

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COULD HAVE SAVED UP TO
\$216 MILLION OVER 5 YEARS
IF PROGRAM SAFEGUARDS HAD
PREVENTED AT-RISK PAYMENTS
FOR DEFINITIVE DRUG
TESTING SERVICES**

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



Amy J. Frontz
Deputy Inspector General
for Audit Services

February 2023
A-09-21-03006

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: February 2023

Report No. A-09-21-03006

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



Why OIG Did This Audit

Drug testing is generally used to detect the presence or absence of drugs in patients undergoing treatment for pain management or substance use disorders. Medicare payments for definitive drug testing services increase based on the number of drug classes tested. The Centers for Medicare & Medicaid Services (CMS) identified overpayments for the definitive drug testing service with the highest reimbursement amount (procedure code G0483, definitive drug testing for 22 or more drug classes) due to noncompliance with Medicare requirements. In addition, a prior OIG report on drug testing services identified that payments for G0483 were at risk for overpayments.

Our objective was to identify Medicare Part B payments for definitive drug testing services that were at risk for noncompliance with Medicare requirements.

How OIG Did This Audit

Our audit covered \$3 billion in Medicare Part B payments for definitive drug testing services with dates of service from January 2016 through December 2020 (audit period). These payments were made to 1,062 “at-risk providers,” which routinely billed procedure code G0483 (for 75 percent or more of their definitive drug testing services), and 4,227 “other providers,” which did not routinely bill this service. We compared characteristics of the at-risk providers and other providers.

Medicare Could Have Saved up to \$216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services

What OIG Found

For the 5-year audit period, Medicare paid \$704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements. Specifically, these payments were for the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments were made to 1,062 at-risk providers that routinely billed this procedure code and may not have been reasonable and necessary. We determined that presumptive drug testing preceded most definitive drug testing services billed by both the at-risk and other providers. However, the at-risk providers may not have always used presumptive testing to determine the number of drug classes that needed to be tested using definitive drug testing, because they routinely billed for testing 22 or more drug classes using G0483 and the other providers did not. Although the at-risk providers billed a significantly higher percentage of definitive drug testing services using G0483 than the other providers, the at-risk and other providers had similar characteristics (such as the types of patients they tested and the frequency of testing). This suggests that the at-risk providers may have been able to bill for definitive drug testing services using primarily procedure codes with lower reimbursement amounts, as the other providers did.

If CMS’s program safeguards had focused on at-risk payments to at-risk providers for procedure code G0483, Medicare could have saved up to \$215.8 million for our audit period.

What OIG Recommends and CMS Comments

We recommend that CMS: (1) expand program safeguards to prevent and detect at-risk payments to at-risk providers for procedure code G0483; (2) review at-risk payments made to at-risk providers during and after our audit period and recover any overpayments; (3) notify appropriate providers to exercise reasonable diligence to identify, report, and return any overpayments; and (4) educate providers that received payments that did not comply with Medicare requirements.

CMS concurred with our first recommendation and provided information on corrective actions it had taken or planned to take, did not concur with our second and third recommendations, and did not state whether it concurred with our fourth recommendation but provided information on corrective actions it had taken or planned to take. After reviewing CMS’s comments, we maintain that our second and third recommendations are valid.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	2
The Medicare Program and the Role of the Centers for Medicare & Medicaid Services.....	2
Drug Testing Services.....	2
Medicare Coverage of Drug Testing Services.....	3
CMS Program Safeguards.....	4
Prior Office of Inspector General Report on Drug Testing Services for Beneficiaries With Substance Use Disorders.....	6
Medicare Requirements for Providers To Identify and Return Overpayments.....	7
How We Conducted This Audit.....	8
FINDINGS.....	9
Medicare Paid Hundreds of Millions of Dollars for Definitive Drug Testing Services That Were at Risk for Noncompliance With Medicare Requirements.....	10
Payments Made to At-Risk Providers May Not Have Been Reasonable and Necessary.....	10
At-Risk Providers May Not Have Always Used Presumptive Drug Testing To Determine the Number of Drug Classes That Needed To Be Tested Using Definitive Drug Testing Services.....	11
At-Risk Providers Had Similar Characteristics to Other Providers and May Have Been Able To Bill Primarily Definitive Drug Testing Services With Lower Reimbursement Amounts.....	12
CMS Program Safeguards Were Not Adequate To Prevent or Detect Payments for Definitive Drug Testing Services at Risk for Noncompliance With Medicare Requirements.....	13
CMS Oversight Activities and Postpayment Reviews Identified Overpayments for Definitive Drug Testing Services.....	14
CMS Program Safeguards Did Not Prevent or Detect At-Risk Payments to At-Risk Providers for Definitive Drug Testing Services.....	15
Medicare Could Have Saved up to \$216 Million Over 5 Years if CMS Program Safeguards Had Been Adequate To Prevent or Detect At-Risk Payments to At-Risk Providers for Definitive Drug Testing Services.....	15

RECOMMENDATIONS	16
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	17
Second Recommendation: Review At-Risk Payments to At-Risk Providers During and After Our Audit Period and Recover Any Overpayments.....	17
CMS Comments.....	17
Office of Inspector General Response	18
Third Recommendation: Notify Appropriate Providers To Exercise Reasonable Diligence To Identify, Report, and Return Any Overpayments in Accordance With the 60-Day Rule	18
CMS Comments.....	18
Office of Inspector General Response	18
 APPENDICES	
A: Audit Scope and Methodology	20
B: Calculation of Estimated Medicare Part B Savings.....	23
C: CMS Comments	25

INTRODUCTION

WHY WE DID THIS AUDIT

Drug testing is generally used to detect the presence or absence of drugs in patients undergoing treatment for pain management or substance use disorders. Definitive drug testing identifies specific medications and illicit substances in the body and reports the results in concentrations of drugs within a drug class.¹ Medicare payments for definitive drug testing services increase based on the number of drug classes tested. For calendar years 2016 through 2020 (audit period), Medicare Part B paid approximately \$3 billion for 17.1 million definitive drug testing services provided to 3.3 million beneficiaries. Through Comprehensive Error Rate Testing (CERT) and other oversight activities, the Centers for Medicare & Medicaid Services (CMS) identified overpayments for the definitive drug testing service with the highest reimbursement amount due to noncompliance with Medicare Part B requirements (e.g., insufficient documentation to support the medical necessity of the tests).² The overpayment rate for this service varied from 42.7 percent to 71.7 percent for fiscal years (FYs) 2018 through 2020.

A prior Office of Inspector General (OIG) report also identified that payments for the definitive drug testing service with the highest reimbursement amount were at risk for overpayments.³ These payments were at risk because Medicare contractors did not have clear and consistent requirements or guidance to use when determining the number of drug classes to bill for definitive drug testing services. The report concluded that without clear and consistent requirements or guidance, there is an increased risk that providers may bill for definitive drug testing services using a procedure code with a higher reimbursement amount to maximize Medicare payments. Although CMS has program safeguards that focus on definitive drug testing services with the highest reimbursement amount, Medicare payments for these services continue to be at risk for noncompliance with Medicare requirements. As a result, we focused our audit on payments made to providers that routinely billed the definitive drug testing services with the highest reimbursement amount.

