

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NOT ALL INTERNAL CONTROLS
IMPLEMENTED BY CDC WERE
EFFECTIVE IN ENSURING THAT WORLD
TRADE CENTER HEALTH PROGRAM
PHARMACY AND MEDICAL CLAIMS WERE
PAID ACCORDING TO FEDERAL
REQUIREMENTS**

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EXECUTIVE SUMMARY

Not all of CDC's internal controls were effective in ensuring that payments for World Trade Center Health Program pharmacy benefits and medical services were made in accordance with Federal requirements.

WHY WE DID THIS REVIEW

The World Trade Center Health Program (WTCHP) was established in January 2011 by the James Zadroga 9/11 Health and Compensation Act of 2010, P.L. No. 111-347 (Zadroga Act). The WTCHP is administered by the Centers for Disease Control and Prevention (CDC) through its National Institute for Occupational Safety and Health (NIOSH). Under the WTCHP, pharmacy benefits and medical services are provided to eligible responders and survivors with certified health conditions related to the September 11, 2001, terrorist attacks on the World Trade Center and the Pentagon and the Shanksville, Pennsylvania, crash site.

We previously reviewed how CDC monitored and evaluated its contracts with clinics that provide pharmacy benefits and medical services to WTCHP members. This review was conducted to fulfill Zadroga Act requirements that the Office of Inspector General review WTCHP expenditures to detect inappropriate billing and payment for services.

The objective of this review was to determine whether CDC's internal controls were effective in ensuring that claims for WTCHP pharmacy benefits and medical services were paid in accordance with Federal requirements.

BACKGROUND

World Trade Center Health Program: Program Administration

NIOSH contracts with various entities to oversee enrollment of new WTCHP members, provide WTCHP pharmacy benefits and medical services, and reimburse WTCHP providers for services. Specifically:

- Seven contracted Clinical Centers of Excellence (CCEs) coordinate pharmacy benefits and medical services to WTCHP members who reside in the New York metropolitan area (NY Metro area members). Logistics Health, Inc. (LHI), coordinates these services for WTCHP members who reside elsewhere (Nationwide Network members).
- Computer Sciences Corporation (CSC) reviews enrollment applications and certifications that enrollees' health conditions are related to the September 11, 2001, terrorist attacks, and adjudicates and processes claims for services.
- Pharmacy Benefit Managers (PBMs) subcontracted by LHI and CSC negotiate drug prices and assist in processing and paying pharmacy benefit claims.
- After adjudication by CSC, claims are denied, held (pending receipt of additional

information), or forwarded to National Government Services (NGS) for payment.

- NGS reimburses claims for pharmacy benefits and medical services using WTCHP funds disbursed by the Centers for Medicare & Medicaid Services (CMS).

World Trade Center Health Program: Providing Services to Program Members

WTCHP members not grandfathered into the program from previous programs aimed at assisting survivors and responders are enrolled after meeting eligibility criteria and having been checked against the Department of Justice's (DOJ) terrorist watch list. The WTCHP covers members' initial health evaluations, monitoring visits, and treatment services. These services are paid with WTCHP funds except when (1) payment has been made, or can reasonably be expected to be made, under a workers' compensation or similar benefit plan or (2) the member has a certified health condition that is not work-related and has other health insurance. To be eligible for reimbursement, providers must be enrolled with the WTCHP, licensed, and not appear on the U.S. Department of Health and Human Services' list of excluded providers. Prescription drugs are reimbursed on the basis of contracts with drug vendors, and medical services are reimbursed on the basis of applicable Federal Employees' Compensation Act rates.

As of March 31, 2014, the WTCHP had enrolled 67,788 members, including 6,706 Nationwide Network members. During the audit period, October 1, 2012, through March 31, 2014, NGS paid 708,157 WTCHP claims totaling \$140,535,932 (363,445 pharmacy benefit claims totaling \$66,206,044 and 344,712 medical services claims totaling \$74,329,888).

HOW WE CONDUCTED THIS REVIEW

We reviewed CDC's internal controls related to enrolling WTCHP members, providing WTCHP pharmacy benefits and medical services, and reimbursing WTCHP claims. To determine the effectiveness of these internal controls, we reviewed a sample of 45 claims randomly selected from the WTCHP claim payment system that were paid by NGS during our audit period and, for each sample claim, reviewed the associated WTCHP member's eligibility and health condition certification records and documentation to support the claim. We also performed other audit procedures, including interviewing officials from NIOSH, CMS, NGS, CSC, CCEs, LHI, and DOJ. Because our review was designed to provide only reasonable assurance that the internal controls we reviewed were effective, it would not necessarily have detected all internal control deficiencies.

WHAT WE FOUND

Not all of CDC's internal controls were effective in ensuring that claims for WTCHP pharmacy benefits and medical services were paid in accordance with Federal requirements.

On the basis of our review of 45 sample claims, we determined that certain internal controls were effective, such as those for enrolling members and providing pharmacy benefits and medical services. However, the internal controls for reimbursing claims for pharmacy benefits and medical services were not always effective in ensuring:

- NY Metro area members' primary prescription drug insurance was billed by pharmacies to maintain the WTCHP as the secondary payer (2 claims),
- Nationwide Network prescribers of members' prescription drugs were WTCHP-authorized (2 claims),
- prescription refills were authorized (1 claim), and
- pharmacy benefit and medical service claims were reimbursed at or below appropriate payment rates (2 claims).

The presence of an internal control deficiency does not necessarily mean that CDC improperly paid a WTCHP claim; however, ineffective controls may limit NIOSH's ability to prevent and detect inappropriate billings and payment for these services.

