

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**OPPORTUNITIES EXIST FOR
CMS AND ITS MEDICARE CONTRACTORS
TO STRENGTHEN PROGRAM
SAFEGUARDS TO PREVENT AND DETECT
IMPROPER PAYMENTS FOR
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

June 2021
A-09-20-03017

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: June 2021

Report No. A-09-20-03017

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



Why OIG Did This Audit

Patients in active treatment for substance use disorder may also be treated for a variety of medical conditions. Medicare Part B covers these patients' drug testing services when reasonable and necessary. For 2019, Medicare paid \$180 million for such services provided to 274,000 beneficiaries with substance use disorders nationwide. Although the 2019 Medicare fee-for-service improper payment rate was 7.3 percent, the improper payment rate was 58.9 percent for the drug test with the highest Medicare fee schedule amount. We conducted this audit to evaluate how the Centers for Medicare & Medicaid Services (CMS) and its Medicare contractors addressed the risk for improper payments for drug testing services.

Our objective was to assess the Medicare contractors' program safeguards for ensuring that Medicare claims for drug testing services for beneficiaries with substance use disorders comply with Medicare requirements.

How OIG Did This Audit

Our audit covered Medicare Part B claims for drug testing services provided in 2019 for beneficiaries with substance use disorders. We interviewed CMS officials and reviewed requirements for drug testing services in all seven Medicare contractors' Local Coverage Determinations (LCDs). We also interviewed staff from seven selected laboratories and analyzed claims data to determine the potential impact of weaknesses we identified.

Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services

What OIG Found

We identified three weaknesses in the Medicare contractors' established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. Specifically, the contractors did not have: (1) clear and consistent requirements or guidance for laboratories to use when determining the number of drug classes to bill for definitive drug testing services, (2) procedures for identifying or limiting the frequency of drug testing services (e.g., the number of drug tests performed per year) for each beneficiary across all Medicare jurisdictions, and (3) consistent requirements in their LCDs or any procedures for identifying claims for direct-to-definitive drug testing. If CMS and its contractors cannot ensure that laboratories' claims for drug testing services comply with Medicare requirements, laboratories may receive improper payments, and beneficiaries with substance use disorders may receive medically unnecessary drug testing services.

What OIG Recommends and CMS Comments

We recommend 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 National Coverage Determination or develop LCDs with more consistent requirements for drug testing services; (2) clearly indicate in LCDs, Local Coverage Articles, or other instructions how laboratories should determine the number of drug classes for billing definitive drug testing services; (3) implement a system edit or procedure to identify and limit the frequency of drug testing services per beneficiary across all Medicare jurisdictions; (4) determine whether a postpayment medical review is necessary for laboratories that have been paid for excessive definitive drug tests (e.g., more than one test) in a 1-week period for the same beneficiary; and (5) consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test.

CMS concurred with our fourth and fifth recommendations and provided information on actions that it had taken or planned to take to address them. However, CMS did not concur with our first three recommendations. After reviewing CMS's comments, we maintain that these recommendations are valid, but we refined our first and second recommendations.

TABLE OF CONTENTS

| | |
|---|----|
| INTRODUCTION..... | 1 |
| Why We Did This Audit..... | 1 |
| Objective..... | 1 |
| Background..... | 1 |
| The Medicare Program and the Role of the Centers for Medicare & Medicaid Services..... | 1 |
| Drug Testing Services..... | 2 |
| Medicare Coverage of Drug Testing Services..... | 2 |
| Medicare Contractors' Program Safeguards..... | 3 |
| How We Conducted This Audit..... | 5 |
| FINDINGS..... | 6 |
| Medicare Contractors Did Not Have Clear and Consistent Requirements or Guidance for Determining the Number of Drug Classes for Billing Definitive Drug Testing Services..... | 7 |
| Procedure Codes for Billing Definitive Drug Testing Services..... | 7 |
| Clear and Consistent Requirements or Guidance Across All Medicare Jurisdictions for Determining the Number of Drug Classes for Billing Definitive Drug Testing Services Did Not Exist..... | 8 |
| Lack of Clear and Consistent Requirements or Guidance Posed an Increased Risk for Maximizing Medicare Payments..... | 9 |
| Medicare Contractors Did Not Have Procedures for Identifying or Limiting the Frequency of Drug Testing Services for Each Beneficiary Across All Medicare Jurisdictions..... | 10 |
| Medicare Contractors' Limit on the Frequency of Drug Testing Services..... | 10 |
| Procedures for Identifying and Limiting the Frequency of Drug Testing Services for Each Beneficiary Across All Medicare Jurisdictions Did Not Exist..... | 11 |
| Lack of Procedures for Identifying and Limiting the Frequency of Drug Testing Services for Each Beneficiary Across All Medicare Jurisdictions Could Lead to Potential Improper Medicare Payments..... | 11 |
| Medicare Contractors Did Not Have Consistent Requirements or Any Procedures for Identifying Direct-to-Definitive Drug Testing..... | 12 |
| Provision of Direct-to-Definitive Drug Testing Based on a Physician Order..... | 12 |
| Medicare Contractors Had Inconsistent Requirements and No Procedures for Identifying Direct-to-Definitive Drug Testing..... | 13 |

| | |
|---|----|
| Lack of Consistent Requirements and Lack of Procedures for Identifying Direct-to-Definitive Drug Testing Could Lead to Potential Improper Medicare Payments | 15 |
| CONCLUSION..... | 17 |
| RECOMMENDATIONS | 18 |
| CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE | 19 |
| First Recommendation: Consistent Requirements for Drug Testing Services..... | 19 |
| CMS Comments..... | 19 |
| Office of Inspector General Response | 20 |
| Second Recommendation: Clear Policy on Determining the Number of Drug Classes.... | 20 |
| CMS Comments..... | 20 |
| Office of Inspector General Response | 20 |
| Third Recommendation: Implementing a System Edit or Procedure for Frequency of Drug Testing Services | 21 |
| CMS Comments..... | 21 |
| Office of Inspector General Response | 21 |
| APPENDICES | |
| A: Audit Scope and Methodology | 22 |
| B: Glossary of Terms | 24 |
| C: CMS Comments | 26 |

INTRODUCTION

WHY WE DID THIS AUDIT

Substance use disorders occur when the recurrent use of drugs or alcohol causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home. Patients in active treatment for substance use disorder (also known as substance abuse or drug addiction) or being monitored across different phases of recovery from substance use disorder may also be treated for a variety of medical conditions. For these patients, the results of drug testing influence health care providers' treatment and level-of-care decisions.¹ Medicare Part B covers drug testing services when they are reasonable and necessary.

