

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE IMPROPERLY PAID
PROVIDERS FOR SPECIMEN VALIDITY
TESTS BILLED IN COMBINATION WITH
URINE DRUG TESTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Daniel R. Levinson
Inspector General

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A-09-16-02034

Office of Inspector General

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Report in Brief

Date: February 2018
Report No. A-09-16-02034

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

Specimen validity testing is used to analyze urine specimens to determine whether they have been adulterated or tampered with. Prior OIG work found that Medicare improperly paid providers that had billed for medically unnecessary specimen validity tests in combination with urine drug tests. Our preliminary review of claims for this audit identified other providers (i.e., clinical laboratories and physician offices) that billed for specimen validity tests that were at risk of noncompliance with Medicare billing requirements.

Our objective was to determine whether payments made to providers for specimen validity tests complied with Medicare billing requirements.

How OIG Did This Review

Our audit covered \$67 million in Medicare Part B payments for tests that we identified as those that can be used to perform specimen validity testing billed in combination with urine drug tests and that had dates of service from calendar years 2014 through 2016. The same individual tests used for specimen validity testing may be medically necessary if performed to diagnose certain conditions. If a claim line for a specimen validity test included a diagnosis code that indicated the test might have been medically necessary, we removed the claim line from our review. After removing such claim lines, we arrived at a population of claims with Medicare payments totaling \$66.3 million.

Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests

What OIG Found

Payments made to providers for specimen validity tests did not comply with Medicare billing requirements. Specifically, Medicare improperly paid 4,480 clinical laboratories and physician offices a total of \$66.3 million for specimen validity tests billed in combination with urine drug tests. Centers for Medicare & Medicaid Services (CMS) officials explained that medically necessary tests used to diagnose certain conditions (which include the same tests that can be used to validate urine specimens) that are performed on the same day as a urine drug test for a single beneficiary should be a rare occurrence.

The improper payments occurred because providers did not follow existing Medicare guidance, and CMS's system edits were not adequate to prevent payment for specimen validity tests billed in combination with urine drug tests. Improper payments decreased but continued to be made during our audit period as Medicare guidance was updated and CMS introduced new automated system edits. Although CMS implemented on April 1, 2016, a system edit designed to identify and prevent these improper payments, we still identified \$1.8 million in improper payments from April 1 through December 31, 2016. At this observed rate, these improper payments would total \$12.1 million over a 5-year period. By strengthening its system edits and educating providers on properly billing for specimen validity and urine drug tests, CMS could save an estimated \$12.1 million over 5 years.

What OIG Recommends and CMS Comments

We recommend that CMS (1) direct the Medicare contractors to recover the \$66.3 million in identified improper payments and (2) strengthen its system edits to prevent improper payments for specimen validity tests and instruct the Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests, which could result in savings of an estimated \$12.1 million over a 5-year period.

CMS concurred with both of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. CMS stated that a medical review would be necessary to determine whether claims were paid properly and requested that we provide the necessary data to follow up on the status of the payments. We will provide the necessary data to CMS.

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INTRODUCTION

WHY WE DID THIS REVIEW

Specimen validity testing is used to analyze urine specimens to determine whether they have been adulterated or tampered with.¹ Prior Office of Inspector General work found that Medicare improperly paid providers that had billed for medically unnecessary specimen validity tests in combination with urine drug tests. Our preliminary review of claims for this audit identified other providers (i.e., clinical laboratories and physician offices) that billed for specimen validity tests that were at risk of noncompliance with Medicare billing requirements.