These deficiencies occurred because NIOSH did not have adequate procedures to ensure that claims were paid according to Federal requirements. Specifically, NIOSH did not (1) establish a procedure for collecting and transmitting NY Metro area members' prescription drug insurance coverage information to the PBMs for benefits coordination, (2) establish a procedure to ensure that Nationwide Network members' prescriptions were written by authorized WTCHP prescribers, (3) require the PBMs to establish procedures to prevent the authorized number of refills from being exceeded, and (4) establish a procedure for ensuring that pharmacy benefit and medical service claims were reimbursed at or below appropriate payment rates.

WHAT WE RECOMMEND

We recommend that CDC:

- establish a procedure for collecting and transmitting NY Metro area members' prescription drug insurance coverage information to PBMs for benefits coordination,
- establish a procedure to ensure that Nationwide Network members' prescriptions are written by authorized WTCHP prescribers,
- require PBMs to establish procedures to prevent the authorized number of refills from being exceeded,
- establish a procedure for ensuring that pharmacy benefit claims are reimbursed at or below appropriate payment rates, and
- determine whether medical service claims processed before October 22, 2012, were reimbursed at or below the appropriate payment rate and recoup any overpayments.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In written comments on our draft report, CDC stated that it generally concurred with our recommendations and described actions that it has taken or planned to take to address most of them. CDC also provided technical comments under separate cover. We addressed those comments, as appropriate.

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LIST OF ACRONYMS

CCE	Clinical Center of Excellence
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CSC	Computer Sciences Corporation
DOJ	Department of Justice
FECA	Federal Employees' Compensation Act
LHI	Logistics Health, Inc.
NGS	National Governmental Services
NIOSH	National Institute for Occupational Safety and Health
OIG	Office of Inspector General
PBM	Pharmacy Benefit Manager
WTC	World Trade Center
WTCHP	World Trade Center Health Program

INTRODUCTION

WHY WE DID THIS REVIEW

The World Trade Center Health Program (WTCHP) was established in January 2011 by the James Zadroga 9/11 Health and Compensation Act of 2010, P.L. No. 111-347 (Zadroga Act).¹ The WTCHP is administered by the Centers for Disease Control and Prevention (CDC) through its National Institute for Occupational Safety and Health (NIOSH). Under the WTCHP, pharmacy benefits and medical services are provided to eligible responders and survivors with certified health conditions related to the September 11, 2001, terrorist attacks on the World Trade Center (WTC) and the Pentagon and the Shanksville, Pennsylvania, crash site.²

We previously reviewed how CDC monitored and evaluated its contracts with clinics that provide pharmacy benefits and medical services to WTCHP members.³ This review was conducted to fulfill Zadroga Act requirements that the Office of Inspector General (OIG) review WTCHP expenditures to detect inappropriate billing and payment for services.⁴

OBJECTIVE

Our objective was to determine whether CDC's internal controls were effective in ensuring that claims for WTCHP pharmacy benefits and medical services were paid in accordance with Federal requirements.

BACKGROUND

World Trade Center Health Program: How Contractors Enroll Members, Coordinate Pharmacy Benefits and Medical Services, and Pay Providers

On January 2, 2011, the President signed the Zadroga Act, which established the WTCHP and funded the program for 5 years, beginning July 1, 2011, with Federal funding capped at

¹ Zadroga Act, P.L. No. 111-347 § 101, Public Health Service Act, §§ 3301-3351, 42 U.S.C. §§ 300mm-300mm-61. This report conforms to colloquial usage and refers to sections 3301-3351 of the Public Health Service Act as sections 3301-3351 of the Zadroga Act (e.g., Zadroga Act, § 3301).

² Responders are individuals who performed rescue, recovery, demolition, debris cleanup, or related services at the three sites related to the 9/11 terrorist attacks. Survivors are individuals who lived, worked, or attended school, childcare, or adult daycare in the New York City WTC disaster area following the terrorist attacks of September 11, 2001. The Zadroga Act defines this area as Manhattan south of Houston Street and any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former WTC site.

³ *World Trade Center Health Program: CDC Should Strengthen Efforts to Monitor and Evaluate Clinic Compliance With Contract Terms* (A-02-11-02003, January 29, 2014). Available at <http://oig.hhs.gov/oas/reports/region2/21102003.pdf>.

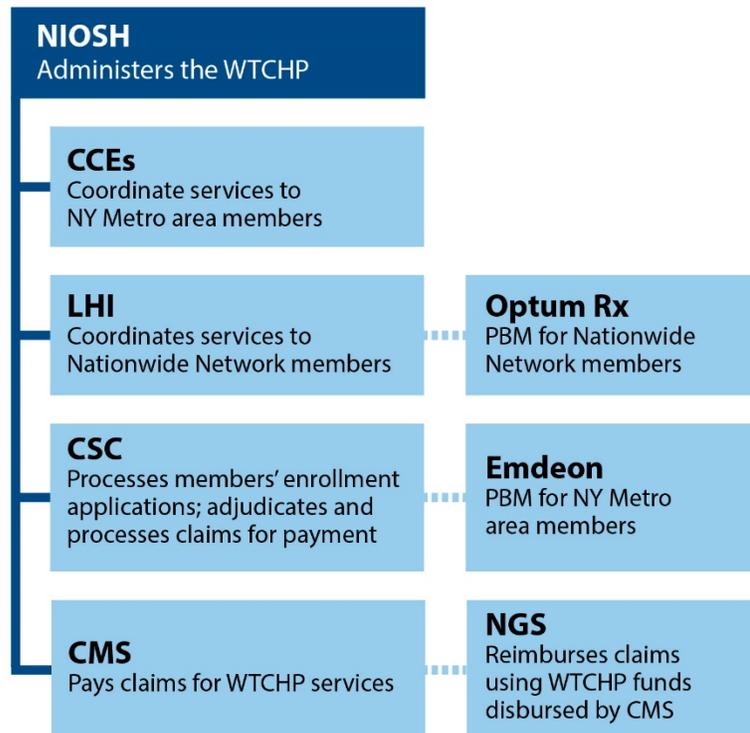
⁴ Section 3301(d) of the Zadroga Act also requires that we review WTCHP administrative costs. We are planning further work in this area.

approximately \$1.6 billion.⁵ In response to the Zadroga Act’s requirement to provide for the uniform collection of claims data, CDC implemented a fee-for-service claims reimbursement process.

