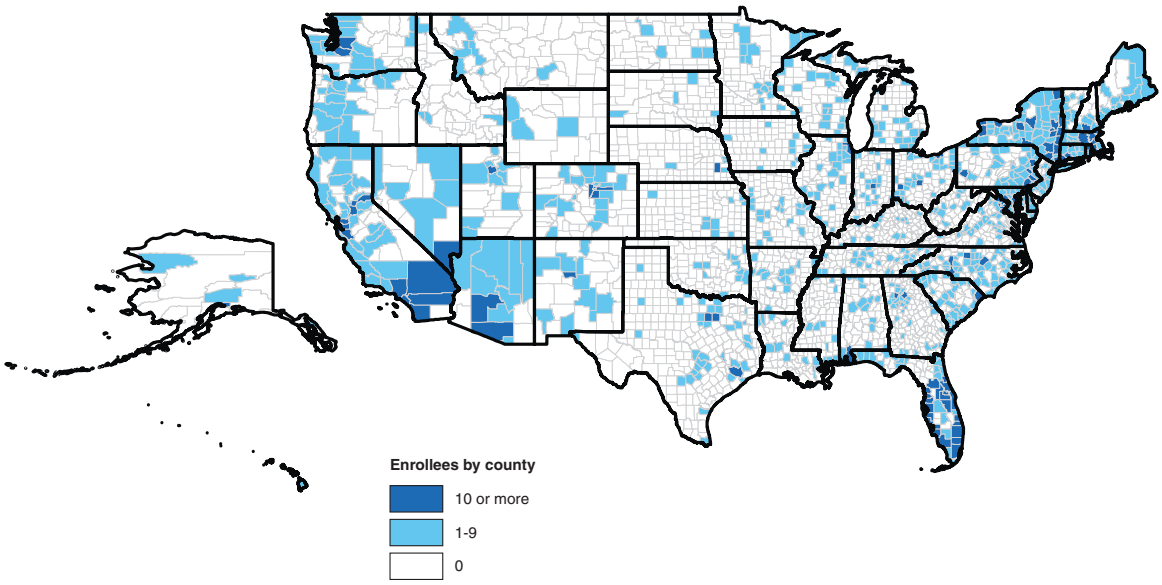
Health Care Services for WTC Responders Residing outside the NYC Area

Since June 2008, NIOSH has contracted with LHI to provide screening, monitoring, and treatment services to WTC responders who live outside the NYC metropolitan area.[29] Although the WTC National Responder Health Program did not have a DCC and does not have a data center, LHI is responsible for tracking and reporting responder information based on claims data. LHI has been providing monitoring services to WTC responders through its national network of providers, and LHI subcontracts with United Medical Resources (UMR) to provide responders with access to treatment services through UnitedHealthcare's provider network.[30] The base year of the current contract between NIOSH and LHI ends on September 29, 2011, and the contract allows for NIOSH to exercise an option to renew the contract for each of the following four fiscal years. See figure 1 for a map of residential locations of WTC responders residing outside the NYC area.

[29]According to NIOSH, about 3,700 responders had been screened by the WTC National Responder Health Program as of March 31, 2011.

[30]UMR is a subsidiary of UnitedHealthcare (a UnitedHealth Group company). UMR provides integrated health benefit management for dental, vision, disability, and medical plans. Under the subcontract, UMR reviews claims and responders have access to treatment services through UnitedHealthcare's national network of health providers.

**Figure 1: World Trade Center (WTC) Responders Residing outside the New York City (NYC) Metropolitan Area, by County and by State (as of March 19, 2011)**