For calendar year (CY) 2019 (audit period), Medicare paid approximately \$180 million for drug testing services provided to about 274,000 beneficiaries with substance use disorders nationwide.² Although the overall Medicare fee-for-service improper payment rate was 7.3 percent for Federal fiscal year 2019, the improper payment rate was 58.9 percent for the drug test with the highest Medicare fee schedule amount.³ Therefore, we conducted this audit to evaluate how the Centers for Medicare & Medicaid Services (CMS) and its Medicare administrative contractors (Medicare contractors) addressed the risk for improper payments related to drug testing services. Appendix B contains a glossary of terms used in this report.

OBJECTIVE

Our objective was to assess the Medicare contractors' program safeguards for ensuring that Medicare claims for drug testing services for beneficiaries with substance use disorders comply with Medicare requirements.

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 Medicare.

¹ The American Society of Addiction Medicine has established five levels of care, such as outpatient and inpatient services, for treatment of substance use disorders. The levels correspond to the intensity of treatment appropriate for a patient's needs.

² Each substance (such as opioids, cannabis, cocaine, or alcohol) used by a beneficiary has its own diagnosis code on a claim. We excluded from our audit those beneficiaries with a diagnosis of alcohol use disorder to focus on beneficiaries with a diagnosis of drug use disorder.

³ The Centers for Medicare & Medicaid Services (CMS) estimates the Medicare fee-for-service program's improper payment rate through the Comprehensive Error Rate Testing program.

Medicare Part B provides supplementary medical insurance for medical and other health services. CMS contracts with Medicare contractors to process and pay Part B claims for a defined geographic area, or jurisdiction, servicing institutional providers, physicians, nonphysician practitioners, and suppliers. CMS also issues National Coverage Determinations (NCDs) that specify whether certain items, services, procedures, or technologies are covered nationally under Medicare. NCDs are developed using an evidence-based process, with opportunities for public participation.⁴

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.⁵ Generally, there are two types of drug testing services: (1) presumptive testing and (2) definitive testing. Presumptive drug testing provides a negative, positive, or numerical result indicating the presence or absence of drugs or drug classes.⁶ Definitive drug testing identifies specific medications, illicit substances, and metabolites and reports the results in concentrations of specific drugs within a drug class.⁷

Medicare Coverage of Drug Testing Services

Medicare covers treatment services for substance use disorders, such as professional services and clinical laboratory services (including drug testing services), in an inpatient or outpatient setting when they are reasonable and necessary for the diagnosis or treatment of a beneficiary's illness.⁸ Medicare requires that drug testing services be ordered and testing results be used by the physician or qualified nonphysician practitioner who is treating the beneficiary.⁹ Clinical laboratories may provide drug testing services and submit Medicare Part B claims to one of the seven Medicare contractors, based on jurisdiction, for those services.¹⁰

⁴ In some cases, CMS's own research is supplemented by an outside technology assessment from or consultation with the Medicare Evidence Development & Coverage Advisory Committee, which was established to provide independent guidance and expert advice to CMS on specific clinical topics.

⁵ Some drugs are chemically altered (metabolized) by the body. The substances that result from this process are called metabolites.

⁶ 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.

⁷ The concentration of a drug is typically reported in nanograms per milliliter.

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

⁹ 42 CFR §§ 410.32(a) and 410.32(a)(2). For the purpose of this report, we refer to both physicians and qualified nonphysician practitioners as "physicians."

¹⁰ In addition to clinical laboratories, physicians may provide certain presumptive drug testing services in their offices.

For presumptive drug testing services, laboratories use one of three CPT¹¹ codes (80305, 80306, and 80307), depending on the level of complexity of the test. For definitive drug testing services, laboratories use one of five Healthcare Common Procedure Coding System (HCPCS) codes (G0480, G0481, G0482, G0483, and G0659), which generally are dependent on the number of drug classes, including metabolites, that are tested.¹² (Throughout this report, we refer to these CPT and HCPCS codes as “procedure codes.”)

Medicare Contractors’ Program Safeguards

To prevent and detect improper payments and promote provider compliance, Medicare contractors implement various CMS-developed or contractor-developed program safeguards, including NCDs, Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs); claim processing edits; and targeted provider-specific reviews.¹³

National Coverage Determinations, Local Coverage Determinations, and Local Coverage Articles

Medicare contractors implement NCDs, which are developed by CMS. An NCD specifies whether a particular item, service, procedure, or technology is covered nationally under Medicare.

Medicare contractors also develop and implement LCDs. An LCD is a contractor’s decision about whether a particular item or service is considered reasonable and necessary within its jurisdiction.¹⁴ LCDs may vary by contractor and result in different coverage in different jurisdictions.¹⁵

¹¹ The five character codes and descriptions included in this report 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.

¹² The HCPCS is a standardized coding system necessary for medical providers to submit health care claims to Medicare and other health insurers in a consistent and orderly manner.

¹³ The *Medicare Program Integrity Manual* (Program Integrity Manual), Pub. No. 100-08, chapter 1, section 1.3, states that addressing improper payments in the Medicare fee-for-service program and promoting compliance with Medicare coverage and coding rules is a top priority for CMS. It also states that preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners, including Medicare contractors and providers.

¹⁴ The Act § 1869(f)(2)(B).

¹⁵ 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)).

Finally, Medicare contractors develop and issue Local Coverage Articles (LCAs), which contain billing, coding, or other guidance that complement LCDs.¹⁶

Claims Processing Edits

Medicare contractors implement CMS-developed or contractor-developed claims processing system edits to prevent and detect improper payments.¹⁷ *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.