OBJECTIVE

Our objective was to identify Medicare Part B payments for definitive drug testing services that were at risk for noncompliance with Medicare requirements.

¹ The concentration of a drug is typically reported in nanograms per milliliter. A drug class is a group of drugs that share scientifically documented properties. For example, the opiates drug class includes the drugs morphine and hydrocodone.

² CMS estimates the Medicare fee-for-service program's improper payment rate through the CERT program by identifying improper payments that did not meet Medicare requirements. Improper payments consist of both overpayments and underpayments. CMS publishes specific overpayment rates and estimated overpayments for the top 20 Medicare Part B services with overpayments.

³ *Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services* ([A-09-20-03017](#)), issued June 8, 2021.

BACKGROUND

The Medicare Program and the Role of the Centers for Medicare & Medicaid Services

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers the program.

Medicare Part B provides supplementary medical insurance for medical and other health services, including drug testing services. During our audit period, CMS contracted with 7 Medicare administrative contractors (MACs) to process and pay Part B claims for 12 defined geographic areas (called jurisdictions) servicing institutional providers, physicians, nonphysician practitioners, and suppliers. In addition, CMS contracts with other contractors, such as Unified Program Integrity Contractors (UPICs), to investigate instances of suspected fraud, waste, and abuse in Medicare.

Drug Testing Services

Drug testing is the process of using a biological sample (e.g., urine or blood) to detect the presence or absence of a drug or its metabolites in the body.⁴ Generally, there are two types of drug testing services: presumptive and definitive. Presumptive drug testing provides a negative, positive, or numerical result indicating the presence or absence of drugs or drug classes.⁵ Definitive drug testing identifies specific medications, illicit substances, and metabolites and reports the results in concentrations of drugs within a drug class.⁶

Generally, the physician or qualified nonphysician practitioner who is treating the beneficiary (i.e., treating physician) collects a urine sample from a patient and performs a presumptive drug test at the point-of-care (e.g., a pain management clinic). The treating physician then sends the urine sample to a clinical laboratory with an order to perform definitive drug testing to confirm a positive result or an unexpected negative result (e.g., a negative result for a prescribed medication) from the presumptive drug test. However, the treating physician may: (1) perform both presumptive and definitive drug tests at the point-of-care or (2) forgo performing drug tests at the point-of-care and send the sample directly to a clinical laboratory to perform presumptive drug testing, definitive drug testing, or both.

Drug testing is generally used to detect the presence or absence of drugs in patients undergoing treatment for pain management or substance use disorders. (Substance use disorder is also

⁴ Some drugs are chemically altered (metabolized) by the body. The substances that result from this process are called metabolites.

⁵ A drug class is a group of drugs that share scientifically documented properties. For example, the opiates drug class includes the drugs morphine and hydrocodone.

⁶ The concentration of a drug is typically reported in nanograms per milliliter.

known as substance abuse or drug addiction.) For pain management, treating physicians test patients to confirm they are taking their prescribed medications and not supplementing them with other legal drugs or with illegal drugs. For substance use disorders, treating physicians generally test patients for abstinence from substance use.⁷

Medicare Coverage of Drug Testing Services

Medicare covers drug testing services when they are reasonable and necessary for the diagnosis or treatment of a beneficiary's illness.⁸ Generally, Medicare requires that drug testing services are ordered and the testing results are used by the treating physician or nonphysician practitioner.⁹ (In this report, the term "physician" refers to both physicians and nonphysician practitioners.) Because drug testing services may be performed by either a treating physician or a clinical laboratory, either type of provider may submit Medicare Part B claims to one of the seven MACs, depending on the jurisdiction in which the provider is located, for those services. (In this report, the term "provider" refers to both clinical laboratories and treating physicians.)

The Healthcare Common Procedure Coding System (HCPCS) is the approved system that providers use to report Medicare Part B procedures, items, and services, including drug testing services.¹⁰ For most Part B services, a provider must use the appropriate HCPCS code or Current Procedural Code (CPT) code on the claim form.¹¹

Providers receive payment for lab tests based on amounts listed on the Clinical Laboratory Fee Schedule (CLFS). For presumptive drug testing services, laboratories use one of three CPT¹²

⁷ Abstinence is a method of addiction treatment that involves the patient's complete avoidance of substance use.

⁸ Social Security Act (the Act) § 1862(a)(1)(A).

⁹ According to 42 CFR § 410.32(a), the treating physician is "the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

¹⁰ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. HCPCS codes are divided into two groups: level I and level II. Level I HCPCS codes consist of Current Procedural Terminology (CPT) codes, a numeric coding system maintained by the American Medical Association (AMA), and are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II HCPCS codes are based on a standardized coding system and are used primarily to identify products, supplies, and services not included in the CPT codes.

¹¹ 45 CFR §§ 162.1002(c)(1) and (a)(5).

¹² **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

codes (80305, 80306, and 80307), depending on the level of complexity of the test.¹³ For definitive drug testing services, laboratories use one of five HCPCS codes (G0480, G0481, G0482, G0483, and G0659), which generally are dependent on the number of drug classes, including metabolites, that are tested. (Throughout this report, we refer to these CPT codes and HCPCS codes as “procedure codes.”) For example, the payment for procedure code G0480 has the lowest reimbursement amount and covers up to 7 drug classes, while G0483 has the highest reimbursement amount and covers 22 or more drug classes. See Table 1 for a list of procedure codes that providers use to bill for definitive drug testing services and CMS’s 2020 Medicare CLFS payment for each code.¹⁴

Table 1: Procedure Codes Used To Bill for Definitive Drug Testing Services

Procedure Code	Number of Drug Classes	2020 Clinical Lab Fee Schedule Payment
G0480	1–7	\$114.43
G0481	8–14	156.59
G0482	15–21	198.74
G0483	22+	246.92

CMS Program Safeguards

Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for CMS. In addition, preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners, including the Medicare contractors and providers.¹⁵

CMS and the Medicare contractors use a variety of program safeguards to prevent and detect improper payments and to promote provider compliance, including but not limited to coverage determinations for specific items and services, claims processing edits, oversight activities, and targeted provider-specific reviews.

¹³ The CPT codes for presumptive drug testing services were effective in calendar year 2017. Before 2017, the HCPCS codes for presumptive drug testing services were G0477, G0478, and G0479.

¹⁴ We excluded procedure code G0659 (simple definitive drug test for all classes) from our audit because total payments for this procedure code were immaterial for our audit period (\$745,962). This procedure code was created for laboratories that perform definitive drug testing services that are less sophisticated than those that are usually performed in a drug testing laboratory. Most providers billed definitive drug testing services using the procedure codes in Table 1.

¹⁵ *Medicare Program Integrity Manual* (Program Integrity Manual), Pub. No. 100-08, chapter 1, § 1.3.