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|---|---|---|---|---|---|---|---|
| Alabama | 34 | Illinois | 129 | Montana | 8 | Rhode Island | 38 |
| Alaska | 26 | Indiana | 56 | Nebraska | 26 | South Carolina | 80 |
| Arizona | 93 | Iowa | 13 | Nevada | 45 | South Dakota | 6 |
| Arkansas | 21 | Kansas | 20 | New Hampshire | 19 | Tennessee | 42 |
| California | 331 | Kentucky | 26 | New Jersey | 43 | Texas | 138 |
| Colorado | 90 | Louisiana | 20 | New Mexico | 38 | Utah | 36 |
| Connecticut | 53 | Maine | 19 | New York | 723 | Vermont | 9 |
| Delaware | 13 | Maryland | 109 | North Carolina | 194 | Virginia | 164 |
| District of Columbia | 25 | Massachusetts | 14 | North Dakota | 8 | Washington | 77 |
| Florida | 711 | Michigan | 48 | Ohio | 14 | West Virginia | 19 |
| Georgia | 121 | Minnesota | 31 | Oklahoma | 16 | Wisconsin | 34 |
| Hawaii | 10 | Mississippi | 14 | Oregon | 48 | Wyoming | 4 |
| Idaho | 8 | Missouri | 43 | Pennsylvania | 205 | | |

Source: GAO analysis of data provided by the New York/New Jersey (NY/NJ) WTC Consortium's data and coordination center (DCC).

Note: The NY/NJ WTC Consortium's DCC, which was operated by the Mount Sinai School of Medicine, managed recruitment for the WTC National Responder Health Program. According to its database, 4,621 WTC responders are known to reside outside the NYC metropolitan area, including in locations outside the country. As of March 19, 2011, the DCC's database included ZIP codes and states for 4,368 of the 4,621 WTC responders; ZIP codes and states were not available for 211 responders, and 42 responders reside outside the country or in Guam, Puerto Rico, or the Virgin Islands. The map represents the locations, by county, for 4,365 of the responders living outside the NYC metropolitan area, but within the country; the counties for 3 responders were not available because we could not match the responders' ZIP codes with counties. The differences in the sizes of the counties are geographical only and do not reflect the number of responders in each county.

The Zadroga Act requires the WTCHP to provide services to WTC responders outside the NYC area through a national network of providers, and permits HHS to enter into an agreement with VA to provide these services in VA facilities.[31] The responsibilities of the WTCHP's national network of providers under the act will be similar to the responsibilities of the national network of providers in the WTC National Responder Health Program. In addition to providing services to veterans, VA provides health services to certain civilians through its Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) program, which

[31]Pub. L. No. 111-347, 124 Stat. 3647 (adding PHSA § 3313). NIOSH officials told us that the agency will use LHI to meet the requirements of the act in the near term. Under the Zadroga Act, responsibilities for providers participating in the national network include collecting and reporting data in accordance with specified standards; following certain monitoring, screening, and treatment protocols; and meeting criteria for credentialing to be established by data centers. In addition to responders, community members (referred to as "survivors") will be eligible for services in the national network.

is primarily a fee-for-service program that provides coverage for certain eligible dependents or survivors of veterans who are permanently and totally disabled because of a service-connected disability. Veterans generally have higher priority for services in VA facilities than do nonveterans;[32] CHAMPVA beneficiaries are eligible to receive health services in most VA facilities, but only on a space-available basis.

Prescription Drug Plans

Prior to July 1, 2011, the WTC responder health programs included seven different prescription drug plans, each of which used program funds to provide responders with full coverage for prescription medications listed on a formulary. The seven plans were associated with the FDNY WTC program, the five clinical centers in the NY/NJ WTC Consortium, and the WTC National Responder Health Program. Generally, the prescription drug plans independently contracted with a pharmacy benefit manager (PBM) to purchase and distribute prescription drugs to its beneficiaries.[33] In 2010, the WTC responder health programs' prescription drug plans filled over 140,000 prescriptions at a cost of $25.3 million. WTC responders paid no premiums or copayments for drugs to treat WTC-related health conditions. Depending on the WTC prescription drug plan, responders could obtain their drugs through a mail order pharmacy, network retail pharmacy, or in-house pharmacy located in their clinic.

The Zadroga Act requires the WTCHP to establish a program to pay for medically necessary outpatient prescription drugs prescribed for WTC-related health conditions.[34] According to a NIOSH official, starting on July 1, 2011, NIOSH began using a single PBM to administer the prescription drug benefit for all of the WTCHP responders in the NYC area. A NIOSH official told us that prescription drugs for WTC responders residing outside the NYC area will continue to be provided through the LHI contract in the near term.