OBJECTIVE

Our objective was to determine whether payments made to providers for specimen validity tests complied with Medicare billing requirements.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Medicare Part B provides supplementary medical insurance for medical and other health services, including clinical laboratory tests performed in a laboratory or a physician's office. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

CMS contracts with 8 Medicare administrative contractors (Medicare contractors) for 12 jurisdictions² to, among other things, process and pay Medicare Part B claims,³ conduct reviews and audits, safeguard against fraud and abuse, and educate providers on Medicare billing requirements. As part of claim processing, the Medicare contractors' responsibilities include implementing certain automated edits, such as system checks to prevent or reduce improper payments by identifying and addressing provider billing errors. These edits flag claim lines for automatic denial or for Medicare contractor review to ensure that the claim lines are

¹ Specimen validity testing includes tests for urinary pH, specific gravity, creatinine, and oxidants. For example, a urinary pH test determines the degree of acidity or alkalinity of a urine sample. If the pH levels are outside the normal range, the sample may have been altered.

² For each jurisdiction, CMS enters into a contract with one entity to serve as the Medicare contractor. Although there are 12 jurisdictions, there are only 8 Medicare contractors because 4 Medicare contractors have been awarded contracts for 2 jurisdictions each. CMS Jurisdiction Map, available at <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-MAC-Jurisdiction-Map-Dec-2015.pdf>. Accessed on July 21, 2017.

³ Each claim contains details regarding each provided service (called a claim line in this report).

appropriate. Some of these edits are required by CMS, and others are initiated by the Medicare contractors.

Medicare Requirements for Part B Claims

To be paid under Medicare, a service must be reasonable and necessary for the diagnosis or treatment of illness or injury (the Social Security Act (the Act) § 1862(a)(1)(A)). More specifically, to be covered under Medicare Part B, clinical laboratory tests must be ordered by a physician who is treating a beneficiary for a specific medical problem and who uses the results in the management of that problem (42 CFR § 410.32(a); *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 80.1). Tests must be related to the beneficiary's illness or injury (or symptom or complaint) (*Medicare Claims Processing Manual* (Claims Manual), Pub. No. 100-04, chapter 16, § 10).

Providers must use the appropriate Healthcare Common Procedure Coding System (HCPCS) code on claim forms for most outpatient services (Claims Manual, chapter 23, § 20.3).⁴ The Act precludes payment to any provider of services or other person without information necessary to determine the amount due such provider or other person (§ 1833(e)).

Urine Drug Testing and Specimen Validity Testing

Urine drug testing provides objective information to assist providers in identifying the presence or absence of drugs or drug classes in the body or to identify the specific quantity of a drug or drug class present in the body. Urine drug testing may be a medically necessary and useful procedure for providers in making treatment decisions.

Specimen validity testing is used to analyze a urine specimen to ensure that it is consistent with normal human urine and has not been adulterated or tampered with. The same tests used for specimen validity testing (e.g., the tests for urinary pH and specific gravity) may be medically necessary if used to diagnose certain conditions, such as a urinary tract infection, kidney stones, or rheumatoid arthritis.⁵ For example, tests for urinary pH and specific gravity may be performed to diagnose diseases of the kidney and urinary system. If these tests are used for diagnosis, treatment, or management, they may be Medicare-covered services. However, when used for the purpose of determining whether a specimen is adulterated, the test results are not being used to manage a beneficiary's specific medical problem. In these cases, specimen validity testing is not a separately billable Medicare-covered service.

⁴ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

⁵ Local Coverage Determination (LCD): Urinalysis (L34029). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34029>. Accessed on August 2, 2017.

Medicare Guidance and CMS's System Edits Related to Specimen Validity Testing

CMS and most Medicare contractors have issued additional guidance that specifically addresses specimen validity testing. Most Medicare contractors' LCDs,⁶ which include descriptions of Medicare's coverage of qualitative drug screening and controlled substance monitoring, specify that tests to validate urine specimens are not allowable. Specifically, by the end of calendar year (CY) 2016, all but one Medicare contractor had at least one LCD containing such language. The earliest effective date for this language in an LCD was January 25, 2010 (First Coast Service Options, Inc.'s LCD 30574). By the end of CYs 2014, 2015, and 2016, the number of Medicare contractors that had such language in at least one of their LCDs was three, six, and seven, respectively.