NIOSH contracts with various entities to oversee the enrollment of new WTCHP members, provide WTCHP pharmacy benefits and medical services, and reimburse WTCHP providers for services (Figure 1). Specifically:

- Seven contracted Clinical Centers of Excellence (CCEs) coordinate pharmacy benefits and medical services to WTCHP members who reside in the New York metropolitan area (NY Metro area members). Logistics Health, Inc. (LHI), coordinates these services for WTCHP members who reside elsewhere (Nationwide Network members).
- Computer Sciences Corporation (CSC) reviews enrollment applications and certifications that enrollees’ health conditions are related to the September 11, 2001, terrorist attacks (WTC-related), and adjudicates and processes claims for services.

Figure 1: WTCHP Contract Structure



- Pharmacy Benefit Managers (PBMs) subcontracted by LHI and CSC negotiate drug prices and assist in processing and paying pharmacy benefit claims.
- After adjudication by CSC, claims are denied, held (pending receipt of additional information), or forwarded to National Government Services (NGS) for payment.
- NGS reimburses claims for pharmacy benefits and medical services using WTCHP funds

⁵ The Zadroga Act specified that the Federal share of WTCHP funding was to be the lesser of (1) 90 percent of expenditures for the respective fiscal year or (2) an amount specified for that fiscal year. The amount provided for fiscal year 2016 is limited to any unexpended funds remaining available from fiscal years 2011 through 2015.

disbursed by the Centers for Medicare & Medicaid Services (CMS).⁶

During the audit period, October 1, 2012, through March 31, 2014, NGS paid WTCHP pharmacy benefit claims totaling \$66,206,044 and medical service claims totaling \$74,329,888.

World Trade Center Health Program: Program Requirements and Internal Controls

Member Enrollment

To be eligible to receive WTCHP benefits, individuals must have participated in one of two Government-funded programs that predated the WTCHP or submit an application and meet specific eligibility criteria (Zadroga Act, §§ 3311(a) and 3321(a)). Further, individuals must be checked against the Department of Justice's (DOJ) terrorist watch list before enrollment (Zadroga Act, §§ 3311(a)(5) and 3321(a)(4)).⁷

As of March 31, 2014, the WTCHP had enrolled 67,788 members,⁸ including 6,706 Nationwide Network members.⁹ Most members were automatically enrolled after being checked against the terrorist watch list because they had participated in the prior programs. Beginning July 1, 2011, individuals seeking enrollment in the WTCHP have been required to submit an application, which NIOSH reviews and determines the individual's eligibility for enrollment. As illustrated in Figure 2, most WTCHP members reside in New York.

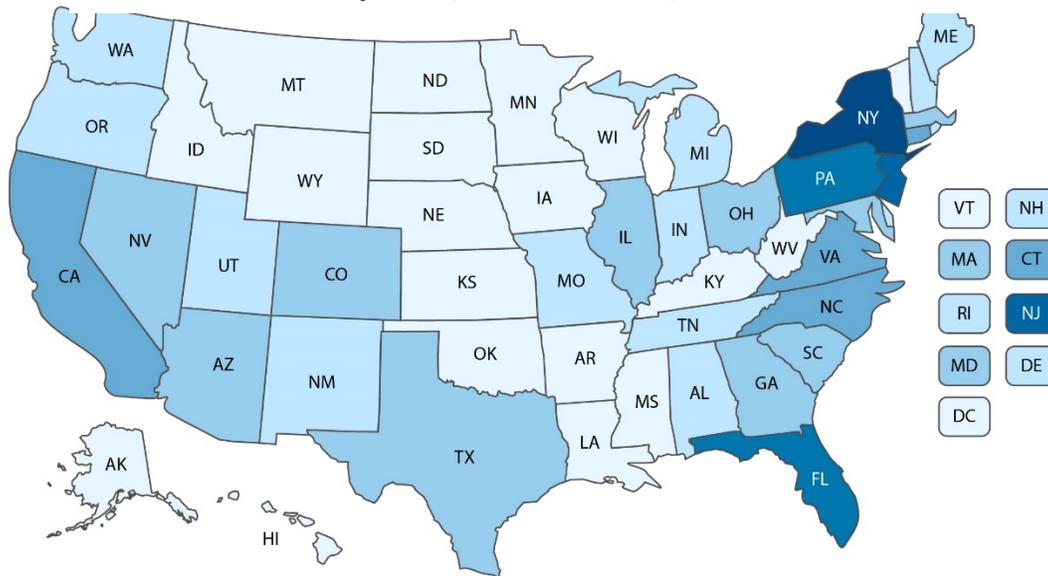
⁶ The Zadroga Act prohibits CDC from paying WTCHP claims (§ 3306(14)(B)). CMS was authorized to pay WTCHP claims through an intradepartmental delegation of authority.