National and Local Coverage Determinations

MACs implement National Coverage Determinations (NCDs), which are developed by CMS. An NCD specifies whether a particular item, service, procedure, or technology is covered nationally under Medicare. MACs also develop and implement Local Coverage Determinations (LCDs). An LCD is a MAC's decision about whether a particular item or service is considered reasonable and necessary within its jurisdiction.¹⁶ LCDs may vary by MAC and result in different coverage in different jurisdictions.¹⁷ Finally, MACs develop and issue Local Coverage Articles (LCAs), which contain billing, coding, or other guidance that complements LCDs.¹⁸

Claims Processing Edits

MACs implement CMS- or MAC-developed claims processing system edits to prevent and detect improper payments.¹⁹ Prepayment edits select claims for electronic review before the claims are paid; evaluate or compare information on the selected claims or other accessible sources; and, depending on the evaluation, take action on each claim, such as paying all or part of the claim, denying all or part of the claim, or suspending all or part of the claim for manual review. Postpayment edits select claims for electronic or manual review after the claims have been paid, and this review results in either no change to the initial payment determination or a revised determination indicating that an overpayment or underpayment occurred.

Oversight Activities

To measure payment compliance in the Medicare FFS program (including Medicare Part B), CMS reviews a statistical sample of approximately 50,000 claims nationwide each fiscal year

¹⁶ The Act § 1869(f)(2)(B).

¹⁷ According to the Act, the Secretary of Health and Human Services shall develop a plan to evaluate new LCDs to determine which ones should be adopted nationally and to what extent greater consistency can be achieved among LCDs (the Act § 1862(l)(5)(A)).

¹⁸ The Program Integrity Manual, Pub. No. 100-08, chapter 1, section 1.3.1, states that CMS has determined that most improper payments in the Medicare FFS program occur because a provider did not comply with Medicare's coverage, coding, or billing rules. It also states that the cornerstone of the Medicare contractors' (including MACs') efforts to prevent improper payments is each contractor's Error Rate Reduction Plan (currently known as the improper payment reduction strategy), which includes initiatives to help providers comply with the rules. One of these initiatives is new or revised LCDs, LCAs, or coding instructions to assist providers in understanding how to correctly submit claims and under what circumstances the services will be considered reasonable and necessary.

¹⁹ The Program Integrity Manual, Pub. No. 100-08, chapter 3, section 3.3.1.3, states that Medicare contractors shall ensure that automated prepayment and postpayment denials are based on clear policy that serves as the basis for denial. When such a policy exists, Medicare contractors (including MACs) have the discretion to automatically deny services without stopping a claim for manual review. "Clear policy" means a statute, a regulation, an NCD, a coverage provision in an interpretive manual, a coding guideline, an LCD, or an LCA that specifies the circumstances under which a service will always be considered noncovered, incorrectly coded, or improperly billed.

under the CERT program.²⁰ This sample size allows CMS to calculate a national improper payment rate and contractor- and service-specific improper payment rates.²¹

Each MAC develops an annual improper payment reduction strategy (IPRS) based on data from a variety of sources (for example, CERT findings, OIG reports, and the results of data analysis). The IPRS is a problem-focused, outcome-based operational plan that includes a prioritized list of payment errors and vulnerabilities that can be addressed through medical review activities, provider outreach education, and other improper payment interventions.

Targeted Provider-Specific Reviews

MACs perform targeted provider-specific prepayment or postpayment reviews only when there is the likelihood of a sustained or high level of payment error. In addition, MACs perform provider-specific prepayment or postpayment Targeted Probe and Educate (TPE) reviews of providers: (1) that have historically high claim denial rates, (2) have billing practices that vary from their peers, or (3) when evidence suggests that there is a potential risk to the Medicare Trust Funds. A TPE review of a specific provider typically includes up to three rounds. As part of these reviews, MACs offer one-on-one education to providers after each round of review to help them correct their billing practices. In addition, other contractors, such as UPICs, may conduct provider-specific reviews to investigate instances of suspected fraud, waste, and abuse in Medicare.

Prior Office of Inspector General Report on Drug Testing Services for Beneficiaries With Substance Use Disorders

A prior OIG report identified weaknesses in the MACs' program safeguards for preventing and detecting improper payments for drug testing services for beneficiaries with substance use disorders and promoting provider compliance with Medicare requirements.²² We confirmed with CMS that the weaknesses identified in the report were relevant for drug testing services for all forms of treatment, not just treatment for substance use disorders.

According to the report, without clear and consistent requirements or guidance for providers to use when determining the number of drug classes to bill for definitive drug testing, there is an increased risk that providers may bill for definitive drug testing services using a procedure code

²⁰ The fiscal year runs from October 1 through September 30. The Medicare FFS sampling period does not correspond with the fiscal year because of practical constraints with claims review and rate calculation methodologies. As a result, the sample includes claims submitted during the 12-month period from July 1 through June 30 before the start of the current fiscal year.

²¹ The improper payment rate is not a "fraud rate" but is a measurement of payments that did not meet Medicare requirements. Improper payments are payments that should not have been made or payments made in an incorrect amount and consist of both overpayments and underpayments.

²² *Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services* ([A-09-20-03017](#)), issued June 8, 2021.

with a higher reimbursement amount to maximize Medicare payments (i.e., “upcoding” to a higher paying code). The report identified differences in the way providers counted drug classes due to differences in the LCD requirements between jurisdictions. The report showed that a provider in one MAC jurisdiction counted the benzodiazepines it tested as one drug class based on CPT guidance.²³ By contrast, a provider in another MAC jurisdiction counted each of the 13 benzodiazepines it tested as 13 separate drug classes based on the MAC’s LCD. This difference in the way drug classes are counted could result in some providers overcounting drug classes and billing procedure codes with higher reimbursement amounts.

To address this vulnerability, the report recommended that CMS work with its Medicare contractors to: (1) take the necessary steps to determine whether clinical evidence exists to support a single, specific reasonable and necessary standard for drug testing services, and if such evidence exists, establish a NCD or develop LCDs with more consistent requirements for drug testing services; and (2) clearly indicate in LCDs, LCAs, or other instructions how laboratories should determine the number of drug classes for billing definitive drug testing services (e.g., using CPT guidance for drug classes).²⁴

However, CMS did not concur with these recommendations. In response to the first recommendation, CMS stated that there is currently no clinical evidence to support a single, specific reasonable and necessary standard for drug testing services, which would be necessary to establish an NCD. CMS also stated that it has already taken a number of steps to achieve more consistency among the LCDs. In response to the second recommendation, CMS stated that there is currently no clinical evidence to support a single, specific reasonable and necessary standard defining how drug classes should be identified for drug testing services in an NCD or a LCD, and as such, it would not be appropriate to discuss in an LCA the billing or coding related to drug classes.

Medicare Requirements for Providers To Identify and Return Overpayments

OIG believes that this audit report on Medicare Part B definitive drug testing services constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.²⁵

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments

²³ Benzodiazepines are a class of drugs most commonly used to treat insomnia and anxiety.

²⁴ The report also included recommendations to address other weaknesses that we identified.