Medically Unlikely Edits

A medically unlikely edit (MUE) for a procedure code is a claims processing edit that is based on the maximum number of units of service that a provider would bill under most circumstances for a single beneficiary on a single date of service. MUEs are CMS-developed prepayment edits to reduce the improper payment rate for certain types of services. A Medicare contractor denies the entire service for payment when the billed units of service exceed MUE criteria. CMS publishes most MUE values on its website. Not all procedure codes have an MUE.

Targeted Provider-Specific Reviews

Medicare contractors can 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, Medicare contractors can 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

¹⁶ 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 fee-for-service 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' efforts to prevent improper payments is each contractor's Error Rate Reduction Plan, 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.

¹⁷ 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 a clear policy exists, Medicare contractors have the discretion to automatically deny services without stopping a claim for manual review. The term "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.

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 TPE reviews, Medicare contractors offer one-on-one education to providers after each round of review to help them correct their billing practices.

HOW WE CONDUCTED THIS AUDIT

Our audit covered Medicare Part B claims for drug testing services for beneficiaries with a diagnosis of substance use disorder (excluding claims for beneficiaries with a diagnosis of alcohol use disorder) provided during our audit period.¹⁸ Medicare paid approximately \$180 million on behalf of 274,000 beneficiaries with substance use disorders for 1.7 million drug testing services.¹⁹

We interviewed CMS officials to obtain an understanding of CMS's policies related to drug testing services. We reviewed requirements for drug testing services in LCDs issued by all seven Medicare contractors for our audit period and interviewed contractor officials to obtain additional information on LCDs and contractor edits for drug testing services claimed.²⁰

To obtain an understanding of how laboratories performed and documented drug testing services for Medicare beneficiaries, we interviewed staff from seven judgmentally selected laboratories, and for each laboratory, we reviewed supporting documentation obtained during our interviews.²¹ In addition, we analyzed the Medicare claims data for drug testing services provided during our audit period to determine the potential impact of weaknesses that we identified. Finally, we reviewed the publication *Examining Clinical Laboratory Services*, issued in

¹⁸ We also excluded procedure code G0659 from our audit because the total amount of paid claims was immaterial, and this procedure code (for one of the definitive drug tests) could be billed for any number of drug classes tested.

¹⁹ Medicare paid about \$51 million (for 232,000 beneficiaries) for presumptive drug testing services and about \$129 million (for 198,000 beneficiaries) for definitive drug testing services. Some beneficiaries received both presumptive and definitive drug tests.

²⁰ During CY 2019, the seven Medicare contractors were CGS Administrators, LLC (CGS); First Coast Service Operations, Inc. (First Coast); National Government Services, Inc. (NGS); Noridian Healthcare Solutions, LLC (Noridian); Novitas Solutions, Inc. (Novitas); Palmetto GBA (Palmetto); and Wisconsin Physicians Service Insurance Corporation (WPS). There were 12 Medicare Part B jurisdictions, and some of these contractors processed claims for more than 1 jurisdiction.

²¹ We selected laboratories in three different jurisdictions and then narrowed our selection to laboratories whose billing practices varied significantly from their peers (e.g., a laboratory that had 82 percent of the claims for procedure code G0483, which had the highest Medicare fee schedule amount).

May 2018 by the Healthcare Fraud Prevention Partnership (HFPP), and interviewed HFPP officials about the publication.²²

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

The Medicare contractors could strengthen their program safeguards for ensuring that Medicare claims for drug testing services for beneficiaries with substance use disorders comply with Medicare requirements. We identified three weaknesses in the established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. Specifically, the Medicare contractors did not have:

- clear and consistent requirements or guidance for laboratories to use when determining the number of drug classes to bill for definitive drug testing services,
- procedures for identifying or limiting the frequency of drug testing services (e.g., the number of drug tests performed per year) for each beneficiary across all Medicare jurisdictions, and
- consistent requirements in their LCDs or any procedures for identifying claims for direct-to-definitive drug testing.²³

These weaknesses occurred because CMS did not issue an NCD to provide uniform requirements for drug testing services or instruct the Medicare contractors to develop LCDs with more consistent requirements. In addition, the weaknesses occurred, in part, because of the following:

²² HFPP is a voluntary public-private partnership among the Federal Government, State and local government agencies, law enforcement, private health insurance plans, employer organizations, and health care antifraud associations. HFPP aims to foster a proactive approach to detect and prevent health care fraud through data and information sharing. CMS is a member of HFPP. The publication is available online at <https://www.cms.gov/files/document/download-clinical-laboratory-services-white-paper.pdf>. Accessed on Sept. 28, 2020. HFPP sought to use this publication to provide foundational information and to set the stage for additional discussions and interventions to address fraud and abuse in this area.

²³ Direct-to-definitive drug testing is the performing of a definitive drug test without first performing a presumptive drug test.

- Six of the seven Medicare contractors stated that they considered the CPT guidance as the most appropriate source for determining the number of drug classes for the purpose of billing definitive drug testing services. However, none of the seven contractors communicated to laboratories in their LCDs or LCAs their views on the use of CPT guidance.
- CMS officials stated that CMS could not develop a nationwide claims processing edit for the Medicare contractors to use to limit the frequency of drug testing services for each beneficiary across all Medicare jurisdictions because frequency requirements among the contractors were not consistent.
- Five Medicare contractors considered laboratories’ billing of a large number of drug classes using direct-to-definitive drug testing as a factor that could increase the risk for improper payments. However, none of these contractors considered this billing as an issue that required further review—by, for example, identifying claims for prepayment or postpayment reviews.

Without strengthening program safeguards, CMS and its Medicare contractors may not be able to identify laboratories that are not billing for drug testing services in compliance with Medicare requirements. If CMS and its contractors cannot ensure that laboratories’ claims for drug testing services comply with Medicare requirements, laboratories may receive improper payments, and beneficiaries with substance use disorders may receive medically unnecessary drug testing services.

MEDICARE CONTRACTORS DID NOT HAVE CLEAR AND CONSISTENT REQUIREMENTS OR GUIDANCE FOR DETERMINING THE NUMBER OF DRUG CLASSES FOR BILLING DEFINITIVE DRUG TESTING SERVICES

Procedure Codes for Billing Definitive Drug Testing Services

Generally, laboratories bill for definitive drug testing services based on the number of drug classes being tested. Table 1 shows four of the procedure codes that laboratories use to bill for definitive drug testing services, the number of drug classes tested, and CMS’s 2019 Medicare Clinical Laboratory Fee Schedule amount for each procedure code.