In CYs 2015 and 2016, CMS updated its billing requirements, HCPCS codes, and system edits to prevent improper payments for specimen validity tests billed in combination with urine drug tests:

- In CY 2015, CMS issued new requirements in its *National Correct Coding Initiative Policy Manual for Medicare Services* (Coding Policy Manual), revised Jan. 1, 2015, chapter 10, section E, which states: "Providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing."⁷
- In CY 2016, CMS created new HCPCS codes for certain urine drug tests. These HCPCS codes include specimen validity testing in their code descriptions and payments, regardless of whether specimen validity testing is performed.⁸
- Effective April 2016, CMS implemented NCCI automated system edits⁹ at the Medicare contractors to help identify and prevent most improper payments for specimen validity

⁶ Medicare contractors issue LCDs that limit coverage for a particular item or service. LCDs must be consistent with all statutes, rulings, regulations, and national policies for coverage, payment, and coding. The coverage policy created by an LCD is applicable only in the States within a Medicare contractor's jurisdiction. (*Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 13, § 13.1.3.)

⁷ CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to control improper coding leading to inappropriate payment of Medicare Part B claims. CMS annually updates the Coding Policy Manual. According to the CMS website, Medicare contractors should use the Coding Policy Manual as a general reference tool that explains the rationale for NCCI edits.

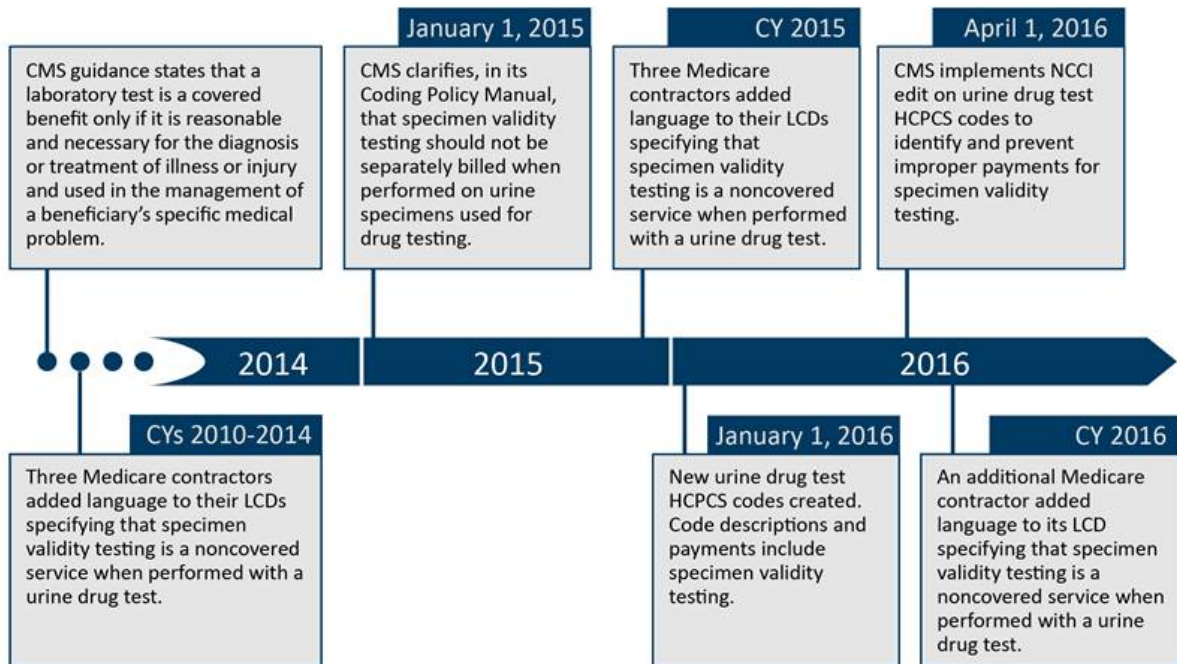
⁸ The Claims Manual, Transmittal 3439, Change Request 9502, January 15, 2016. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3439CP.pdf>. Accessed on July 21, 2017.