The federal government operates several prescription drug purchasing programs[35]—including VA's drug purchasing program, DOD's TRICARE, and HRSA's 340B Drug Pricing Program—which receive prices that are typically lower than those otherwise available. VA and TRICARE provide drug benefits for eligible beneficiaries by purchasing and distributing prescription drugs. The 340B Drug Pricing Program gives enrolled entities access to discounted drug prices, called 340B ceiling prices,

[32]Not all veterans, however, have the same priority for receiving health services in VA facilities. Veterans are assigned to priority groups based on certain factors, such as service-connected disability status and income.

[33]One of the Consortium's clinical centers did not independently contract with a PBM and provided prescription drugs to WTC responders through an in-house pharmacy. Of the remaining six WTC prescription drug plans, three plans received discounts from retail pharmacies or rebates from manufactures through their PBMs and three plans did not.

[34]Pub. L. No. 111-347, 124 Stat. 3646 (adding PHSA § 3312(c)(1)(B)).

[35]Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and others rely on negotiations with manufacturers, either directly or through private health plans. See GAO, *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs,* GAO-07-358T (Washington, D.C.: Jan. 11, 2007).

and gives them the option to contract with a prime vendor, which can negotiate discounts with manufacturers at or below the mandatory 340B ceiling price.

VA's drug purchasing program includes a national formulary to help standardize veterans' access to medications across the country.[36] The formulary includes drugs that generally must be prescribed by a VA provider and filled through VA's mail order pharmacy or at a VA pharmacy. VA pays the lowest of several prices available for a given drug and can negotiate with suppliers to receive additional discounts.

DOD's prescription drug benefit is provided to active duty and retired uniformed service members and their families through TRICARE. In 2005, DOD implemented a uniform formulary that includes drugs prescribed for TRICARE beneficiaries by providers at military treatment facilities and by outside providers. Beneficiaries can obtain their medications through TRICARE's mail order pharmacy, network retail pharmacies, nonnetwork retail pharmacies, and military treatment facilities. Like VA, TRICARE pays the lowest of several prices and can receive additional discounts through negotiation with suppliers.

HRSA's 340B Drug Pricing Program gives access to discounted drug prices to enrolled entities that provide services to low-income and other individuals who experience barriers gaining access to care.[37] The 340B Drug Pricing Program enables enrolled entities to stretch federal resources so that they can serve additional eligible patients and provide more comprehensive services. In order to have their drugs covered by Medicaid, drug manufacturers must agree to charge entities that participate in the 340B program prices that do not exceed an amount determined by statutory formula. Enrolled entities establish their own formularies and may dispense drugs through in-house pharmacies, contracted retail pharmacies, or both.[38]

### Creating a Consolidated Data Center Could Reduce Costs and Enhance Research, but Would Require Upfront Investment and Might Adversely Affect Enrollment Retention

#### Creating a Consolidated Data Center Has Potential for Cost Savings and Enhanced Research, but Upfront Investment Would Be Needed

Creating a consolidated data center could lead to cost savings, such as by reducing duplicative staff positions for data management and analysis. The FDNY and Consortium DCCs conducted similar activities related to the collection and maintenance of data, such as data monitoring, data cleaning, and the preparation of quality assurance reports. According to Consortium DCC officials, the DCC monitored, for example, types and dates of clinical visits by responders and regularly

[36]The formulary does not apply to the CHAMPVA program.

[37]Entities eligible to enroll in the 340B Drug Pricing Program are specified in statute and include certain health centers and hospitals that provide comprehensive health care services for a high proportion of low-income patients, as well as programs that serve patients with specific conditions or diseases. See 42 U.S.C. § 256b(a)(4). Not all eligible entities choose to enroll in the program. The categories of entities that are eligible to participate in the program have been expanded over time.