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

| Procedure Code | Number of Drug Classes | 2019 Medicare Fee Schedule Amount |
|-----------------------|-------------------------------|--|
| G0480 | 1–7 | \$114.43 |
| G0481 | 8–14 | 156.59 |
| G0482 | 15–21 | 198.74 |
| G0483 | 22 and more | 246.92 |

Clear and Consistent Requirements or Guidance Across All Medicare Jurisdictions for Determining the Number of Drug Classes for Billing Definitive Drug Testing Services Did Not Exist

The Medicare contractors did not have clear and consistent requirements in their LCDs or guidance in their LCAs for laboratories to use to determine the number of drug classes when identifying a procedure code to bill for definitive drug testing services.

Six of the seven contractors stated that they considered the CPT guidance as the most appropriate source for determining the number of drug classes for the purpose of billing definitive drug testing services.²⁴ The seventh contractor, CGS Administrators, LLC, stated that “any standardized list” of drug classes would be acceptable for determining the number of drug classes. However, none of the contractors’ LCDs or LCAs explained how laboratories should determine the number of drug classes or which source to use for the determination. Further, LCDs for four of the seven contractors listed some but not all of the drugs and their metabolites.²⁵ The other three contractors did not list any drugs in their LCDs.²⁶

Six of seven judgmentally selected laboratories identified drug classes differently when counting the number of drug classes for billing definitive drug testing services.²⁷ Specifically, the laboratories used different sources to identify drug classes. For example, a laboratory in 1 Medicare contractor’s jurisdiction stated that it used the CPT guidance to identify drug classes and tested for up to 31 of the total 38 drug classes in the guidance. (This laboratory did not have the capability to test for all 38 drug classes.) Based on the guidance, this laboratory counted benzodiazepines as one drug class. A laboratory in another jurisdiction stated that it used its own list of drugs that was developed based on its Medicare contractor’s LCD and tested for up to 67 drug classes. This laboratory counted 13 drugs categorized as benzodiazepines as 13 separate drug classes.²⁸

Impact of 2016 Revision to Drug Testing Procedure Codes

One Medicare contractor stated that the procedure codes were revised in 2016 to include ranges of drug classes and that this change was supposed to have fixed the issue of laboratories billing for tests for individual drugs to increase Medicare reimbursement. However, based on what we learned from seven laboratories, providers may still increase their Medicare reimbursement by billing for a procedure code with a higher reimbursement amount after improperly determining the number of drug classes tested.

²⁴ The six contractors were First Coast, NGS, Noridian, Novitas, Palmetto, and WPS.

²⁵ The four contractors were CGS, Noridian, Palmetto, and NGS.

²⁶ The three contractors were First Coast, Novitas, and WPS.

²⁷ We were not able to confirm how the remaining laboratory identified drug classes.

²⁸ Under the drug class benzodiazepines, there are various drugs and metabolites (such as clonazepam and its metabolite, 7-aminoclonazepam).

CMS officials informed us that each Medicare contractor may identify drug classes differently, and CMS would expect laboratories to work with their respective contractors to determine how to count the number of drug classes for billing definitive drug testing services. CMS also stated that each LCD should have a bibliography, which lists the source that the Medicare contractor used (e.g., the American Medical Association (AMA) or Food and Drug Administration) to identify drug classes for billing purposes.²⁹ Further, CMS stated that billing and coding instructions would be included in a policy article (i.e., an LCA), not in an LCD.³⁰

Lack of Clear and Consistent Requirements or Guidance Posed an Increased Risk for Maximizing Medicare Payments

Without clear and consistent requirements or guidance for identifying the number of drug classes tested, there is an increased risk that laboratories may bill for a procedure code with a higher reimbursement amount and maximize Medicare payments. For example, a laboratory in 1 jurisdiction could bill for 15 drug classes, but a laboratory in a different jurisdiction could bill for 25 drug classes, even though the laboratories performed the same drug test. The laboratory that billed for 25 drug classes would be paid more than the laboratory that billed for 15 drug classes.

Figure 1 shows the number of definitive drug tests and the Medicare payments made for each procedure code for our audit period. For definitive drug testing services with 15 or more drug classes (procedure codes G0482 and G0483), the 365,000 tests paid accounted for 49 percent of the total number of definitive drug tests paid, and the Medicare payments of \$81 million accounted for 63 percent of the total Medicare payments for definitive drug tests.

Figure 1: The Number of Definitive Drug Tests and Medicare Payments by Procedure Code

| | Procedure Code for Definitive Testing | | | | Total |
|--|---------------------------------------|--------------|--------------|--------------|---------------|
| | G0480 | G0481 | G0482 | G0483 | |
| Number of Tests Paid | 265,237 | 118,123 | 148,414 | 216,611 | 748,385 |
| Percentage of Total Number of Tests Paid | 35% | 16% | 20% | 29% | 100% |
| Amount Paid | \$29,477,240 | \$17,998,474 | \$28,814,068 | \$52,229,631 | \$128,519,413 |
| Percentage of Total Amount Paid | 23% | 14% | 22% | 41% | 100% |
| Combined G0482 + G0483 | | | | | |
| Percentage of Number of Tests Paid: 49% | | | | | |
| Percentage of Amount Paid: 63% | | | | | |

²⁹ The Program Integrity Manual, Pub. No. 100-08, chapter 13, section 13.5.3, states that Medicare contractors must list in the bibliography all articles and sources that led to the LCD. However, none of the LCDs for the seven contractors included the source used to identify drug classes for billing purposes.

³⁰ The Program Integrity Manual, Pub. No. 100-08, chapter 13, section 13.5.1, states that CPT codes shall be placed in billing and coding articles or policy articles related to the LCD.

There is no assurance that Medicare properly paid the \$81 million for procedure codes G0482 and G0483 because laboratories may determine the number of drug classes differently.