⁷ NIOSH sends a list of applicants' names to the Department of Justice to be checked against the list.

⁸ Of these 67,788 members, 61,055 were transferred from the two programs that predated the WTCHP. The remaining 6,733 members were enrolled beginning in July 2011.

⁹ Beginning in 2013, the WTCHP began enrolling individuals who responded to the terrorist attack sites in Shanksville, Pennsylvania, and at the Pentagon in Arlington, Virginia.

Figure 2: World Trade Center Health Program Members by State, as of March 31, 2014



LEGEND

WTCHP Member Concentration



Member Services

The WTCHP covers members’ initial health evaluations, monitoring visits, and treatment services. Monitoring and treatment services must be medically necessary and provided in accordance with approved protocols (Zadropa Act, §§ 3311(b), 3312(b)(3)(A), 3312(d), 3321(b) and 3322(a)). To receive treatment, a member must have a documented, NIOSH-certified medical condition related to the September 11, 2001, terrorist attacks (certified health condition) or a medically associated health condition based on a WTCHP physician’s determination (Zadropa Act, §§ 3312(b) and 3322(a)).¹⁰

Members are examined at a CCE or LHI provider to determine whether they have a WTC-related health condition. For members who were enrolled and receiving treatment through the prior programs, the CCEs or LHI attested to having determined that the members had a WTC-related health condition and provided NIOSH with the diagnostic code for each condition.¹¹ For members enrolled in the WTCHP after July 1, 2011, or members from the prior programs with

¹⁰ Treatment services may be provided and paid for while a certification decision on a member’s health condition is pending (Zadropa Act, §§ 3312(b)(5) and 3322(a)). For certification purposes, the member’s exposure and symptoms must be documented by a medical professional (Zadropa Act, §§ 3312(a)(2) and 3321(b)).

¹¹ The CCEs and LHI retained the documents detailing the members’ related WTC exposure.

health conditions determined to be WTC-related after July 1, 2011, the CCEs or LHI provide NIOSH with an attestation form and supporting documentation that details the member's exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks. NIOSH reviews the attestation forms and supporting documentation and certifies whether the member's condition is related to the attacks.

Claims Reimbursement

The WTCHP pays for initial health evaluations, monitoring visits, and treatment services except when (1) payment has been made, or can reasonably be expected to be made, under a workers' compensation¹² or similar benefit plan or (2) the member has a certified health condition that is not work-related and has other health insurance (Zadroga Act, § 3331). In addition, providers must be enrolled with the WTCHP,¹³ licensed, and not appear on the U.S. Department of Health and Human Services' list of excluded providers (Social Security Act, §§ 1128 and 1128A). WTCHP prescription drugs are reimbursed on the basis of contracts with drug vendors (Zadroga Act, § 3312(c)(1)). Medical services are reimbursed on the basis of the applicable Federal Employees' Compensation Act (FECA) rate—the rate the Federal Government uses to pay for medical services for Federal employees injured while on the job.

Pharmacy benefit claims are electronically processed at the point of sale and sent to a PBM, which validates the member, prescriber, plan level, and coverage. The PBM forwards prescription claim information to CSC, where it is recorded and sent to NGS for payment. CSC adjudicates WTCHP medical service claims on the basis of a CMS methodology for promoting correct coding, the member's enrollment status, the member's certified health condition, and the listing of enrolled providers. Members with other medical insurance are tagged in the WTCHP claims processing system as having other insurance so that the payment of medical service claims can be coordinated with the other insurance providers.

HOW WE CONDUCTED THIS REVIEW

We reviewed CDC's internal controls related to enrolling WTCHP members, providing WTCHP pharmacy benefits and medical services, and reimbursing WTCHP claims. Appendix A provides general information on internal controls.

To determine the effectiveness of these internal controls, we reviewed a sample of 45 claims randomly selected from the WTCHP claim payment system that were paid by NGS during our

¹² These may include workers' compensation plans or other work-related injury or illness benefit plans for a work-related health condition. This provision does not apply for any workers' compensation law or plan, including line-of-duty compensation, for which New York City is obligated to make payments (Zadroga Act, § 3331(b)(2)).

¹³ Providers must be enrolled with a CCE if treating NY Metro area members or be part of the Nationwide Network managed by LHI if treating Nationwide Network members (Zadroga Act, §§ 3305(b) and 3313; CCE contracts, § C.3.4.1; LHI contract, "Performance Work Statement Addendum 7").

audit period.¹⁴ We also performed other audit procedures, including interviewing NIOSH, CMS, NGS, CSC, CCE, LHI, and DOJ officials.

For the 45 sample claims,¹⁵ we reviewed supporting documentation to evaluate whether the member was eligible, services were related to a certified health condition, and payment for services met selected billing requirements. Because our review was designed to provide only reasonable assurance that the internal controls we reviewed were effective, it would not necessarily have detected all internal control deficiencies.

We conducted this performance audit 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.

Appendix B contains the details of our audit scope and methodology.

FINDINGS

Not all of CDC's internal controls were effective in ensuring that claims for WTCHP pharmacy benefits and medical services were paid in accordance with Federal requirements. On the basis of our review of 45 sample claims, we determined that certain internal controls were effective, such as those for enrolling members and providing pharmacy benefits and medical services. However, the internal controls for reimbursing claims for pharmacy benefits and medical services were not always effective in ensuring:

- NY Metro area members' primary prescription drug insurance was billed by pharmacies to maintain the WTCHP as the secondary payer (2 claims),
- Nationwide Network prescribers of members' prescription drugs were WTCHP-authorized (2 claims),
- prescription refills were authorized (1 claim), and
- pharmacy benefit and medical service claims were reimbursed at or below appropriate payment rates (2 claims).