²⁵ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.²⁶

HOW WE CONDUCTED THIS AUDIT

The prior OIG report on drug testing services (A-09-20-03017) identified that payments for the definitive drug testing service with the highest reimbursement amount were at risk for overpayments. However, that audit was limited to services provided to beneficiaries with substance use disorders. This audit covers definitive drug testing services provided to all Medicare beneficiaries, not just beneficiaries undergoing treatment for substance use disorders. For our audit period, Medicare Part B paid approximately \$3 billion on behalf of 3.3 million beneficiaries for 17.1 million definitive drug testing services billed by 8,663 providers. Most of these services were for beneficiaries undergoing treatment for pain management.

We focused our audit on payments made to providers that routinely billed procedure code G0483 (i.e., the definitive drug testing service with the highest reimbursement amount). Specifically, we identified 1,062 providers that billed this procedure code for 75 percent or more of the definitive drug testing services they provided and that received at least \$5,000 for those services during our audit period. (We refer to these providers as “at-risk providers.”) Medicare Part B paid at-risk providers \$760.8 million on behalf of 805,080 beneficiaries for 3.4 million definitive drug testing services, and \$704.2 million of these payments were for procedure code G0483.

For comparison purposes, we identified 4,227 providers that did not routinely bill procedure code G0483. These providers billed this procedure code for less than 75 percent of the definitive drug testing services they provided and received at least \$5,000 for those services during our audit period. (We refer to these providers as “other providers.”) Medicare Part B paid the other providers \$2.2 billion on behalf of 2.9 million beneficiaries for 13.7 million definitive drug testing services, and \$676 million of these payments were for procedure code G0483.

In total, our audit covered approximately \$3 billion in Medicare Part B payments to 5,289 at-risk and other providers for definitive drug testing services.²⁷

We interviewed CMS officials to obtain an understanding of program safeguards and oversight activities for Medicare Part B drug testing services. We also confirmed that the findings in the

²⁶ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual—Part 1*, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

²⁷ We removed 3,374 providers from our audit that did not receive at least \$5,000 for definitive drug testing services during our audit period. In total, these providers received \$3.6 million for definitive drug testing services during our audit period.

prior OIG report (A-09-20-03017) were relevant for all forms of treatment, not just treatment for substance use disorders.

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.

FINDINGS

For the 5-year audit period, Medicare paid \$704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements.²⁸ Specifically, these payments were for the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments were made to 1,062 at-risk providers that routinely billed procedure code G0483 and may not have been reasonable and necessary. We determined that presumptive drug testing preceded most definitive drug testing services billed by both the at-risk and other providers. However, the at-risk providers may not have always used presumptive testing to determine the number of drug classes that needed to be tested using definitive drug testing, because they routinely billed for testing 22 or more drug classes using procedure code G0483 and the other providers did not. Although the at-risk providers billed a significantly higher percentage of definitive drug testing services using procedure code G0483 than the other providers, the at-risk and other providers had similar characteristics: They were similar types of providers, they tested similar types of patients, and they tested patients at a similar frequency. This suggests that the at-risk providers may have been able to bill for definitive drug testing services using primarily procedure codes with lower reimbursement amounts, as the other providers did, rather than billing the procedure code with the highest reimbursement amount (G0483) for 89.6 percent of their definitive testing services.

Although CMS identified overpayments for procedure code G0483 through oversight activities, such as the CERT review and postpayment reviews, these program safeguards were not adequate to prevent or detect payments to at-risk providers for procedure code G0483 that were at risk for noncompliance with Medicare requirements (i.e., at-risk payments). If program safeguards had focused on at-risk payments to these providers, Medicare could have saved up to \$215.8 million for our audit period.²⁹

²⁸ The unrounded amount is \$704,157,430.

²⁹ The unrounded amount is \$215,839,412.

MEDICARE PAID HUNDREDS OF MILLIONS OF DOLLARS FOR DEFINITIVE DRUG TESTING SERVICES THAT WERE AT RISK FOR NONCOMPLIANCE WITH MEDICARE REQUIREMENTS

Medicare paid \$704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements: (1) These payments were made to 1,062 at-risk providers that routinely billed procedure code G0483 and may not have been reasonable and necessary, (2) the at-risk providers may not have always used presumptive drug testing to determine the number of drug classes that needed to be tested using definitive drug testing, and (3) the at-risk providers had similar characteristics to the other providers and may have been able to bill for definitive drug testing services with lower reimbursement amounts.

Payments Made to At-Risk Providers May Not Have Been Reasonable and Necessary

Medicare paid \$704.2 million to 1,062 at-risk providers that routinely billed the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments, which were processed by all of the MACs, may not have been reasonable and necessary.

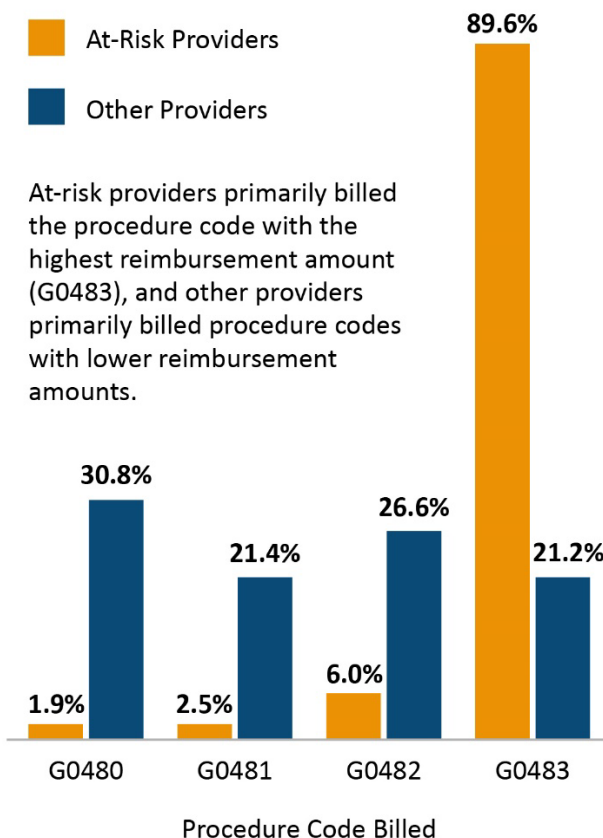
CMS does not have specific guidance stating when definitive drug testing services may be reasonable and necessary, leaving this determination to MAC discretion. LCDs issued by six of the seven MACs state that definitive drug testing may be reasonable and necessary based on patient-specific indications, including historical use (of legal or illegal drugs), medication response, and clinical assessment when accurate results are necessary to make clinical decisions. The LCDs also state that performing definitive drug testing services without presumptive drug testing services is reasonable and necessary when individualized for a particular patient (i.e., based on patient-specific indications).³⁰ Providers that routinely bill procedure code G0483 (definitive drug testing for 22+ drug classes) may not be testing based on patient-specific indications, and payments for those services may not be reasonable and necessary.