MEDICARE CONTRACTORS DID NOT HAVE PROCEDURES FOR IDENTIFYING OR LIMITING THE FREQUENCY OF DRUG TESTING SERVICES FOR EACH BENEFICIARY ACROSS ALL MEDICARE JURISDICTIONS

Medicare Contractors’ Limit on the Frequency of Drug Testing Services

The procedure codes for all drug testing services had an MUE to limit Medicare payment to payment for one presumptive and one definitive drug testing service per day per beneficiary. In addition to the MUE, 1 Medicare contractor had a prepayment edit limiting the frequency for each type of drug test (i.e., presumptive and definitive) to 12 per year per beneficiary.³¹ Further, five contractors had LCDs stating that payment was limited based on a certain frequency of drug testing services.³²

HFPP Partners’ Concerns About Excessive Drug Testing

“... virtually all HFPP Partners reported concerns about the widespread fraud and abuse associated with excessive urine drug testing being performed primarily to increase provider reimbursement. Partners note that urine drug testing has become a major source of revenue for many providers, thereby encouraging potential fraud and abuse.”
(HFPP, *Examining Clinical Laboratory Services*, May 2018.)

These testing frequencies are shown in Table 2.³³ Testing more frequently was not considered reasonable and necessary and was not covered by Medicare.³⁴

Table 2: Five Medicare Contractors’ Maximum Allowable Frequency of Drug Testing Services Based on the Number of Days of Abstinence for Beneficiaries With Substance Use Disorders

| No. of Days of Abstinence | Frequency of Definitive Drug Test | Frequency of Presumptive Drug Test |
|---------------------------|-----------------------------------|------------------------------------|
| 0–30 | 1 per week | 1–3 per week |
| 31–90 | 1–3 per month | 1–3 per week |
| >90 | 1–3 in 3 months | 1–3 per month |

³¹ Palmetto stated that it allowed laboratories to provide supporting documentation to appeal claims for drug tests above the limit that were previously denied for payment. Palmetto also stated that it had received about 7,900 appeals in CY 2019. However, only about 5.6 percent of previously denied claims associated with the appeals were reversed. Palmetto said that the low reversal rate was due to providers’ lack of documentation for the appeals.

³² The five contractors were CGS, First Coast, NGS, Noridian, and Palmetto.

³³ The frequency requirements listed in the LCDs were related to the number of consecutive days of abstinence (i.e., days not having taken the abused drug).

³⁴ Novitas’s LCD had frequency requirements for only presumptive drug testing, and WPS’s LCD did not have any frequency requirements.

Procedures for Identifying and Limiting the Frequency of Drug Testing Services for Each Beneficiary Across All Medicare Jurisdictions Did Not Exist

Based on our data analysis, we concluded that the MUE that all seven Medicare contractors implemented to limit payments for presumptive and definitive drug tests to payment for one of each test per day for each beneficiary worked as intended, which was to reduce the improper Medicare payment rate for drug testing services within each jurisdiction. None of the contractors paid for more than one of each test per day for each beneficiary.³⁵ However, the contractors did not have any procedures besides the MUE to prevent potential improper payments, such as identifying and further limiting the frequency of drug testing services for each beneficiary across all Medicare jurisdictions.

Some laboratories were aware of the LCDs' frequency requirements or one Medicare contractor's prepayment edit but did not have procedures to identify and limit the frequency of drug testing services by beneficiary. For example, officials at one laboratory stated that they did not track the frequency of drug testing and would run all tests that were ordered because "it was up to the ordering physician to determine medical necessity."

CMS officials stated that CMS could not develop a nationwide claims processing edit for the Medicare contractors to use to limit the frequency of drug testing services for each beneficiary across all Medicare jurisdictions because frequency requirements among the contractors were not consistent. They stated that individual Medicare contractors should issue their own frequency requirements through LCDs. They also stated that contractors did not identify the frequency of drug testing services by beneficiary across contractor jurisdictions but if there were a policy in place under which all contractors had the same limit, CMS could enforce that limit via a claims processing edit.

Lack of Procedures for Identifying and Limiting the Frequency of Drug Testing Services for Each Beneficiary Across All Medicare Jurisdictions Could Lead to Potential Improper Medicare Payments

If Medicare contractors do not have procedures to identify the number of drug tests performed by laboratories across all Medicare jurisdictions for each beneficiary, a laboratory with multiple locations in different contractor jurisdictions could bill for drug testing services for the same beneficiary, and the contractors would not be able to identify this billing pattern.

For our audit period, about 9 percent of all beneficiaries with presumptive or definitive drug tests, or both, had claims processed by more than one Medicare contractor, which accounted for about 20 percent (or \$36.2 million) of all drug testing services paid nationwide. Figure 2 on the following page shows the total Medicare payments, the number of beneficiaries, and the

³⁵ Medicare contractors could have paid for more than one of each type of drug test per day for each beneficiary when laboratories submitted claims with a modifier.

average amount paid per beneficiary for claims for drug testing services processed by one or more Medicare contractors.

Figure 2: Medicare Payments, Number of Beneficiaries, and Average Amount Paid per Beneficiary for Drug Testing Claims Processed by One or More Medicare Contractors

| | Number of Contractors With Claims for the Same Beneficiary | Amount Paid | Number of Beneficiaries | Average Amount Paid per Beneficiary |
|---|--|----------------------|-------------------------|-------------------------------------|
| | 1 | \$143,710,643 | 249,063 | \$577 |
| \$36.2 Million Paid by More Than One Contractor With Claims for the Same Beneficiary | 2 | 32,078,535 | 23,399 | 1,371 |
| | 3 | 3,738,474 | 1,486 | 2,516 |
| | 4 | 383,543 | 89 | 4,309 |
| | 5 | 34,262 | 5 | 6,852 |
| | Total | \$179,945,457 | 274,042 | |

In addition, for our audit period, of the \$129 million paid for definitive drug testing services on behalf of 198,000 beneficiaries, about \$5.6 million (4 percent) was paid for definitive drug testing services in excess of 1 test a week on behalf of about 11,300 beneficiaries (6 percent of the beneficiaries).³⁶

MEDICARE CONTRACTORS DID NOT HAVE CONSISTENT REQUIREMENTS OR ANY PROCEDURES FOR IDENTIFYING DIRECT-TO-DEFINITIVE DRUG TESTING

Provision of Direct-to-Definitive Drug Testing Based on a Physician Order

Generally, a presumptive drug test is performed to rapidly obtain test results used in a clinical assessment and for treatment decisions. When there is a need for more accurate test results, such as identifying specific drugs in a drug class, a definitive drug test may be performed. In certain cases, a physician may order a definitive drug test without having ordered a presumptive test first, which is known as direct-to-definitive testing.