¹⁴ Our attribute sampling approach is commonly used to test the effectiveness of internal controls for compliance with laws, regulations, and policies. According to the Government Accountability Office and President's Council on Integrity and Efficiency's (now called the Council of the Inspectors General on Integrity and Efficiency) *Financial Audit Manual* (July 2008), section 450, auditors may use a randomly selected sample of 45 items to perform a compliance review. If all sample items are determined to be in compliance with requirements, a conclusion that the controls are effective can be made. If one or more sample items are determined not to be in compliance with requirements, a conclusion that the controls are ineffective can be made. Our sampling methodology was limited to forming an opinion about whether the internal controls at NIOSH were effective and was not designed to estimate the percentage of claims paid inappropriately.

¹⁵ The sample included 26 pharmacy benefit and 19 medical service claims.

The presence of an internal control deficiency does not necessarily mean that CDC improperly paid a WTCHP claim; however, ineffective controls may limit NIOSH's ability to prevent and detect inappropriate billings and payment for these services.

These deficiencies occurred because NIOSH did not have adequate procedures to ensure that claims were paid according to Federal requirements. Specifically, NIOSH did not (1) establish a procedure for collecting and transmitting NY Metro area members' prescription drug insurance coverage information to PBMs for benefits coordination, (2) establish a procedure to ensure that Nationwide Network members' prescriptions were written by authorized WTCHP prescribers, (3) require PBMs to establish procedures to prevent the authorized number of refills from being exceeded, and (4) establish a procedure for ensuring that pharmacy benefit and medical service claims were reimbursed at or below appropriate payment rates.

NIOSH DID NOT ENSURE THAT PHARMACIES ALWAYS BILLED NEW YORK METRO AREA MEMBERS' PRESCRIPTION DRUG INSURANCE BEFORE BILLING THE WORLD TRADE CENTER HEALTH PROGRAM

The WTCHP is the secondary payer to any workers' compensation insurance or other work-related injury or illness benefit plan of the employer that a member has for work-related health conditions (Zadroga Act, § 3331(b)). For a non-work-related certified health condition, the WTCHP is the secondary payer to the member's primary insurance (Zadroga Act, § 3331(c)).

NIOSH established a procedure to ensure that NY Metro area members' medical insurance coverage information is collected by CCEs and recorded by CSC. Therefore, payments for medical services claims are coordinated with other medical insurance carriers. However, NIOSH did not establish a similar control to collect and record members' prescription drug insurance coverage information because CCEs do not submit claims for pharmacy benefits. Rather, NIOSH relied on members and pharmacies¹⁶ to ensure that members' prescription drug insurance was billed before the WTCHP. As a result, NIOSH did not coordinate with other insurance carriers to ensure that the WTCHP was the secondary payer for pharmacy benefit claims. NIOSH stated that although the PBM has the ability to coordinate pharmacy benefits through a system edit, NIOSH has not yet developed a procedure for collecting and transmitting member prescription drug insurance coverage to the PBM for benefits coordination.

We identified two pharmacy benefit claims in our sample that should have been covered by a member's other insurance. Specifically:

- One member had a non-work-related, certified health condition and declared having other insurance to his or her CCE. Specifically, this member had a total of 19 pharmacy benefit claims paid during our audit period (including our sample item), totaling \$6,848. All of these claims would have been covered by the other insurance.
- The other member had a work-related health condition and was identified as having an active workers' compensation claim related to his or her certified health condition.

¹⁶ Specifically, NIOSH relied on members to report other prescription drug coverage to the pharmacies and expected pharmacies to bill any other insurance available.

Specifically, this member had a total of 31 pharmacy benefit claims paid during our audit period (including our sample item), totaling \$2,493, that would have been covered by workers' compensation.

For these claims, we determined that the pharmacies did not attempt to bill the members' other insurances because the pharmacies did not have the members' other insurance information. Without ensuring NY Metro area members' primary prescription drug insurance is billed by pharmacies before the WTCHP, the WTCHP may be paying for pharmacy benefits that should be covered by other insurance.

NIOSH DID NOT ALWAYS ENSURE THAT ALL NATIONWIDE NETWORK PRESCRIBERS WERE AUTHORIZED BY THE WORLD TRADE CENTER HEALTH PROGRAM

NIOSH determines which providers may provide treatment under the WTCHP on the basis of their experience treating or diagnosing health conditions included in the WTCHP's list of WTC-related health conditions (Zadropa Act, §§ 3305(a)(2)(B) and 3313). WTCHP members' medications must be prescribed by providers identified as authorized prescribers.¹⁷

NIOSH established a procedure in the claims processing system to ensure that prescriptions for NY Metro area members were written by authorized WTCHP prescribers. However, NIOSH did not establish a similar control to ensure that prescriptions for Nationwide Network members were written by authorized WTCHP prescribers.

Of the 26 pharmacy benefit claims in our sample, 3 were associated with Nationwide Network members. For two of these three claims, the provider who wrote the member's prescription was not part of the WTCHP's prescriber network.¹⁸

Without additional controls, the WTCHP may continue to pay for Nationwide Network members' prescription drugs that were not prescribed by an authorized provider (Figure 3). Further, there may be quality-of-care issues because there is no assurance that individuals writing these prescriptions are familiar with WTCHP program requirements and treating WTC responders and survivors.

¹⁷ NIOSH operates a closed network of authorized prescribers to maintain control over pharmacy benefits provided to WTCHP members (NIOSH, *Implementing the Closed Prescriber Network* (WTCHP Bulletin No. 12-18, effective 3/1/12) and LHI contract addendum 7, effective 9/30/12).