[38]The WTC responder health programs were not independently eligible for the 340B Drug Pricing Program. The Bellevue and Mt. Sinai clinical centers are located within hospitals that meet current eligibility criteria and are enrolled in the program.

conducted data cleaning as part of its quality assurance efforts in generating required reports for NIOSH. FDNY's DCC worked on similar data- and quality-assurance-related tasks, such as revising patient questionnaires and data cleaning. In a consolidated data center, such activities would be conducted by a single entity, which could result in cost savings due to reduced duplication of effort. Such savings have been projected for other data center consolidations. For example, according to the federal interagency Chief Information Officers Council—which was established to improve agency practices related to the development and implementation of federal information resources—the FDCCI would likely lead to cost savings through the reduction of redundant and duplicative information technology projects and infrastructure.[39]

Using a consolidated data center could also enhance opportunities to conduct research on health effects by increasing the number of WTC responders whose information is in the data set and available for analysis. The FDNY and Consortium DCCs maintained separate data sets for their respective groups of WTC responders. The single, merged data set that would result from a consolidated data center could facilitate enhanced epidemiologic research because this larger data set would likely allow researchers to perform analyses that would not be possible with smaller data sets. For example, researchers could more effectively study conditions that are experienced by WTC responders less frequently, such as cancer and pulmonary fibrosis, including the efficacy of treatments for such conditions.

Before cost savings can be realized, however, consolidation could require upfront expenditures, including investments in information technology systems. A NIOSH official said there would be upfront costs associated with merging the FDNY and Consortium DCCs' responder population data sets. For example, the two DCCs had different information technology systems for collecting clinical data. Creation of a consolidated data center could result in the need to invest in standardizing information technology systems. In our 2011 report on opportunities to reduce potential duplication in government, we noted that there are upfront costs associated with data center consolidation in the FDCCI.[40] We also reported that although data center consolidation could achieve more efficient information technology operations, upfront funding would be needed for the consolidation effort long before any cost savings could accrue.[41,42]

[39]Chief Information Officers Council, *Memorandum for Chief Information Officers: Federal Data Center Consolidation Initiative Initial Plans*, http://cio.gov/documents/fddci-initial-plan-memo-5-26.pdf (accessed June 24, 2011); and Chief Information Officers Council, *Cracking Down on Wasteful, Duplicative Spending*, http://www.cio.gov/pages.cfm/page/Cracking-Down-on-Wasteful-Duplicative-Spending (accessed May 9, 2011).

[40]GAO-11-318SP, p. 67-68.

[41]Ibid.

[42]For example, in September 2010, the Office of Inspector General in the Department of Homeland Security, a federal agency involved in the FDCCI, reported that the department's consolidation efforts would cost about $560 million. See U.S. Department of Homeland Security. Office of Inspector General, *Management of DHS' Data Center Consolidation Initiative Needs Improvement* (Washington, D.C.: September 2010), 5.

## Effort to Create a Consolidated Data Center Could Result in a Loss of Responders and Data from the WTCHP

Establishing a consolidated data center could create a need for a new consent process to enable the center to use responders' previously collected data and collect future data. Responders provided consent to their respective clinical centers to send their clinical data to the center's DCC for research purposes, and according to Consortium officials, existing consent may not authorize the use of such data by a consolidated data center. For example, Consortium officials told us that if the clinical centers have to transfer clinical data to a consolidated data center that is an entity different from the DCC to which they are already sending data, each responder would have to sign a new consent form. The officials said that responders might be unavailable or unwilling to provide consent again. This could lead to decreased enrollment retention. If retention declines, the WTCHP could lose access to responder data.[43] Such a loss of data could pose a problem for the WTCHP, because one of the major goals of the WTCHP is to conduct research on responders to inform the provision of care for conditions resulting from exposure during the WTC disaster.

In addition to the need for a new consent process, potential resistance from stakeholder organizations and WTC responders, resulting in part from long-standing professional loyalties, could affect the success of a consolidated data center. We previously reported that a potential challenge to creating a consolidated data center is overcoming cultural resistance to major organizational change.[44] WTC officials said that the FDNY and Consortium DCC organizations and responders have unique identities and loyalties. For example, FDNY DCC officials attributed their high rate of responder retention to the fact that they maintained an employer/employee-based WTC program and the FDNY responders identify closely with the FDNY institution. FDNY DCC officials told us that responders were significantly more willing to accept the program's outreach through telephone calls the responders knew originated from the FDNY in comparison with calls where they did not recognize the caller's telephone number. If NIOSH chooses to use a consolidated data center, buy-in from stakeholders—including organizations providing services to WTC responders, unions, and respective groups of responders—would be critical.