³⁶ We analyzed the claims data using the least stringent requirement in the LCDs, which was one test per week assuming that a beneficiary had 30 or fewer days of abstinence. For each week, we identified beneficiaries who had more than one definitive drug test paid. For example, if a beneficiary had two definitive tests paid in 1 week, we counted the second test as in excess of one per week.

Medicare Contractors Had Inconsistent Requirements and No Procedures for Identifying Direct-to-Definitive Drug Testing

Medicare contractors did not have consistent requirements in their LCDs for direct-to-definitive drug testing and did not have procedures for identifying direct-to-definitive drug testing.

LCD requirements related to definitive drug testing services performed without a presumptive drug test (i.e., direct-to-definitive testing) differed among the Medicare contractors, as illustrated in Table 3. Two of seven contractors had specific requirements in their LCDs indicating the specific circumstances when direct-to-definitive drug testing was reasonable and necessary. However, the remaining five contractors had a vague requirement or no requirement.³⁷

Table 3: Different Requirements Among Medicare Contractors for Direct-to-Definitive Drug Testing

| No Requirement: One Medicare Contractor | Vague Requirement: Four Medicare Contractors | Specific Requirement: Two Medicare Contractors |
|---|---|---|
| Laboratories in this Medicare contractor’s jurisdiction could bill direct-to-definitive drug testing however they wanted. | LCDs stated: “Direct to definitive [drug testing] without a presumptive [test] is reasonable and necessary, when individualized for a particular patient.” However, there was no explanation of what “individualized” meant. | LCDs included four specific circumstances when direct-to-definitive testing is reasonable and necessary: <ul style="list-style-type: none"> • to identify a specific substance that is in a large class of drugs or inadequately detected by presumptive drug testing; • for use in assessing medication efficacy, side effects, or drug interactions; • to identify nonprescribed medications or illicit substance use for ongoing safe prescribing of controlled substances; or • to identify a drug when a definitive concentration of a drug is needed to guide the management of a treatment plan. |

³⁷ The one contractor with no requirement was WPS. The four contractors with a vague requirement were CGS, NGS, Noridian, and Palmetto. The two contractors with specific requirements were First Coast and Novitas.

Further, the Medicare contractors did not have procedures for identifying billing of direct-to-definitive drug testing provided to beneficiaries. Identifying this billing may enable contractors to more effectively monitor claims for drug testing services and identify aberrant billing practices. Five Medicare contractors considered laboratories' billing of a large number of drug classes using direct-to-definitive drug testing as a factor that could increase the risk for improper payments.³⁸ However, none of these contractors considered this billing as an issue that required further review—by, for example, identifying claims for prepayment or postpayment reviews so that improper payments could be prevented.³⁹ Only one of the seven contractors performed provider-specific prepayment or postpayment TPE reviews for drug testing services, but these reviews did not focus specifically on direct-to-definitive drug testing.⁴⁰ Also, none of the contractors had a process (e.g., use of a modifier established by CMS) to identify billing patterns of laboratories that routinely billed for direct-to-definitive drug testing.

All seven judgmentally selected laboratories stated that they routinely performed direct-to-definitive testing for a large number of drug classes. Three of them stated that they would perform any test ordered by a physician. In addition, one laboratory did not provide an option for the physician to order presumptive testing for certain drug classes.

Figure 3 on the following page shows one laboratory's form for establishing drug testing profiles, allowing a physician to request (i.e., check the box for) presumptive testing on only two drug classes.⁴¹

HFPP Partners' Concern About the Routine Use of Direct-to-Definitive Drug Testing

According to HFPP's publication, the routine use of definitive urine drug testing, in place of lower-cost presumptive testing, was a major concern. Some HFPP partners suggested that definitive testing in the absence of a presumptive test result (i.e., direct-to-definitive testing) should trigger a clinical record exam or be unallowable.

The publication also stated that a commonly reported problem is the use of more expensive, excessively broad panels in place of smaller panels. While this use may be clinically warranted in some cases, it can also be used for the purpose of maximizing reimbursement in the absence of medical necessity. A related problem that can be difficult to control is the use of definitive drug testing for a wide range of substances for which the patient has no history of abuse. (HFPP, *Examining Clinical Laboratory Services*, May 2018.)

³⁸ The five contractors were CGS, First Coast, NGS, Noridian, and Palmetto.

³⁹ One contractor stated that the medical records should show a rationale for direct-to-definitive testing for specific drugs and a long list of drugs should not need to be tested all the time (i.e., routine testing).

⁴⁰ The contractor was Noridian.

⁴¹ Drug testing profiles are developed by a laboratory and allow a physician to select a list of drugs to be ordered for testing.

Figure 3: One Laboratory's Form To Create a Testing Profile for Ordering Presumptive or Definitive Drug Testing Services