The at-risk providers had significantly less variability in the procedure codes they used to bill for definitive drug testing compared with the other providers. Of the 3.4 million definitive drug testing services that the at-risk providers billed, 3 million (89.6 percent) were billed using procedure code G0483. In contrast, of the 13.7 million definitive drug testing services that the other providers billed, 2.9 million services (only 21.2 percent) were billed using G0483. Figure 1

³⁰ The MAC for Medicare Part B jurisdictions 5 and 8 (Wisconsin Physicians Service Insurance Corporation) has different LCD requirements than the other MACs. Its LCD states that definitive drug testing is reasonable and necessary when: (1) presumptive test results are positive; (2) presumptive test results are negative and the negative finding is inconsistent with the patient's medical history (e.g., the test is negative for a prescribed medication); and (3) general Medicare coverage criteria are met *and* there is no presumptive test available, as may be the case for certain synthetic or semisynthetic opioids. The LCD does not state when performing definitive drug testing services without presumptive drug testing services is reasonable and necessary when presumptive tests are available.

shows the percentage of definitive drug testing services billed using each of the four procedure codes for each type of provider.

Figure 1: Percentage of Definitive Drug Testing Services That At-Risk and Other Providers Billed to Medicare Using Each Procedure Code



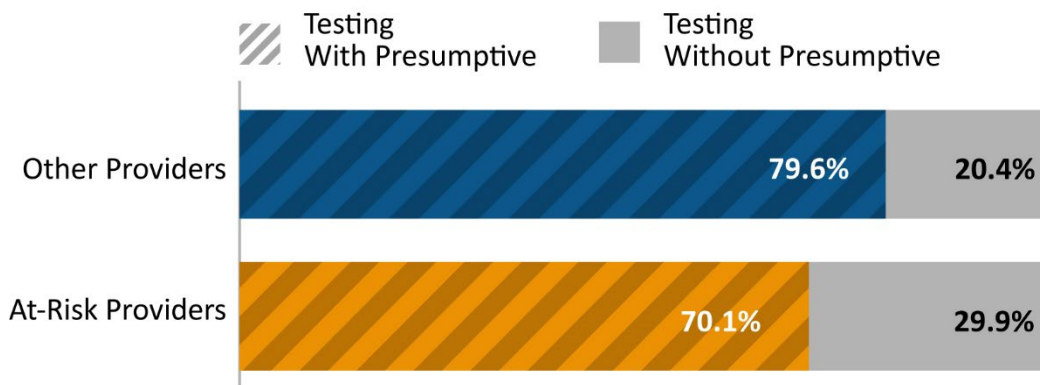
At-Risk Providers May Not Have Always Used Presumptive Drug Testing To Determine the Number of Drug Classes That Needed To Be Tested Using Definitive Drug Testing Services

According to LCD requirements, presumptive drug testing should generally precede definitive drug testing. Performing presumptive before definitive drug testing services may result in a reduction of the number of drug classes that need to be tested using definitive drug testing. For example, a treating physician could perform or request that a laboratory perform presumptive drug testing to identify which drug classes need definitive drug testing. As a result, the laboratory would perform definitive drug testing for a smaller number of drug classes rather than performing definitive testing for all drug classes. In this instance, the laboratory would bill using a procedure code with a lower reimbursement amount (i.e., G0480, G0481, or G0482) rather than using procedure code G0483.

Based on our analysis, we determined that presumptive drug testing preceded 70.1 percent of all the definitive drug testing services billed by the at-risk providers and 79.6 percent of all the

definitive drug testing services billed by the other providers. (See Figure 2.) However, the at-risk providers may not have always used presumptive testing for all drug classes or presumptive testing results to determine the number of drug classes that needed to be tested using definitive drug testing because they routinely billed for testing 22 or more drug classes using procedure code G0483 and the other providers did not.³¹ For example, in the prior OIG report on drug testing services for beneficiaries with substance use disorders (A-09-20-03017), we identified a laboratory that offered presumptive testing on only two drug classes and offered definitive testing for all other drug classes.

Figure 2: Percentage of All Definitive Drug Testing Services Preceded by a Presumptive Drug Test for At-Risk and Other Providers



At-Risk Providers Had Similar Characteristics to Other Providers and May Have Been Able To Bill Primarily Definitive Drug Testing Services With Lower Reimbursement Amounts

We determined that the at-risk providers had similar characteristics to the other providers: most at-risk and other providers were clinical laboratories, not treating physicians; they tested similar types of patients, and they tested patients at a similar frequency. This suggests that the at-risk providers may have been able to bill primarily definitive drug testing services with lower reimbursement amounts, as the other providers did, rather than billing the procedure code with the highest reimbursement amount (G0483) for 89.6 percent of their definitive testing services.

Provider Type (Clinical Laboratory or Treating Physician). The at-risk providers and other providers were similar types of providers. For our audit period, most of the at-risk providers (72.6 percent) and other providers (77.2 percent) were clinical laboratories.

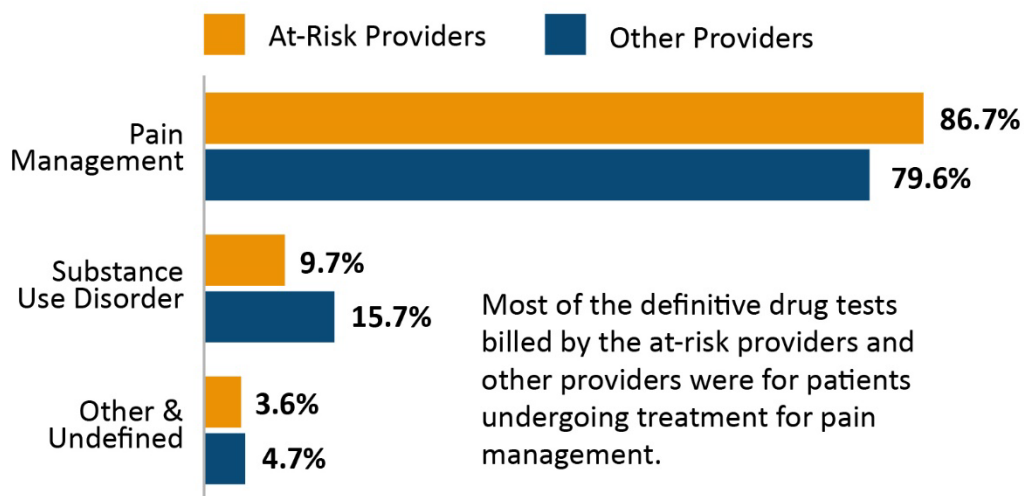
Patient Type. The at-risk providers and other providers tested similar types of patients. For our audit period, most of the definitive drug testing services billed by the at-risk providers

³¹ Payment for presumptive drug testing services varies based on the complexity of the test performed rather than the number of drug classes tested. As a result, we do not know how many drug classes were tested each time and whether the results could have led to less definitive testing.

(86.7 percent) and other providers (79.6 percent) were for patients undergoing treatment for pain management. Specifically, the most billed diagnosis code for the at-risk providers (43.7 percent) and other providers (33 percent) was “Z79.891 - Long term (current) use of opiate analgesic,” which we categorized as pain management.

Figure 3 shows definitive drug testing services per patient type billed by at-risk providers and other providers.