According to DCC officials, the creation of a consolidated data center could also disrupt the close relationships and bonds of trust that have been developed over the past decade among the DCCs, the clinical centers, and their respective groups of responders. The officials believe these bonds are important for outreach and retention. As part of their scope of activities, the DCCs were involved in the programs' outreach efforts, either directly or by supporting the efforts of the clinical centers. For example, the Consortium DCC employed several outreach strategies targeting responders, including issuing quarterly newsletters, sending e-mails with relevant stories from the press, organizing conferences, and translating materials into multiple languages. Consortium DCC officials told us that nothing replaced the

[43]If access to data were lost it would be difficult for researchers to conduct analyses examining the progression of WTC-related conditions in responder populations over time.

[44]GAO-11-318SP, p. 67.

value of a responder having face-to-face contact with a familiar institution and that one of the Consortium DCC's key outreach strategies was to have staff in the community maintain direct contact with responders. DCC officials observed that for a consolidated data center to be successful in maintaining responder retention, it would have to establish strong relationships with the clinical centers and responders.

### Using VA Facilities to Provide WTCHP Services outside NYC Area Could Affect Access and Enrollment Retention

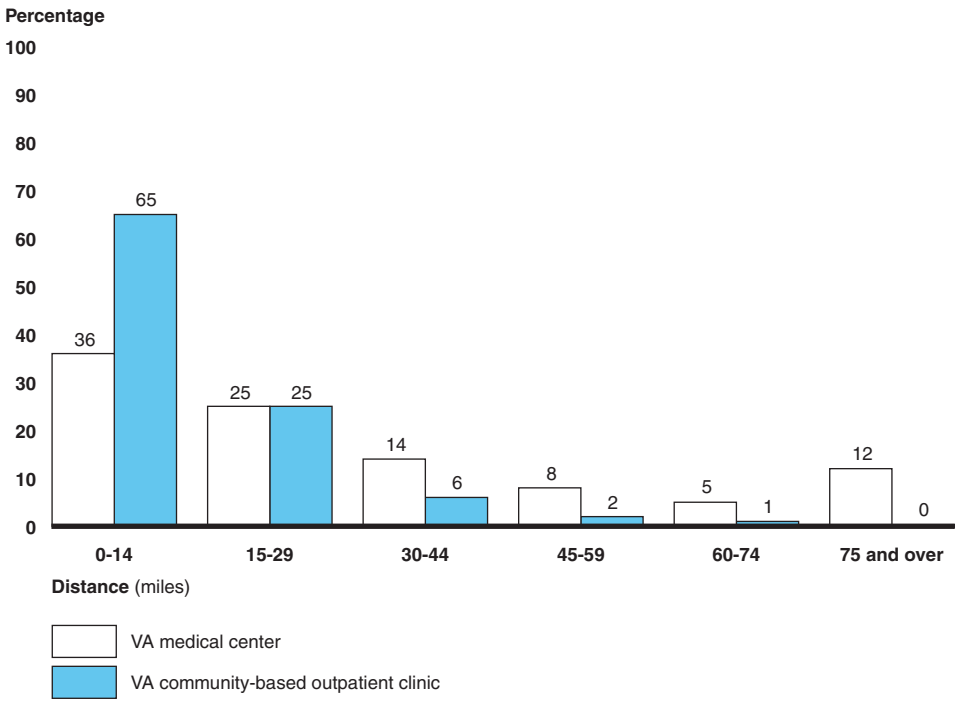
Most WTC Responders outside NYC Area Live Near a VA Facility

Most WTC responders outside the NYC area live near a VA facility. About 61 percent of the WTC responders outside the NYC area (2,665 of the 4,368 in the NY/NJ WTC Consortium DCC database)[45] reside less than 30 miles from a VAMC, and about 90 percent (3,947 of the 4,368) reside less than 30 miles from a CBOC.[46] Figure 2 shows the percentages of responders outside the NYC area living within certain designated distances of VAMCs and CBOCs.

[45]As of March 19, 2011, the NY/NJ WTC Consortium DCC database included ZIP codes and states for 4,368 of the 4,621 WTC responders living outside the NYC area. We conducted our analysis on these 4,368 responders.