| <u>Drug Name</u> | <u>Presumptive Testing</u> (Chemistry Analyzer) | <u>Definitive Testing</u> (LC/MS/MS – GC/MS) | <u>Drug Class</u> |
|-----------------------|--|---|----------------------------|
| Amphetamine | <input type="checkbox"/> | <input type="checkbox"/> ** | Amphetamines |
| Barbiturates | <input type="checkbox"/> | <input type="checkbox"/> | Barbiturates |
| Benzodiazepines | <input type="checkbox"/> | <input type="checkbox"/> | Benzodiazepines |
| Cocaine | <input type="checkbox"/> | <input type="checkbox"/> | Cocaine |
| Methadone | <input type="checkbox"/> | <input type="checkbox"/> | Methadone |
| MDMA | <input type="checkbox"/> | <input type="checkbox"/> | MDMA |
| Opiates | <input type="checkbox"/> | <input type="checkbox"/> | Opiates |
| Oxycodone | <input type="checkbox"/> | <input type="checkbox"/> | Oxycodone |
| THC | <input type="checkbox"/> | <input type="checkbox"/> ** | Cannabinoids |
| Buprenorphine | <input type="checkbox"/> | <input type="checkbox"/> | Buprenorphine |
| Fentanyl | <input type="checkbox"/> | <input type="checkbox"/> | Fentanyl |
| Heroin metabolite | <input type="checkbox"/> | <input type="checkbox"/> | Heroin metabolite |
| Tapentadol | <input type="checkbox"/> | <input type="checkbox"/> | Tapentadol |
| Tramadol | <input type="checkbox"/> | <input type="checkbox"/> | Tramadol |
| Synthetic Cannabinoid | <input type="checkbox"/> | <input type="checkbox"/> | Synthetic Cannabinoid |
| TCA | <input type="checkbox"/> | <input type="checkbox"/> | Antidepressants, Cyclicals |
| Bath Salts | <input type="checkbox"/> | <input type="checkbox"/> | Synthetic Stimulants |

** Available upon request

Additional Tests:

According to CMS, laboratories perform direct-to-definitive testing for drugs that cannot be detected by presumptive tests, such as newer drug classes and synthetic drugs.⁴² CMS stated that the ordering physician would decide whether to request drug testing services for these substances and that laboratories generally performed all drug tests ordered.

Lack of Consistent Requirements and Lack of Procedures for Identifying Direct-to-Definitive Drug Testing Could Lead to Potential Improper Medicare Payments

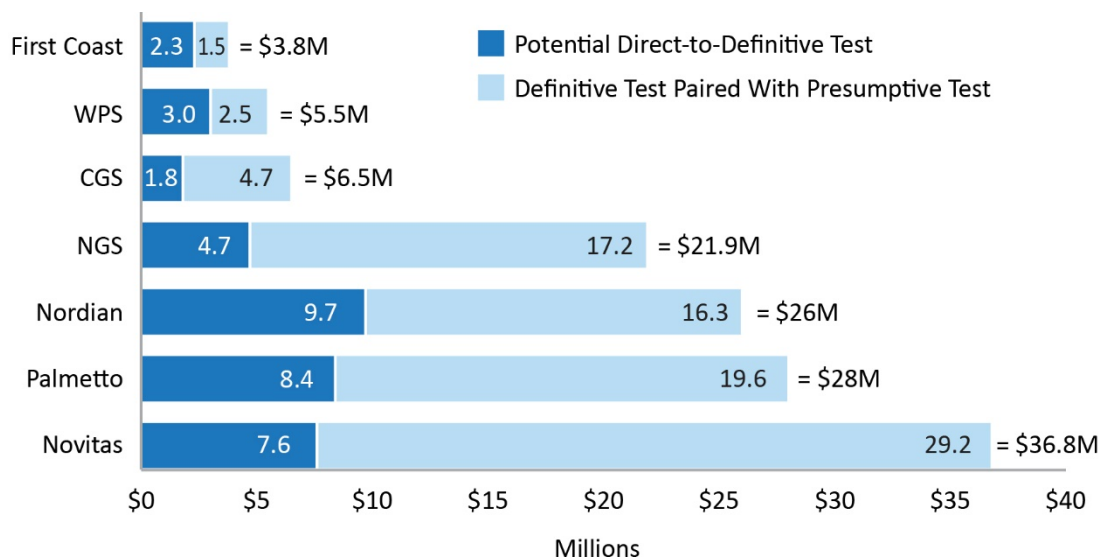
If Medicare contractors do not have consistent requirements and do not have procedures to identify for further analysis and review the billing of direct-to-definitive drug testing, the contractors cannot ensure that they allow only reasonable and necessary direct-to-definitive testing.

For our audit period, of the approximately \$129 million paid for definitive drug testing services, \$37 million (29 percent) was paid when no presumptive drug testing service was performed on the same date of service for the same beneficiary. Figure 4 on the following page compares the amounts paid by each contractor for definitive drug testing services when: (1) no presumptive

⁴² A synthetic drug is a drug with properties and effects similar to a known hallucinogen or narcotic but having a slightly altered chemical structure, especially such a drug created in order to evade restrictions against illegal substances. The LCDs for all of the Medicare contractors stated that synthetic drugs require definitive testing for detection.

drug testing was performed on the same date of service (potential direct-to-definitive drug testing⁴³) and (2) presumptive drug testing was performed on the same date of service.

Figure 4: Amounts Paid for Potential Direct-to-Definitive vs. Definitive Tests Paired With Presumptive Tests on the Same Date of Service



In addition, 68 percent of the total number of potential direct-to-definitive tests claimed were for the procedure codes with higher reimbursement amounts (i.e., G0482 and G0483), which totaled \$29.4 million.

If all Medicare contractors had the same specific LCD requirements for when direct-to-definitive drug testing was reasonable and necessary, all laboratories in all jurisdictions would be subject to the same direct-to-definitive drug testing requirements. Further, if all contractors had procedures to identify direct-to-definitive drug testing, the contractors could identify laboratories that routinely billed for direct-to-definitive drug testing. Having consistent requirements and having procedures would allow CMS and Medicare contractors to monitor billing of direct-to-definitive drug testing to prevent and detect improper payments.

⁴³ We use the term “potential” because some services claimed may have been included as direct-to-definitive drug testing when they were not. For example, this could have occurred if a physician had reviewed the presumptive drug test results and then ordered a definitive drug test for the same specimen at a later date. In another example, some claims may not have been included as potential direct-to-definitive drug testing if presumptive and definitive drug tests were billed on the same date of service, but each test was for different drugs within the same specimen. We were unable to determine the number of claims that would have been included in either scenario.

CONCLUSION

We identified three weaknesses in the Medicare contractors' established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. Specifically, the Medicare contractors did not have: (1) clear and consistent requirements or guidance for laboratories to use when determining the number of drug classes to bill for definitive drug testing services, (2) procedures for identifying or limiting the frequency of drug testing services for each beneficiary across all Medicare jurisdictions, and (3) consistent requirements in their LCDs or any procedures for identifying claims for direct-to-definitive drug testing.