⁹ NCCI edits include procedure-to-procedure edits that define pairs of HCPCS codes (code pairs) that generally should not be reported together for the same beneficiary on the same date of service. In certain circumstances, a provider may include a modifier that allows both services in a code pair to be reported so that the claim can bypass the procedure-to-procedure code-pair edit. (The modifier should be used only if the clinical circumstances justify its use.) A modifier is a two-digit code that further describes the service performed.

tests billed in combination with urine drug tests.¹⁰ These edits are designed to deny claim lines for specimen validity tests billed by the same provider for the same beneficiary on the same date of service as a urine drug test. Payment for specimen validity testing is already included in the HCPCS codes for urine drug tests.

See Figure 1 below for a timeline of CMS’s changes to the billing requirements, HCPCS codes, and system edits for specimen validity tests billed in combination with urine drug tests.

Figure 1: Timeline of CMS’s Changes to Billing Requirements, HCPCS Codes, and System Edits for Specimen Validity Tests Billed in Combination With Urine Drug Tests



¹⁰ <https://www.cms.gov/Medicare/Coding/NationalCorrectCodinitEd/NCCI-Coding-Edits.html>. Accessed on July 21, 2017.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$67,009,401 in Medicare Part B payments for tests that we identified as those that can be used to perform specimen validity testing (e.g., tests for urinary pH and specific gravity) billed in combination with urine drug tests and that had dates of service from CYs 2014 through 2016 (audit period). The same individual tests used for specimen validity testing may be medically necessary if performed to diagnose certain conditions. CMS officials explained that medically necessary tests used to diagnose certain conditions that are performed on the same day as a urine drug test for a single beneficiary should be a rare occurrence. If a claim line for a specimen validity test included a diagnosis code¹¹ that indicated the test might have been medically necessary, we removed the claim line from our review. After removing such claim lines, we arrived at a population of claims with Medicare payments totaling \$66,309,751. These payments were made to 4,480 providers, consisting of clinical laboratories and physician offices.¹²

We did not review entire claims; rather, we reviewed specific claim lines within the claims. A claim line represented a single specimen validity test that was paid in combination with a paid urine drug test for a single beneficiary on a single date of service at a single provider (some claims had claim lines for more than one specimen validity test).¹³ We did not perform medical review to determine medical necessity for either the urine drug tests or specimen validity tests performed, nor did we review any claim line for which the specimen validity test was paid but the urine drug test was not paid.

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 A contains the details of our audit scope and methodology.

¹¹ Diagnosis codes are standardized codes used to describe diagnoses for medical conditions. The top two diagnosis codes associated with specimen validity tests billed in combination with urine drug tests were V5869 (long-term (current) use of other medications) and V5883 (encounter for therapeutic drug monitoring). The specimen validity tests associated with these two diagnosis codes would not be considered medically necessary.

¹² We defined a provider by the Federal tax identification number rather than the National Provider Identifier (NPI). The actual number of providers may be higher than 4,480 because a single tax identification number could be associated with more than 1 NPI.

¹³ A specimen validity test could have been billed on the same claim as the urine drug test or on a different claim.

FINDINGS

Payments made to providers for specimen validity tests did not comply with Medicare billing requirements. Specifically, Medicare improperly paid providers a total of \$66,309,751 for specimen validity tests billed in combination with urine drug tests.

These improper payments occurred because providers did not follow existing Medicare guidance, and CMS's system edits were not adequate to prevent payment for specimen validity tests billed in combination with urine drug tests. Although CMS implemented on April 1, 2016, a system edit designed to identify and prevent these improper payments, our data analysis showed that specimen validity tests continued to be improperly billed and paid after that date.

FEDERAL REQUIREMENTS

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act § 1862(a)(1)(A)). More specifically, Medicare Part B covers clinical laboratory tests only if the treating physician uses the test results in the management of the beneficiary's specific medical problem (42 CFR § 410.32(a); *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 80.1). Tests must be related to the beneficiary's illness or injury (or symptom or complaint) (Claims Manual, chapter 16, § 10).