[46]As of September 30, 2010, VA's database included 739 CBOCs and 5 IOCs. For this analysis, we included the IOCs with the CBOCs.

**Figure 2: Percentages of the World Trade Center (WTC) Responders outside the New York City (NYC) Area Living within Designated Distances of Department of Veterans Affairs (VA) Medical Facilities**




Source: GAO analysis of data provided by the New York/New Jersey (NY/NJ) WTC Consortium's data and coordination center (DCC) and VA.

Note: The NY/NJ WTC Consortium's DCC, which was operated by the Mount Sinai School of Medicine, managed recruitment for the WTC National Responder Health Program. According to its database, 4,621 WTC responders are known to reside outside of the NYC metropolitan area, including in locations outside the country. As of March 19, 2011, the DCC's database included residential locations (including ZIP codes and states) for 4,368 of those 4,621 WTC responders. As of September 30, 2010, VA's database included 150 VA medical centers and 739 VA community-based outpatient clinics (CBOC) located in the United States, as well as the locations for 5 VA independent outpatient clinics (IOC) also located in the United States. For this analysis, we included the IOCs with the CBOCs. Percentages in figure for CBOCs do not add to 100 due to rounding.

## Using VA Facilities for WTCHP Could Affect Access

Use of VAMCs and CBOCs for the WTCHP could affect access to health services for WTC responders—whether veterans or nonveterans—because not all types of clinical expertise are available at all VA facilities. According to VA officials, many VA providers have treatment expertise in disorders that may be experienced by responders, such as pulmonary diseases and PTSD, but certain specialists are less frequently employed by CBOCs. For example, all VAMCs provide PTSD specialty care on site, but CBOCs are less likely to provide these services on site. VA officials told us that it may be possible for responders who do not live near a VA facility with on-site PTSD specialty care to use telehealth services.[47]

VA facilities do not always have space available to serve nonveterans, so using these facilities for the WTCHP could have an effect on access for those WTC responders who are not veterans. VA officials told us that each VAMC periodically (at least annually) assesses whether it, or its associated CBOCs, has space available to provide any health services to nonveterans. VAMCs conduct periodic

[47]According to VA officials, larger CBOCs are required by VA to have on-site mental health services, and other CBOCs use telehealth to offer such services. Telehealth services are provided from a distance using telecommunications technologies, such as videoconferencing.

assessments for each type of health service they provide to veterans, and these assessments may result in expansions or reductions of health services for nonveterans in the medical center or in its associated CBOCs. VA officials told us that it may be possible to establish an agreement with HHS for the WTCHP's use of VA facilities that would allow WTC responders to obtain treatment services in all VA facilities, regardless of the space available to serve nonveterans.

Access to WTCHP services could also be affected by the length of time needed to take the administrative actions necessary to implement an agreement between VA and HHS. VA officials told us that the length of time needed would depend on the extent of administrative action—such as developing a process for WTCHP to reimburse VA for services it provides or for hiring new staff—that would be needed.

Responders' Need to Change Providers Could Affect Enrollment Retention

The use of VA facilities for the WTCHP could affect enrollment retention. WTC responders living outside the NYC area would have to switch from providers in the LHI and UnitedHealthcare networks to providers in VA facilities.[48] NIOSH officials expressed concern that some responders might choose to no longer participate in the WTCHP because of a reluctance to discontinue seeing providers with whom they have an established relationship. Officials said they were especially concerned about mental health care because developing an effective relationship between a patient and a mental health provider can be a sensitive process.

**Providing Prescription Drugs to WTC Responders through an Existing Federal Prescription Drug Purchasing Program Could Reduce Drug Prices, but Might Affect Access**

Use of an Existing Federal Prescription Drug Purchasing Program Could Result in Lower Drug Prices for the WTCHP