Figure 3: Definitive Drug Testing Services per Patient Type Billed by At-Risk Providers and Other Providers



Testing Frequency. The at-risk and other providers tested patients at a similar frequency. Specifically, for our audit period, the at-risk providers billed definitive drug tests an average of 4.2 times per patient, and the other providers billed these tests an average of 4.7 times per patient. However, the at-risk providers billed a significantly higher number of drug classes each time they tested (procedure code G0483, definitive drug testing for 22+ drug classes).

Because the at-risk providers had similar characteristics to the other providers, the at-risk providers may have been able to bill a higher percentage of definitive drug testing services with lower reimbursement amounts, as the other providers did, rather than billing the procedure code with the highest reimbursement amount (G0483) for 89.6 percent of their definitive testing services.

CMS PROGRAM SAFEGUARDS WERE NOT ADEQUATE TO PREVENT OR DETECT PAYMENTS FOR DEFINITIVE DRUG TESTING SERVICES AT RISK FOR NONCOMPLIANCE WITH MEDICARE REQUIREMENTS

CMS conducted oversight activities to prevent and detect improper payments for definitive drug testing services. CMS also conducted oversight activities, including postpayment reviews, to recover overpayments for these services. However, CMS’s program safeguards were not

adequate to prevent or detect payments to at-risk providers for procedure code G0483 that were at risk for noncompliance with Medicare requirements.

CMS Oversight Activities and Postpayment Reviews Identified Overpayments for Definitive Drug Testing Services

CMS identified overpayments for procedure code G0483 (the definitive drug testing service with the highest reimbursement amount) through its annual CERT program reviews. For FYs 2018 through 2020 (which overlaps our audit period), procedure code G0483 was identified as 1 of the top 20 Medicare Part B services with overpayments.³² In total, CMS estimated that Medicare overpaid providers \$423.5 million for this procedure code. Figure 4 shows the overpayment rate and estimated overpayment amounts for FYs 2018 through 2020.³³

Figure 4: CERT Overpayment Rate and Estimated Overpayments (in Millions) by Fiscal Year for Procedure Code G0483

Procedure Code G0483			
	2018	2019	2020
CERT Overpayment Rate	71.7%	58.9%	42.7%
CERT Estimated Overpayment (in Millions)	\$169.6	\$149.2	\$104.7
Total CERT Estimated Overpayment (in Millions)			\$423.5

According to CMS officials, the overpayments for procedure code G0483 identified in the CERT review were improper because there was insufficient documentation to support the medical necessity of the definitive drug testing services. Common documentation that was missing or inadequate was: (1) a risk assessment for a urine drug test, (2) documentation to support frequency of billing or the medical necessity of testing, and (3) a physician order for the drug test or an intent to order (e.g., a signed progress note, signed office visit note, or signed physician order).

³² For FYs 2016 and 2017, procedure code G0483 was not in the top 20 Medicare Part B services with overpayments, and the overpayment rates and estimated overpayment amounts for procedure code G0483 were not listed in the annual CERT reports for these fiscal years.

³³ The results of each CERT review are published annually in reports on the CMS website called the *[Year] Medicare Fee-for-Service Supplemental Improper Payment Data*. Table L1 of the report provides the overpayment rate and estimated overpayment amounts for the top 20 Medicare Part B services with overpayments. However, the report does not provide definitions or details on how the figures were calculated.

To prevent and detect these types of overpayments, CMS stated that it has Fraud Prevention System models and edits for drug testing services.³⁴ CMS also stated that all but one of the seven MACs included definitive drug testing services in their annual IPRS and recovered some overpayments from providers through postpayment reviews. CMS stated that other contractors, such as UPICs, have also performed postpayment reviews. In total, CMS stated that \$10.8 million was recovered through its oversight activities and postpayment reviews for definitive drug testing services billed using procedure code G0483 during our audit period.

CMS Program Safeguards Did Not Prevent or Detect At-Risk Payments to At-Risk Providers for Definitive Drug Testing Services

Although CMS identified overpayments for procedure code G0483 through oversight activities and postpayment reviews, CMS's program safeguards were not adequate to prevent or detect at-risk payments to at-risk providers (i.e., those that routinely billed procedure code G0483). CMS stated that it has Fraud Prevention System models and edits for drug testing services; however, these safeguards did not prevent or detect at-risk payments to providers that routinely bill procedure code G0483. CMS also stated that there are some educational materials for providers covering other issues related to drug testing services but nothing specific to the routine billing of procedure code G0483.

MEDICARE COULD HAVE SAVED UP TO \$216 MILLION OVER 5 YEARS IF CMS PROGRAM SAFEGUARDS HAD BEEN ADEQUATE TO PREVENT OR DETECT AT-RISK PAYMENTS TO AT-RISK PROVIDERS FOR DEFINITIVE DRUG TESTING SERVICES

If CMS's program safeguards had been adequate to prevent or detect at-risk payments to at-risk providers for the definitive drug testing service with the highest reimbursement amount (procedure code G0483), Medicare might have prevented overpayments for this procedure code. If the at-risk providers had billed the same percentage of definitive drug testing services with lower reimbursement amounts as the other providers (primarily procedure codes G0480, G0481, and G0482), Medicare could have saved up to \$215.8 million for our audit period. (See Figure 5 on the following page.) See Appendix B for details on how this estimated amount was calculated.

³⁴ The Fraud Prevention System is a state-of-the-art predictive analytics technology that runs predictive algorithms and other sophisticated analytics nationwide against all Medicare FFS claims prior to payment. Details on the models and edits used in the Fraud Prevention System are confidential and may not appear in public-facing publications.

Figure 5: Potential Medicare Savings if At-Risk Providers Had Billed the Same Percentage of Definitive Drug Testing Services With Lower Reimbursement Amounts as Other Providers

Payments to At-Risk Providers		VS	Revised Payments to At-Risk Providers		Potential Medicare Savings
Procedure Code	Total Payments		Procedure Code	Revised Total Payments	
G0480	\$6,599,893		G0480	\$106,247,325	
G0481	12,145,078		G0481	105,180,977	
G0482	37,897,433		G0482	166,873,489	
G0483	704,157,430		G0483	166,658,631	
Total	\$760,799,834		Total	\$544,960,422	\$215,839,412

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- expand program safeguards to prevent and detect at-risk payments to at-risk providers for the definitive drug testing service with the highest reimbursement amount (procedure code G0483), which could have saved up to \$215.8 million for our audit period;
- review at-risk payments made to at-risk providers during and after our audit period to determine whether payments for procedure code G0483 complied with Medicare requirements and recover any overpayments;
- notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- educate providers that received payments that did not comply with Medicare requirements for definitive drug testing services.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first recommendation and provided information on actions that it had taken or planned to take to address this recommendation. CMS did not concur with our second and third recommendations but provided information on actions that it planned to take to address the second recommendation. CMS did not state whether it concurred with our fourth recommendation but provided information on actions that it had already taken and planned to take to address this recommendation.