In addition to the Federal requirements listed above, further Medicare guidance was issued before and during our audit period to clarify that specimen validity testing to determine whether urine has been adulterated is not a Medicare-covered service. For example, by the end of CY 2014, three Medicare contractors' LCDs had added language that specimen validity testing was a noncovered service when performed in combination with urine drug tests; by the end of CY 2016, seven Medicare contractors had at least one LCD containing similar language.

Further, in January 2015, CMS revised its Coding Policy Manual to state the following:

Providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing. For example, if a laboratory performs a urinary pH [test] . . . to confirm that a urine specimen is not adulterated, this testing is not separately billed. . . . [A] laboratory test is a covered benefit only if the test result is utilized for management of the beneficiary's specific medical problem. Testing to confirm that a urine specimen is unadulterated is an internal control process that is not separately reportable. (Coding Policy Manual, revised Jan. 1, 2015, chapter 10, § E.)

PAYMENTS MADE FOR SPECIMEN VALIDITY TESTS DID NOT COMPLY WITH MEDICARE BILLING REQUIREMENTS

Medicare improperly paid 4,480 providers a total of \$66,309,751 for specimen validity tests billed in combination with urine drug tests. CMS officials explained that medically necessary tests used to diagnose certain conditions (which include the same tests that can be used to validate urine specimens) that are performed on the same day as a urine drug test for a single beneficiary should be a rare occurrence. Although during our audit period, CMS made changes to its billing requirements, HCPCS codes, and system edits for specimen validity tests billed in combination with urine drug tests, our data analysis showed that specimen validity tests continued to be improperly billed and paid. (See the table below.)

Table: Improper Payments for Specimen Validity Tests by Year

Calendar Year	Payments for Specimen Validity Tests Billed in Combination With Urine Drug Tests
2014	\$37,054,887
2015	24,919,836
2016	4,335,028
Total	\$66,309,751

For our audit period, approximately 91 percent of the improper payment amount was paid to providers that routinely billed specimen validity tests in combination with urine drug tests. In addition, all of the Medicare contractors made payments for specimen validity tests billed in combination with urine drug tests throughout our audit period.

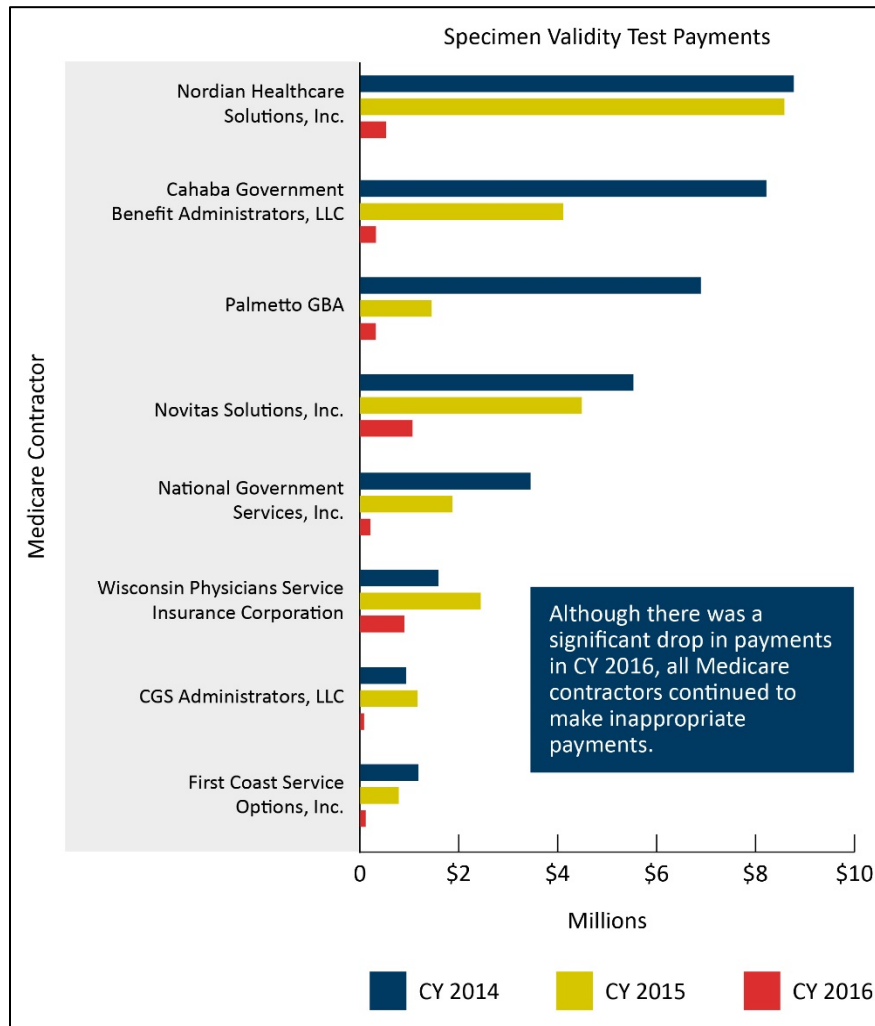
Almost All of the Improper Payments Were Made to Providers That Routinely Billed Specimen Validity Tests in Combination With Urine Drug Tests