Use of VA's drug purchasing program, TRICARE, or the 340B program could result in lower prescription drug prices for the WTCHP. Prices available to VA and TRICARE and through the 340B program are typically lower than those otherwise available. For example, VA and DOD, along with the Public Health Service and the U.S. Coast Guard, have access to federal ceiling prices, also called Big Four prices, which are based on calculations prescribed by statute and generally are at least 24 percent lower than nonfederal average manufacturer prices.[49] According to HRSA's Web site, participation in the 340B program results in significant savings —estimated to be 20 percent to 50 percent—on the cost of outpatient prescription drugs for enrolled entities. None of the seven WTC prescription drug plans that existed before July 1, 2011, received the special prescription drug prices available to these programs, and a NIOSH official told us NIOSH has not investigated participation in federal purchasing programs in detail, but expects to do so during the

[48]Some responders might be able to continue seeing their LHI or UnitedHealthcare provider. According to VA officials, it might be possible to provide some responders with access to non-VA providers on a fee-for-service basis if they do not live near a VA facility or cannot access services in nearby VA facilities.

[49]See 38 U.S.C. § 8126(a)(2), (c), (d).

course of the program's first year of operation.[50] VA officials were uncertain whether legal authority exists to extend the lower pricing available to VA to the WTCHP if it used VA's program to provide prescription drugs to responders. In addition, VA officials told us that, in the past, drug manufacturers challenged an attempt by another federal agency to extend VA's negotiated prices to nonveteran populations. DOD officials said that current authority would not allow DOD to obtain lower pricing for prescription drugs provided to WTC responders at retail pharmacies. DOD officials were unsure whether legal authority exists to extend the lower pricing to the WTCHP for prescription drugs provided through DOD's mail order pharmacy. According to a HRSA official, legislation would be needed to provide authority for the WTCHP to become eligible to participate in the 340B program.

Use of an Existing Federal Prescription Drug Purchasing Program Might Change Responders' Options for Filling Prescriptions

Options for filling prescriptions varied among the WTC prescription drug plans that were in place before July 1, 2011, and included mail order, network retail pharmacy, and in-house pharmacy. In 2010, four of the plans offered responders more than one option for filling prescriptions. (See table 1 for the options in 2010 for filling prescriptions.) According to a NIOSH official, the WTCHP will provide all WTC responders in the NYC area with at least two options for obtaining their medications—mail order and retail pharmacies.[51]

[50]NIOSH awarded a task order to Computer Sciences Corporation that includes the services of a pharmacy benefit manager to administer the prescription drug benefit for all of the WTCHP responders in the NYC area. A NIOSH official told us that the PBM will negotiate rebates with manufacturers and drug prices with retail pharmacies as part of its contract with NIOSH. The official told us that prescription drugs for WTC responders residing outside the NYC area will continue to be provided through the LHI contract in the near term. The PBM used by LHI currently negotiates rebates with manufacturers and drug prices with retail pharmacies for the WTC National Responder Health Program.

[51]It is uncertain whether an in-house pharmacy option will be available through the WTCHP.

**Table 1: Options for Filling Prescriptions under Each of the WTC Prescription Drug Plans, in 2010**

| WTC prescription drug plan | Options for filling prescriptions | | |
|---|---|---|---|
| | Mail order pharmacy | Network retail pharmacy | In-house pharmacy |
| Center for the Biology of Natural Systems at CUNY, Queens College[a] | | X | |
| Long Island Occupational and Environmental Health Center at SUNY, Stony Brook[a] | X | | |
| Mount Sinai School of Medicine[a] | X | X | |
| New York City Fire Department's (FDNY) WTC Medical Monitoring and Treatment Program | X | X | |
| New York University School of Medicine/Bellevue Hospital Center[a] | X | | X |
| University of Medicine and Dentistry of New Jersey Robert Wood Johnson Medical School, Environmental and Occupational Health Sciences Institute[a] | | X | |
| WTC National Responder Health Program | X | X | |

Source: GAO analysis of information from WTC prescription drug plans.

Note: The seven prescription drug plans in place prior to July 1, 2011, were associated with the three WTC responder health programs. The New York/New Jersey (NY/NJ) WTC Consortium consisted of five clinical centers, each of which had its own prescription drug plan. The other two plans were associated with the FDNY WTC Medical Monitoring and Treatment Program and the WTC National Responder Health Program.

[a]A NY/NJ WTC Consortium clinical center.