¹⁸ These 2 providers prescribed medication for 4 WTCHP members during our audit period, resulting in 88 pharmacy benefit claims totaling \$25,094.

Figure 3: Unauthorized Prescriber

One of the claims in our sample was associated with a Florida-based psychiatrist who was not part of the WTCHP's prescriber network. The psychiatrist treated three WTCHP members during our audit period. The WTCHP paid more than \$20,000 in pharmacy benefit claims (54 total) for the three members.

The psychiatrist's office staff told us that they were aware that the patient associated with our sample claim was a WTCHP member and stated that they thought the psychiatrist was authorized to prescribe for the WTCHP.

WTCHP members can obtain covered prescriptions through a mail-order service or at a pharmacy of their choice. However, members' medications must be prescribed by WTCHP-authorized providers.

NIOSH DID NOT ENSURE THAT PRESCRIPTION REFILLS WERE AUTHORIZED

Treatment of WTC-related health conditions must be medically necessary and in accordance with medical treatment protocols (Zadroga Act, §§ 3312(b)(3)(A) and 3322(a)). We determined that NIOSH did not implement effective internal controls to ensure that members were not dispensed more prescription drugs than they were prescribed to take. Instead, NIOSH relied on pharmacies to ensure that pharmacy benefit claims were medically necessary and in accordance with medical treatment protocols.

For one pharmacy benefit claim in our sample, the WTCHP paid for an unauthorized prescription refill associated with a Nationwide Network member. Specifically, the claim was related to the fourth refill of a prescription that was authorized to be refilled only three times. This happened because the PBM did not have an edit in place to prevent such an occurrence.¹⁹

Without ensuring that prescription refills are authorized, the WTCHP may be paying for excess prescription drugs that were not prescribed. Further, WTCHP members may be given prescription drugs without a physician's knowledge. This could affect quality of care because members' conditions are not reevaluated to assess the need for additional prescription drugs.

NIOSH DID NOT ENSURE THAT ALL CLAIMS WERE REIMBURSED AT OR BELOW APPROPRIATE PAYMENT RATES

Pharmacy Benefits

For pharmacy benefit claims, reimbursement must be made in accordance with rates established in contracts with PBMs (Zadroga Act, § 3312(c)(1)(B)(i)). NIOSH relied on PBMs to comply with contracts and did not ensure that payments for NY Metro area pharmacy benefits were made in accordance with contract terms.

For one pharmacy benefit claim associated with a NY Metro area member, the pharmacy was paid more than the contracted rate, according to the CCE's contract with the PBM.²⁰ NIOSH officials stated that they could not provide support for the rate that the pharmacy was paid.

Without ensuring that pharmacy benefit claims are reimbursed at or below the appropriate payment rate, the WTCHP may overpay for pharmacy benefits.

¹⁹ During our audit period, the associated prescriber wrote two prescriptions for which the number of authorized refills was exceeded. In total, pharmacy benefit claims exceeded the prescribed number of refills five times (including our sample claim). The refills in excess of prescribed amounts totaled \$932.

²⁰ During our audit period, this pharmacy submitted 9,611 claims (including our sample claim), totaling \$2,933,957, that may not have been paid in accordance with the contracted rate.

Medical Services

The WTCHP reimburses costs for medical services according to payment rates established under FECA. Reimbursement must not exceed the established FECA rate (Zadroga Act, § 3312(c)(1)(A)). Beginning on October 22, 2012, NIOSH implemented internal controls at the claims processing level to ensure that payments did not exceed these rates. Specifically, the claims processor (CSC) used a computerized system loaded with FECA rates that prevented WTCHP payments from exceeding the FECA rates. For claims manually processed before October 22, 2012, the claims pricing was manually calculated by a claims processor; claims supervisors reviewed the claims pricing calculation for accuracy. However, this internal control was not always effective.

For one medical service claim associated with a NY Metro area member, which was processed before October 22, 2012, the WTCHP's payment for services was not paid at the appropriate rate. Specifically, the payment exceeded the appropriate FECA rate because, according to NIOSH officials, the claims processor made a manual keying error (i.e., clerical error) that was not detected by the claims supervisor.

Without ensuring that medical service claims were reimbursed at or below the appropriate payment rate, the WTCHP may have overpaid for medical services before October 22, 2012.

CONCLUSION

As the WTCHP expands its member enrollment and list of covered health conditions, including a number of cancers, it is reasonable to expect that the WTCHP's costs for services will increase. Therefore, significant Federal funds may be at risk if CDC does not implement internal controls to ensure that pharmacy benefits (1) are not paid if covered by other insurance, (2) are prescribed by a WTCHP-approved provider, (3) do not exceed prescribed levels, and (4) are paid at the appropriate rate.

RECOMMENDATIONS

We recommend that CDC:

- establish a procedure for collecting and transmitting NY Metro area members' prescription drug insurance coverage information to PBMs for benefits coordination,
- establish a procedure to ensure that Nationwide Network members' prescriptions are written by authorized WTCHP prescribers,
- require PBMs to establish procedures to prevent the authorized number of refills from being exceeded,
- establish a procedure for ensuring that pharmacy benefit claims are reimbursed at or below appropriate payment rates, and

- determine whether medical service claims processed before October 22, 2012, were reimbursed at or below the appropriate payment rate and recoup any overpayments.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CDC stated that it generally concurred with our recommendations and described actions that it had taken or planned to take to address them. Regarding our third recommendation, CDC stated that in April 2015 it had implemented edits to prevent prescription refills beyond the authorized number. For our fourth recommendation, CDC stated that it is transitioning to contract directly with one PBM, instead of subcontracting, to enable better control and oversight of the adjudication and payment of pharmacy claims. Regarding our fifth recommendation, CDC believes its established review process resulted in a high level of accuracy for medical service claims processed before October 22, 2012, but it acknowledged that the payment error we identified was not caught during the WTCHP review. CDC stated that it had taken action to recoup the overpayment identified during our audit.