For our audit period, of the \$66,309,751 in improper payments, \$60,156,614, or approximately 91 percent, was paid to providers that routinely billed specimen validity tests in combination with urine drug tests. We considered a provider to be a routine biller if, out of the total number of urine drug tests performed for a single beneficiary on a single day (urine drug test encounters), specimen validity tests were billed in combination with those urine drug test encounters 50 percent or more of the time.

All of the Medicare Contractors Paid for Specimen Validity Tests Billed in Combination With Urine Drug Tests

All of the Medicare contractors paid for specimen validity tests billed in combination with urine drug tests throughout our audit period. Figure 2 on the following page shows the \$66,309,751 of improper payments by Medicare contractor and calendar year for specimen validity tests that were billed in combination with urine drug tests.

Figure 2: Improper Payments by Medicare Contractor for Specimen Validity Tests Billed in Combination With Urine Drug Tests (CYs 2014 Through 2016)



MEDICARE GUIDANCE AND CMS’S SYSTEM EDITS DID NOT PREVENT IMPROPER PAYMENTS FOR SPECIMEN VALIDITY TESTS

Medicare improperly paid \$66,309,751 for specimen validity tests billed in combination with urine drug tests because providers did not follow existing Medicare guidance, and CMS’s system edits were not adequate to prevent the improper payments. The following shows that the improper payments decreased but continued to be made during our audit period as Medicare guidance was updated and CMS introduced new automated system edits:

- January 1 through December 31, 2014.** Medicare made improper payments of \$37,054,887, resulting in average monthly improper payments of \$3,087,907. During this period, three Medicare contractors had language in their LCDs specifying that specimen validity testing was a noncovered service with respect to urine drug tests.

Although there was no specific CMS guidance that related to specimen validity tests billed in combination with urine drug tests, a laboratory test was a covered benefit under Medicare only if it was reasonable and necessary for the diagnosis or treatment of illness or injury and was used to manage a beneficiary's specific medical problem.