Options for filling prescriptions vary among the existing federal prescription drug purchasing programs, and WTCHP's use of any of these programs might change responders' options for filling prescriptions. VA beneficiaries may obtain drugs prescribed by VA providers only at a VA pharmacy or through VA's mail order pharmacy and generally do not have the option to use retail pharmacies.[52] If the WTCHP used VA's drug purchasing program, some responders would have to discontinue their use of retail or in-house pharmacies and begin using mail order or obtain prescriptions at VAMCs or CBOCs. In contrast, TRICARE currently offers mail order and network and nonnetwork retail pharmacy options to its beneficiaries, and the 340B Drug Pricing Program allows for the use of in-house pharmacies and contract retail and mail order pharmacies. WTCHP's use of either of these programs would likely expand the number of access options for some responders in comparison to the options offered by their WTC prescription drug plans.

[52]A VA official told us that some CBOCs have contracts with retail pharmacies for VA beneficiaries to access prescription medications in an emergency and that a small number of prescriptions are filled this way.

Use of an Existing Federal Prescription Drug Purchasing Program Might Affect Responders' Access to Certain Prescription Drugs

WTCHP's use of an existing federal prescription drug purchasing program might affect responders' access to certain prescription drugs. VA's formulary includes 16 of the 29 prescription drugs most frequently used by WTC responders in 2010. VA beneficiaries generally must obtain approval through their providers to obtain nonformulary drugs.[53] According to a VA official, however, it may be possible to establish an agreement between VA and HHS that would result in VA providing all prescription drugs on the NIOSH formulary for WTC responders, regardless of whether the drugs are on VA's formulary. TRICARE's formulary includes all 29 of the drugs that were most frequently used by WTC responders in 2010.[54] Responders' access to prescription drugs would not be affected by WTCHP's enrollment in the 340B program because 340B-enrolled entities are generally not precluded from purchasing drugs that are not covered by the 340B program.[55] However, purchasing drugs that are not covered by the 340B program could potentially result in higher costs to the entity.

WTCHP's Use of VA's Prescription Drug Purchasing Program or TRICARE Would Require Administrative Changes to Either Program

VA and DOD officials told us that use of their drug purchasing programs for WTC responders would result in a need for administrative changes to their respective programs. VA and DOD officials said that new administrative procedures would be needed, for example, for verifying that a responder is eligible for their programs' prescription benefits. In addition, a VA official said that VA would need a method for verifying that only prescription drugs that are covered by the WTCHP prescription drug plan are provided to responders. Officials were unsure how much time would be required to implement these and other administrative changes.

## Agency Comments

In written comments, DOD concurred with a draft of this report. HHS and VA provided technical comments, which we incorporated as appropriate.

[53]VA fills prescriptions for nonformulary drugs for CHAMPVA beneficiaries without prior approval.

[54]TRICARE's formulary includes all 29 of the drugs that were most frequently used by WTC responders in 2010; however, either prior authorization or proof of medical necessity is required to obtain 6 of the 29 drugs.

[55]Twenty-eight of the 29 prescription drugs most frequently used by WTC responders in 2010 were 340B-covered drugs.

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Debra A. Draper
Director, Health Care

Enclosures – 2

Enclosure I

## Abbreviations

| | |
|---|---|
| CBOC | community-based outpatient clinics |
| CDC | Centers for Disease Control and Prevention |
| CHAMPVA | Civilian Health and Medical Program of the Department of Veterans Affairs |
| DCC | Data and Coordination Center |
| DOD | Department of Defense |
| FDCCI | Federal Data Center Consolidation Initiative |
| FDNY | New York City Fire Department |
| HHS | Department of Health and Human Services |
| HRSA | Health Resources and Services Administration |
| IOC | Independent Outpatient Clinic |
| LHI | Logistics Health, Incorporated |
| NIOSH | National Institute for Occupational Safety and Health |
| NYC | New York City |
| NY/NJ | New York/New Jersey |
| PBM | Pharmacy Benefit Manager |
| PTSD | post-traumatic stress disorder |
| UMR | United Medical Resources |
| VA | Department of Veterans Affairs |
| VAMC | VA medical center |
| WTC | World Trade Center |
| WTCHP | World Trade Center Health Program |

Enclosure II

## GAO Contact and Staff Acknowledgments

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