However, we noted instances in which CDC offered possible solutions that do not fully address what we found. For our first recommendation, CDC did not identify proposed actions to address the lack of procedures for collecting and transmitting prescription drug insurance coverage information before payment of claims for NY Metro area members with active workers' compensation insurance. Further, CDC did not directly address our second recommendation to establish a procedure to ensure that Nationwide Network members' prescriptions are written by authorized WTCHP prescribers. Rather, CDC indicated that, to maintain continuity of care, it allows existing prescriptions to be filled for NY Metro area members who transfer to the National Network. CDC did not provide documentation to support that the claims identified in our draft report fell under this particular scenario.²¹

CDC also provided technical comments under separate cover. We addressed those, as appropriate. CDC's comments, except for technical comments, are included as Appendix C.

²¹ As described in footnote 18, we identified 2 providers who prescribed medication for 4 National Network members during our audit period, resulting in 88 pharmacy benefit claims totaling \$25,094. Neither provider was enrolled in the WTCHP. Both providers wrote the prescription associated with our sample claim and did not indicate that the prescription was an existing prescription that originated at a NY Metro area clinic.

APPENDIX A: OVERVIEW OF INTERNAL CONTROLS

INTERNAL CONTROLS IN THE FEDERAL GOVERNMENT²²

Internal controls are an integral component of an organization's management that provide reasonable, not absolute, assurance that the following objectives of an agency are being achieved: (1) effectiveness and efficiency of operations, (2) reliability of financial reporting, and (3) compliance with applicable laws and regulations.

Internal controls are plans, policies, methods, and procedures used to meet the organization's mission, goals, and objectives. They include the processes and procedures for planning, organizing, directing, and controlling program operations and management's system for measuring, reporting, and monitoring program performance.

A deficiency in an internal control exists when the design, implementation, or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to achieve control objectives and address related risks.

FIVE COMPONENTS OF INTERNAL CONTROL²³

Internal control consists of five interrelated components:

- **Control Environment:** The set of standards, processes, and structures that provide the basis for carrying out internal control across the organization. The control environment includes factors such as the organizational structure, assignment of authority and responsibilities, and ethical value.
- **Risk Assessment:** The process for identifying and assessing risks to achieve objectives, which is a basis for determining how the risks should be managed.
- **Control Activities:** The actions established through policies and procedures that help ensure management's directives to mitigate risks to the achievement of objectives are carried out. These activities include authorizations and approvals, verifications, and reconciliations.
- **Information and Communication:** Management uses relevant and quality information to support functioning of other internal control components. Communication is the process of providing, sharing, and obtaining necessary information.
- **Monitoring:** Ongoing or separate evaluations, or both, to ascertain whether the components are present and functioning.

²² Government Accountability Office, *Standards for Internal Control in the Federal Government*, November 1999, and *Government Auditing Standards*, December 2011.

²³ Committee of Sponsoring Organizations of the Treadway Commission, *Internal Control—Integrated Framework*, "Executive Summary," May 2013.

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered WTCHP claims paid by NGS from October 1, 2012, through March 31, 2014. We did not perform an overall assessment of the internal control structures of NIOSH, WTCHP-contracted entities, or CMS. Rather, we limited our review to those internal controls related to member enrollment, provision of services, and claims reimbursement. In our review, we focused on control activities, which is one of the five components of internal controls, as described in Appendix A.

To determine the effectiveness of internal controls over the WTCHP, we:

- tested controls by reviewing a sample of 45 claims randomly selected from the WTCHP claim payment system that were paid by NGS from October 1, 2012, through March 31, 2014, and
- performed other audit procedures, which included interviews with NIOSH, CMS, NGS, CSC, CCE, LHI, and DOJ officials, and reviews of eligibility records, health condition certification records, and supporting claim documentation.

Our attribute sampling approach is commonly used to test the effectiveness of internal controls for compliance with laws, regulations, and policies. According to the Government Accountability Office and President's Council on Integrity and Efficiency's *Financial Audit Manual* (July 2008), section 450, auditors may use a randomly selected sample of 45 items to perform a review of compliance controls. If all sample items are determined to be in compliance with requirements, a conclusion that the controls are effective can be made. If one or more sample items are determined not to be in compliance with requirements, a conclusion that the controls are ineffective can be made. Our sampling methodology was limited to forming an opinion about whether the internal controls at NIOSH were effective and was not designed to estimate the percentage of claims paid inappropriately.

For the 45 sample claims,²⁴ we reviewed supporting documentation to evaluate whether the member was eligible, the service was related to a certified health condition, and the payment met selected billing requirements. Our review of internal controls would not necessarily have detected all internal control deficiencies because internal controls provide only reasonable assurance that NIOSH complied with Federal requirements.

We conducted our audit from June 2014 through July 2015 at NIOSH administrative offices in Atlanta, Georgia; CMS administrative offices in Baltimore, Maryland; and at six²⁵ CCEs throughout the New York/New Jersey area.

²⁴ The sample included 26 pharmacy benefit and 19 medical service claims.

²⁵ Only six of the seven CCEs appeared in our statistical sample.