- **January 1 through December 31, 2015.** Medicare made improper payments of \$24,919,836, resulting in average monthly improper payments of \$2,076,653. During this period, an additional three Medicare contractors added language to their LCDs specifying that specimen validity testing was a noncovered service with respect to urine drug tests. In addition, CMS issued guidance stating that providers that performed specimen validity testing on urine specimens should not separately bill for the tests.
- **January 1 through March 31, 2016.** Medicare made improper payments of \$2,513,018, resulting in average monthly improper payments of \$837,673. During this period, CMS introduced new HCPCS codes for urine drug tests that included specimen validity testing in their code descriptions and payments.
- **April 1 through December 31, 2016.** Medicare made improper payments of \$1,822,010, resulting in average monthly improper payments of \$202,446. At the beginning of this period, CMS implemented NCCI automated system edits to prevent improper payments for specimen validity tests billed by the same provider for the same beneficiary on the same date of service as a urine drug test. Payment for specimen validity testing was now included in the code for urine drug testing. The providers that inappropriately continued to bill specimen validity tests in combination with urine drug tests included a two-digit modifier to bypass the edits. These payments were improper because the diagnosis codes reported on the claims were not related to conditions for which specimen validity tests may have been medically necessary. By the end of this period, seven Medicare contractors had at least one LCD with language specifying that specimen validity testing was a noncovered service with respect to urine drug tests.

Although CMS implemented system edits, we still identified \$1,822,010 in improper payments from April 1 through December 31, 2016. At this observed rate, these improper payments would total \$12,146,760 over a 5-year period.¹⁴ CMS could reduce or eliminate these potential improper payments by strengthening its system edits to prevent improper payments for specimen validity tests and instructing the Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests.

¹⁴ On the basis of the \$1,822,010 of improper payments made from April 1 through December 31, 2016, we calculated savings of \$202,446 per month. Over a 5-year period (or 60 months), savings to the Medicare program would total \$12,146,760 assuming similar conditions exist throughout the period.

RECOMMENDATIONS

We recommend that CMS:

- direct the Medicare contractors to recover the \$66,309,751 in identified improper payments and
- strengthen its system edits to prevent improper payments for specimen validity tests and instruct the Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests, which could result in savings of an estimated \$12,146,760 over a 5-year period.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with both of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations:

- Regarding our first recommendation, CMS stated that a medical review would be necessary to determine whether claims were paid properly. CMS requested that we provide the necessary data to follow up on the status of the payments and stated that it would work with its contractors to recoup identified overpayments in accordance with its policies and procedures.
- Regarding our second recommendation, CMS stated that it would examine the possibility of additional system edits to prevent improper payments for specimen validity tests and would work with its contractors to provide national education on properly billing for urine drug tests.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix B.

Regarding our first recommendation, we will provide the necessary data to CMS.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$67,009,401 in Medicare Part B payments for tests that we identified as those that can be used to perform specimen validity testing (e.g., tests for urinary pH and specific gravity) billed in combination with urine drug tests and that had dates of service from CYs 2014 through 2016. The same individual tests used for specimen validity testing may be medically necessary if performed to diagnose certain conditions. CMS officials explained that medically necessary tests used to diagnose certain conditions that are performed on the same day as a urine drug test for a single beneficiary should be a rare occurrence. If a claim line for a specimen validity test included a diagnosis code¹⁵ that indicated the test might have been medically necessary, we removed the claim line from our review. After removing such claim lines, we arrived at a population of claims with Medicare payments totaling \$66,309,751. These payments were made to 4,480 providers, consisting of clinical laboratories and physician offices.¹⁶

We did not review entire claims; rather, we reviewed specific claim lines within the claims. A claim line represented a single specimen validity test that was paid in combination with a paid urine drug test for a single beneficiary on a single date of service at a single provider (some claims had claim lines for more than one specimen validity test).¹⁷

We did not perform medical review to determine medical necessity for either the urine drug tests or specimen validity tests performed, nor did we review any claim line for which the specimen validity test was paid but the urine drug test was not paid.

We did not review the overall internal control structure of CMS because our objective did not require us to do so. Rather, we limited our review of CMS's internal controls to those applicable to claims submitted for specimen validity tests billed in combination with urine drug tests. Our review enabled us to establish reasonable confidence in the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file for our audit period, but we did not assess the completeness of the file.

We conducted our audit from June 2016 through March 2017.