Regarding our first recommendation, CMS stated that it will assess whether additional program safeguards would be feasible, given available resources and expected return. CMS also stated that determination of improper payment for procedure code G0483 requires medical record review, which is a resource-intensive process. CMS stated that it already has a prepayment edit and conducts postpayment reviews that include medical review. Regarding our fourth recommendation, CMS stated that it has already issued national provider education on Medicare rules for urine drug testing and that it will continue to educate providers as appropriate (for example, by sending a comparative billing report to at-risk providers).

In addition to addressing our specific recommendations, CMS provided information on its strategy to reduce and prevent improper payments, such as automated system edits within the claims processing system and prepayment and postpayment medical reviews. CMS stated that it “leverages tools like the Fraud Prevention System to alert MACs of providers who bill at an anomalous rate.” Furthermore, CMS stated that MACs and other contractors, such as UPICs, recovered \$10.8 million for procedure code G0483 through postpayment reviews. It stated that the UPICs undertook various activities, including proactive data analytics; review of medical records and documentation; provider education; and, when appropriate, making referrals to law enforcement for further criminal investigation and for administrative actions (such as payment suspensions or revocations). Finally, CMS stated that it educates health care suppliers on Medicare billing through various channels, including the Medicare Learning Network.

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 C.

After reviewing CMS’s comments, we maintain that our second and third recommendations are valid. Our summaries of CMS’s specific comments and our responses follow.

SECOND RECOMMENDATION: REVIEW AT-RISK PAYMENTS TO AT-RISK PROVIDERS DURING AND AFTER OUR AUDIT PERIOD AND RECOVER ANY OVERPAYMENTS

CMS Comments

CMS did not concur with our recommendation and stated that our classification of at-risk providers was based only on the frequency at which those providers billed procedure code

G0483 and the amount of Medicare reimbursement those providers received during our audit period. CMS also stated that analysis alone does not provide findings of improper payments, which would have required medical review. CMS stated that conducting medical review for all providers that we classified as “at-risk” would not be a sufficiently targeted use of resources. CMS stated that it will send a comparative billing report to those providers that we identified, alerting them to the fact that their billing is an outlier compared with their peers. In addition, CMS stated that it will review our list of at-risk providers against providers that CMS has already taken action on, through other methods, to see if there is an opportunity for more engagement.

Office of Inspector General Response

We appreciate CMS’s concern that medical review was not conducted to determine whether payments were improper. However, medical review is not required to identify payments at risk for being improper. The at-risk providers routinely billed the procedure code with the highest reimbursement amount (procedure code G0483) for their definitive drug testing services, whereas other providers with similar characteristics (i.e., similar provider type, patient type, and testing frequency) billed this procedure code for less than a quarter of their definitive drug testing services. Although during our audit period the MACs and other contractors, such as UPICs, have recovered \$10.8 million for procedure code G0483, this amount is less than 3 percent of the \$423.5 million in estimated overpayments that CMS identified in its CERT reviews. Therefore, we believe that CMS should review at-risk payments to at-risk providers, for which CMS determines that such a review is an efficient use of resources (e.g., by reviewing at-risk providers with the highest at-risk payment amounts).

THIRD RECOMMENDATION: NOTIFY APPROPRIATE PROVIDERS TO EXERCISE REASONABLE DILIGENCE TO IDENTIFY, REPORT, AND RETURN ANY OVERPAYMENTS IN ACCORDANCE WITH THE 60-DAY RULE

CMS Comments

CMS did not concur with our recommendation and stated that our audit does not constitute credible information of overpayments because no overpayments were identified. CMS stated that, therefore, our audit “is not sufficient basis upon which CMS can support a 60-day rule notice to identified providers.”

Office of Inspector General Response

We believe that this audit report constitutes credible information of potential overpayments. The 60-day rule does not require identification of actual overpayments to trigger a provider’s obligation to exercise reasonable diligence to identify, report, and return overpayments. Instead, the 60-day rule requirements are triggered when a provider receives credible information of potential overpayments.

The at-risk providers identified in this report billed procedure code G0483 for a significantly higher percentage of drug testing services than the other providers, even though the at-risk and other providers had similar characteristics. If CMS recovers overpayments based on our second recommendation or sends a comparative billing report to the at-risk providers we identified notifying them that their billing is an outlier compared to their peers, we believe that CMS should notify appropriate providers (i.e., those providers that CMS determines this audit constitutes credible information of potential overpayments) so that those providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

From January 1, 2016, through December 31, 2020, Medicare Part B paid approximately \$2,990,810,867 on behalf of 3,293,205 beneficiaries for 17,074,804 definitive drug testing services billed by 8,663 providers.

We focused our audit on payments made to providers that routinely billed procedure code G0483 (i.e., the definitive drug testing service with the highest reimbursement amount). Specifically, we identified 1,062 providers that billed this procedure code for 75 percent or more of the definitive drug testing services they provided and that received at least \$5,000 for these services during our audit period (i.e., the at-risk providers).³⁵ Medicare Part B paid at-risk providers \$760,799,834 on behalf of 805,080 beneficiaries for 3,353,347 definitive drug testing services, and \$704,157,430 of these payments were for procedure code G0483.

For comparison purposes, we identified 4,227 providers that did not routinely bill procedure code G0483. These providers billed this procedure code for less than 75 percent of the definitive drug testing services they provided and received at least \$5,000 for those services during our audit period (i.e., the other providers). Medicare Part B paid the other providers \$2,226,447,351 on behalf of 2,911,186 beneficiaries for 13,692,336 definitive drug testing services, and \$675,999,965 of these payments were for procedure code G0483.

In total, our audit covered \$2,987,247,185 in Medicare Part B payments to 5,289 at-risk and other providers for definitive drug testing services.³⁶

We did not perform an overall assessment of the internal control structures of CMS or its contractors. Rather, we limited our review to those internal controls related to compliance with Medicare requirements for definitive drug testing services. Specifically, we interviewed CMS officials to identify national and local coverage determinations, claims processing edits, oversight activities, and targeted provider-specific reviews for Medicare Part B definitive drug testing services.

³⁵ We used the National Provider Identifier (NPI) to identify individual providers. To identify routine providers, for each NPI, we divided the payment count for procedure code G0483 by the payment count for any definitive drug testing service. For example, if a provider received 800 payments for procedure code G0483 and an additional 200 payments for other definitive drug testing procedure codes, the provider would have routinely billed 80 percent of the time (800 divided by 1,000).

³⁶ We removed 3,374 providers from our audit that did not receive at least \$5,000 for definitive drug testing services during our audit period. In total, these providers received \$3,563,682 for definitive drug testing services during our audit period.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file (NCH), but we did not assess the completeness of the file.