METHODOLOGY

To accomplish our objective, we:

- reviewed relevant Federal laws and regulations, including the Government Accountability Office's *Standards for Internal Control in the Federal Government: 1999*;
- reviewed WTCHP contracts awarded to CSC, the CCEs, and LHI;
- assessed internal controls by:
 - interviewing officials from NIOSH, CMS, NGS, CSC, CCEs, LHI, and DOJ to gain an understanding of WTCHP internal controls related to member enrollment, provision of services, and claims reimbursement and
 - reviewing NIOSH-issued policy and procedure documents;
- obtained from NIOSH a database of 708,157 WTCHP claims, totaling \$140,535,932 (363,445 pharmacy benefit claims totaling \$66,206,044 and 344,712 medical services claims totaling \$74,329,888), that were paid from October 1, 2012, through March 31, 2014;
- performed tests, such as data validation checks and a reconciliation to previously reported numbers in the Government Accountability Office report GAO-14-606, issued in July 2014, to determine whether the claims data were reliable;
- performed testing of internal controls used by NIOSH to detect inappropriate billing and payment for services by:
 - randomly selecting 45 claims (26 pharmacy benefits and 19 medical services) paid from October 1, 2012, through March 31, 2014, using OIG, Office of Audit Services, statistical software, and
 - obtaining and reviewing supporting documentation for each claim that we sampled to determine whether the member was eligible, the treatment was for a documented WTC-related health condition, and the payment met selected billing requirements; and
- discussed the results of our review with NIOSH officials.

We conducted this performance audit 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.

APPENDIX C: CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

TO: Inspector General, U.S. Department of Health and Human Services

FROM: Director, Centers for Disease Control and Prevention (CDC)

DATE: August 18, 2016

SUBJECT: General Comments of the Centers for Disease Control and Prevention (CDC) on the Department of Health and Human Services (HHS) Office of the Inspector General's (OIG) Draft Report, *Not All Internal Controls Implemented by CDC Were Effective in Ensuring That World Trade Center Health Program Pharmacy and Medical Claims Were Paid According to Federal Requirements* (A-02-14-02008)

The Centers for Disease Control and Prevention (CDC) wishes to thank the Office of the Inspector General (OIG) for the opportunity to review and comment on this draft report. CDC generally concurs with the OIG's recommendations and submits the following general comments.

With regard to the recommendation to establish a procedure for collecting and transmitting prescription drug insurance coverage information to the Pharmacy Benefits Managers (PBMs) for benefit coordination (for non-work-related health conditions/survivors), CDC is in the process of transitioning to a new PBM and exploring how best to implement this recommendation. Possible solutions may include:

- Educating World Trade Center Health Program (WTCHP) survivor members about coordination of benefits of pharmaceutical benefits;
- Asking WTCHP survivor members insurance questions at the point of sale of the prescription (and tracking responses);
- Collecting non-WTCHP pharmacy benefits information from the Clinical Centers of Excellence (CCEs)/Nationwide Provider Network (NPN) that provide services to WTCHP survivor members; and
- Expanding the current WTCHP process that recoups from workers' compensation (WC) carriers the cost of pharmacy claims for health conditions that are work-related to one that recoups from non-WC insurance carriers the cost of pharmacy claims for health conditions that are not work-related.

With regard to the recommendation to establish a procedure that the NPN members' prescriptions be written by authorized WTCHP prescribers, all providers who are part of the NPN are authorized to write prescriptions for WTCHP members based on the conditions that are certified for a member and the corresponding formulary for that member. If the provider has not previously submitted a medical service claim related to a member's health care, that provider must be registered in the WTCHP before a medical claim will be processed; however, the NPN

provider does not need to be registered with the WTCHP prior to writing a prescription. In situations where members transfer to the NPN from a Clinical Center of Excellence (CCE), any existing prescriptions are allowed to be filled in order to maintain continuity of care. Thus, there may be instances where the prescriber is not included in the NPN, but the prescriber's authorization remains valid.

With regard to the recommendation to require the PBMs to establish procedures to prevent the authorized number of refills from being exceeded, the WTCHP implemented edits in April 2015 that prevent prescription refills beyond the authorized number indicated on the original prescription. These edits are still in place and the WTCHP is working with the new PBM to maintain current, and potentially add new, controls.

With regard to the recommendation to establish a procedure for ensuring that pharmacy benefit claims are reimbursed at or below the appropriate payment rates, the claim discovered by the OIG occurred before the WTCHP had a centralized PBM for all New York metro area members. The identified claim was processed and paid for through one of the CCE's PBMs that had been in place prior to the passing of the Zadroga Act. Therefore, the contract and negotiated rates were established between the CCE and the PBM. After that point, the WTCHP used one centralized PBM for all New York metro area CCEs and a separate PBM for the NPN. The WTCHP is currently transitioning to one PBM for all CCEs and the NPN; the WTCHP will contract directly with that PBM, not subcontract through another contract. The WTCHP decided to have a direct contract with one PBM for all CCEs and the NPN to enable better control and oversight of adjudication and payment of pharmacy claims and easier access to complete pharmacy data.

With regard to the recommendation to determine if medical service claims processed before October 22, 2012, were reimbursed at or below the appropriate rate and to recoup any overpayments that occurred, all claims processed before this date were examined by a team of claim reviewers and a supervisor for accuracy, including the pricing amount, before the claims were sent for payment. The WTCHP acknowledges that the claim payment error identified by the OIG was not caught during that review process, but the WTCHP believes the process resulted in a high level of accuracy. For this particular claim, the WTCHP recouped the overpayment by reducing payment for a future claim to the same provider by an amount equal to the overpayment.



Thomas R. Frieden, MD, MPH