¹⁵ Diagnosis codes are standardized codes used to describe diagnoses for medical conditions. The top two diagnosis codes associated with specimen validity tests billed in combination with urine drug tests were V5869 (long-term (current) use of other medications) and V5883 (encounter for therapeutic drug monitoring). The specimen validity tests associated with these two diagnosis codes would not be considered medically necessary.

¹⁶ We defined a provider by the Federal tax identification number rather than the NPI. The actual number of providers may be higher than 4,480 because a single tax identification number could be associated with more than 1 NPI.

¹⁷ A specimen validity test could have been billed on the same claim as the urine drug test or on a different claim.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS program officials to obtain an understanding of the billing requirements, system edits, and HCPCS codes used for specimen validity and urine drug tests;
- used CMS's NCH file to identify claim lines for specimen validity tests that were billed in combination with urine drug tests for a single beneficiary on a single date of service at a single provider;
- used computer matching, data mining, and other analytical techniques to identify claim lines totaling \$67,009,401 potentially at risk for noncompliance with Medicare billing requirements;
- removed claim lines with diagnosis codes related to conditions for which the specimen validity testing may have been medically necessary, resulting in a total of \$66,309,751 in Medicare payments for specimen validity tests; and
- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government accounting 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: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: NOV 29 2017

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma *SV*
Administrator

SUBJECT: "Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests" (A-09-16-02034)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to protecting the Medicare Trust Funds by combatting fraud, waste, and abuse.

Under federal law and regulations, a service must be reasonable and necessary for the diagnosis or treatment of illness or injury in order to qualify for Medicare payment. To be covered by Medicare, laboratory tests must be ordered by the physician who is treating the beneficiary, and the physician must use the results in the management of the beneficiary's specific medical problem.

Medicare does not pay for separately billed laboratory tests associated with specimen validity testing when performed solely to determine whether a specimen is adulterated, because the validity test alone is not used for the diagnosis or treatment of an illness or injury. It is important to note that these tests can be medically necessary to diagnose certain conditions, such as urinary tract infections or kidney stones. For that reason, providers may use a modifier code to bill these laboratory tests in combination with urine drug tests, only if the clinical circumstances justify use of modifier.

As a result of annual reviews of Healthcare Common Procedure Code System utilization, CMS implemented additional procedures to assist in preventing potential improper payments. Changes included new requirements in the National Correct Coding Initiative Policy Manual for Medicare Services to clarify that providers performing validity testing on urine specimens for drug testing should not separately bill the validity testing, new Healthcare Common Procedure Coding System codes that include specimen validity testing in their code descriptions and payments, and automated system edits that deny claim lines for specimen validity tests billed by the same provider for the same beneficiary on the same date of service as a urine drug test. In addition, CMS plans to further update the National Correct Coding Initiative Policy Manual for Medicare Services to strengthen language prohibiting separate billing of validity testing of urine specimens used for drug testing. Once those changes are in place, CMS will educate providers on how to properly bill Medicare for specimen validity testing and urine drug tests.

OIG's recommendations and CMS's responses are below.

OIG Recommendation

CMS should direct the Medicare contractors to recover the \$66,309,751 in identified improper payments.

CMS Response

CMS concurs with the recommendation. However, medical review would be necessary to determine if these claims were paid properly as OIG examined only specific claim lines and it would be necessary to review the entire claim to verify whether a relevant diagnosis code is present. CMS requests that OIG furnish the necessary data to follow up on the status of the payments. Upon receipt of the files from OIG, CMS will work with its contractors to recoup identified overpayments in accordance with the agency's policies and procedures.

OIG Recommendation

CMS should strengthen its system edits to prevent improper payments for specimen validity tests and instruct the Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests, which could result in savings of an estimated \$12,146,760 over a 5-year period.

CMS Response

CMS concurs with this recommendation. CMS will examine the possibility of additional system edits to prevent improper payments for specimen validity tests, while protecting beneficiary access to care and reducing provider burden. CMS will also work with contractors to provide national education to providers on properly billing for urine drug tests.