We conducted our audit from February 2021 to October 2022.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed CMS's CERT data for FYs 2016 through 2020 to identify overpayments for Medicare Part B drug testing services;
- interviewed CMS officials to obtain an understanding of program safeguards and oversight activities for Medicare Part B drug testing services and confirmed that the findings in the OIG report on drug testing services for beneficiaries with substance use disorders (A-09-20-03017) were relevant for all beneficiaries, including those undergoing treatment for pain management;
- obtained from CMS's NCH file the Medicare Part B paid claims data for drug testing services with dates of service for our audit period;
- analyzed the data to identify 1,062 at-risk providers and 4,227 other providers that received at least \$5,000 for definitive drug testing services during our audit period;
- compared the following characteristics of the at-risk providers and other providers during our audit period: the types of providers who performed the tests (clinical laboratories or treating physicians), the types of patients they tested (e.g., those undergoing treatment for pain management), and the frequency of testing their patients;
- estimated the amount that Medicare could have saved if CMS's program safeguards had been adequate to prevent and detect at-risk payments to at-risk providers for the definitive drug testing service with the highest reimbursement rate (procedure code G0483) (Appendix B); and
- discussed the results of our audit with CMS 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 B: CALCULATION OF ESTIMATED MEDICARE PART B SAVINGS

Table 2: Potential Medicare Savings if At-Risk Providers Had Billed the Same Percentage of Definitive Drug Testing Services With Lower Reimbursement Amounts as Other Providers

Procedure Code	No. of Services Billed by At-Risk Providers	Percentage of Services Billed by At-Risk Providers (Rounded)	Payments to At-Risk Providers	Average Payment to At-Risk Providers (Rounded)	Percentage of Services Billed by Other Providers (Rounded)	No. of Services Billed by At-Risk Providers if They Billed Like Other Providers (Rounded)	Revised Payments to At-Risk Providers (Rounded)	Potential Medicare Savings
G0480	64,159	1.9%	\$6,599,893	\$102.87	30.8%	1,032,831	\$106,247,325	(\$99,647,432)
G0481	82,860	2.5%	12,145,078	146.57	21.4%	717,616	105,180,977	(93,035,899)
G0482	202,577	6.0%	37,897,433	187.08	26.6%	891,990	166,873,489	(128,976,056)
G0483	3,003,751	89.6%	704,157,430	234.43	21.2%	710,910	166,658,631	\$537,498,799
Total	3,353,347	100.0%	\$760,799,834		100.0%	3,353,347	\$544,960,422	\$215,839,412

To estimate potential Medicare savings, we recalculated payments made to at-risk providers that routinely billed the procedure code with the highest reimbursement amount (G0483) using primarily procedure codes with lower reimbursement amounts (G0480, G0481, and G0482). Specifically, we recalculated the payments to at-risk providers by using the same percentage of services billed for each procedure code as the other providers did. Reducing the number of services billed using procedure code G0483 and increasing the number of services billed using the procedure codes with lower reimbursement amounts results in a net potential savings. (In Table 2, the yellow columns show the number of services billed by and payments to the at-risk providers, and the blue columns show the revised amounts.)

For example, the potential savings for procedure code G0483 is calculated as follows:

- The at-risk providers billed 89.6 percent (3,003,751/3,353,347) of their definitive drug testing services using procedure code G0483 and received total payments of \$704,157,430 for this procedure code.
- If the at-risk providers had only billed 21.2 percent (710,910/3,353,347) of their definitive drug testing services using procedure code G0483, as the other providers did, they would have received only \$166,658,631 (710,910 units × the average payment for G0483 of \$234.43) for this procedure code.

- This calculation results in a savings of \$537,498,799 for procedure G0483. However, payments for the procedure codes with lower reimbursement amounts (G0480, G0481, and G0482) would increase.

Our calculation assumes that the services billed by the at-risk providers are not disallowed but are revised to match the percentage of services billed for each procedure code by the other providers. If the at-risk providers had billed the same percentage of services per procedure code as the other providers, Medicare could have saved up to \$215.8 million for our audit period.

APPENDIX C: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: November 15, 2022

TO: Amy Frontz
Deputy Inspector General for Audit Services

FROM: Chiquita Brooks-LaSure *Chiquita LaS*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Could Have Saved up to \$216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services, A-09-21-03006

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 recognizes the importance of providing Medicare beneficiaries with access to medically necessary services, and, at the same time, working to prevent improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system and prepayment and postpayment medical reviews. As part of this strategy, CMS recovers identified improper payments in accordance with relevant law and agency policies and procedures. In addition, CMS leverages tools like the Fraud Prevention System to alert Medicare Administrative Contractors (MACs) of providers who bill at an anomalous rate.

While OIG identified providers that it considered to be "at-risk" for improper billing because they billed the definitive drug testing code with the highest reimbursement amount more than other providers, medical review is the only way to determine whether a particular instance of billing this code was improper.

As OIG recognized, MACs and other contractors such as Unified Program Integrity Contractors (UPICs) recovered \$10.8 million for this code through postpayment reviews. The UPICs undertook activities including proactive data analytics, provider and beneficiary interviews and site visits, review of medical records and documentation, education and identification of overpayments, and when appropriate, made referrals to law enforcement for further criminal investigation and for administrative actions (such as payment suspensions or revocations).

CMS has also taken action to prevent improper Medicare payments by educating health care suppliers on proper billing of urine drug tests. CMS educates health care suppliers on Medicare billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters. CMS will continue to review guidance and educate suppliers as necessary on an ongoing basis.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should expand program safeguards to prevent and detect at-risk payments to at-risk providers for the definitive drug testing service with the highest reimbursement amount (procedure code G0483), which could have saved up to \$215.8 million for our audit period.

CMS Response

CMS concurs with this recommendation and will assess whether additional program safeguards would be feasible, given available resources and expected return. As stated above, determination of improper payment for this code requires medical record review, which is a resource-intensive process. CMS already has a prepayment edit in place, and conducts postpayment reviews that include medical review, recovering \$10.8 million for code G0483 through during the audit period.

OIG Recommendation

CMS should review at-risk payments made to at-risk providers during and after our audit period to determine whether payments for procedure code G0483 complied with Medicare requirements and recover any overpayments.

CMS Response

CMS does not concur with this recommendation. As stated above, OIG classified providers as “at-risk” for improper payment only due to the frequency at which they billed this code and the amount of Medicare reimbursement they received during the audit period. This analysis alone does not provide findings of improper payment, which would have required medical review. Conducting medical review for all providers that OIG classified as “at-risk” under this definition would not be a sufficiently targeted use of resources. However, CMS will send a comparative billing report to those providers that OIG identified, alerting them to the fact that their billing is an outlier compared to their peers. In addition, CMS will review this list of providers against providers CMS has already taken action on through other methods, to see if there is an opportunity for more engagement.

OIG Recommendation

CMS should notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

CMS Response

CMS does not concur with this recommendation. As stated above, this audit does not constitute credible information of overpayments because no overpayments were identified. Therefore, this audit is not sufficient basis upon which CMS can support a 60-day rule notice to identified providers.

OIG Recommendation

CMS should educate providers that received payments that did not comply with Medicare requirements for definitive drug testing services.

CMS Response

CMS has already issued national provider education on Medicare rules for urine drug testing. CMS marketed the education products seven times over the past four years and directed the Medicare Administrative Contractors to also educate providers on properly billing for specimen validity testing and urine drug tests. CMS will continue to educate providers as appropriate. In addition, as stated above, CMS will send a comparative billing report to providers that OIG cited as “at-risk.”

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.