Our claims data analysis showed the following payments as having an increased risk of being potentially improper:

- The Medicare payments for 15 or more drug classes (procedure codes G0482 and G0483) were about \$81 million. However, there was no assurance that the \$81 million in payments were made properly for the procedure codes representing the actual numbers of drug classes tested.
- Medicare paid about \$36.2 million for drug testing services on behalf of beneficiaries who had claims processed by more than one Medicare contractor.
- Of the approximately \$129 million paid for definitive drug testing services, \$37 million (29 percent) was paid when no presumptive drug testing service was performed on the same date of service for the same beneficiary.

These weaknesses occurred because CMS did not issue an NCD to provide uniform requirements for drug testing services or instruct the Medicare contractors to develop LCDs with more consistent requirements. In addition, the weaknesses occurred, in part, because: (1) six of the seven contractors stated that they considered the CPT guidance as the most appropriate source for determining the number of drug classes for the purpose of billing definitive drug testing services, but none of the seven contractors communicated to laboratories in their LCDs or LCAs their views on the use of CPT guidance; (2) CMS officials stated that CMS could not develop a nationwide claims processing edit for the contractors to use to limit the frequency of drug testing services for each beneficiary across all Medicare jurisdictions because of inconsistent frequency requirements among the contractors; and (3) five contractors considered laboratories' billing of a large number of drug classes using direct-to-definitive drug testing as a factor that could increase the risk for improper payments, but none of these contractors had considered this billing as an issue that required further review—by, for example, identifying claims for prepayment or postpayment reviews.

Without strengthening program safeguards, CMS and its Medicare contractors may not be able to identify whether laboratories are billing for drug testing services in compliance with Medicare requirements. If CMS and its contractors cannot ensure that laboratories' claims for

drug testing services comply with Medicare requirements, laboratories may receive improper payments, and beneficiaries with substance use disorders may receive medically unnecessary drug testing services.

RECOMMENDATIONS

To strengthen program safeguards for preventing and detecting improper payments for drug testing services and to address the three specific weaknesses we identified in this report, we recommend that the Centers for Medicare & Medicaid Services work with its Medicare contractors to do the following:

- Take the necessary steps to determine whether clinical evidence exists to support a single, specific reasonable and necessary standard that: (1) laboratories could use when determining the number of drug classes to bill for definitive drug testing services and (2) indicates the specific circumstances when direct-to-definitive drug testing is reasonable and necessary, and if clinical evidence exists, establish an NCD or develop LCDs with more consistent requirements for drug testing services.
- Clearly indicate in LCDs, LCAs, or other instructions how laboratories should determine the number of drug classes when identifying which procedure code to bill for definitive drug testing services (e.g., using CPT guidance as a specific source).
- Implement a system edit or procedure to identify and limit the frequency of drug testing services per beneficiary across all Medicare jurisdictions. System edits or procedures that CMS and its contractors could consider include: (1) adding a modifier to claims that represents the number of days of abstinence to track frequency or (2) determining the number of reasonable and necessary drug tests per calendar year per beneficiary and performing postpayment reviews of those tests that exceed the number.
- Determine whether a postpayment medical review is necessary for laboratories that have been paid for excessive definitive drug tests (e.g., more than one test) in a 1-week period for the same beneficiary.
- Consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test so that Medicare contractors can identify for followup those laboratories that routinely bill direct-to-definitive drug testing for a large number of drug classes.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our fourth and fifth recommendations and provided information on actions that it had taken or planned to take to address these recommendations. However, CMS did not concur with our first, second, and third recommendations.

Regarding our fourth recommendation, CMS stated that it will share our report with the Medicare contractors for their consideration in adding medical review activities for potentially excessive definitive drug testing services to their improper payment review strategies. Regarding our fifth recommendation, CMS stated that Medicare contractors can already determine whether there was a presumptive test by searching claims history. CMS also stated that it will determine whether adding a modifier to claims would be feasible and whether it would be helpful to the Medicare contractors in following up with identified laboratories.

In addition to addressing our specific recommendations, CMS provided information on its strategy to reduce and prevent Medicare improper payments, such as automated system edits within the claims processing system, prepayment and postpayment medical reviews, and provider education through various channels, including the Medicare Learning Network. CMS stated that it “has also taken a number of steps to achieve more consistency among LCDs when appropriate.” CMS also stated that it convenes regular meetings with the Medicare contractors “to collaborate on LCD evidentiary development and discuss development processes to the extent permitted by their contracts.” Furthermore, CMS stated that to “measure, incentivize, and ensure increased collaboration among the [Medicare contractors], CMS has added a metric related to LCD collaboration to the [Medicare contractor] Award Fee, which [Medicare contractors] can earn if their performance exceeds basic requirements.”

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 first, second, and third recommendations are valid, but we refined our first and second recommendations. Our responses to CMS’s specific comments are described in the sections below.

FIRST RECOMMENDATION: CONSISTENT REQUIREMENTS FOR DRUG TESTING SERVICES

CMS Comments

CMS stated the following: “Requirements placed in NCDs and LCDs must be based on medical evidence and provide coverage policies based on the reasonable and necessary standard.” 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 LCDs are not required to be consistent across MAC jurisdictions. CMS

stated, however, that it has already taken a number of steps to achieve more consistency among LCDs when appropriate.

Office of Inspector General Response

Although CMS is not currently aware of any clinical evidence to support a single, specific reasonable and necessary standard for drug testing services, we believe that CMS should initiate action to determine whether such clinical evidence exists. For example, during regular meetings with Medicare contractors, CMS could discuss the findings in our report and ask the contractors whether they are aware of any clinical evidence that would support a single, specific reasonable and necessary standard. Our report shows that two contractors had LCDs that included four specific circumstances when direct-to-definitive testing is reasonable and necessary. We recognize that CMS has already taken a number of steps to achieve more consistency among LCDs when appropriate. However, our findings show that CMS has not taken steps to achieve more consistency among LCDs for drug testing services. Therefore, we strongly encourage CMS to take steps to achieve more consistency.

After reviewing CMS's comments, we refined our first recommendation by adding specific language that CMS take the necessary steps to determine whether clinical evidence exists to support a single, specific reasonable and necessary standard, and if clinical evidence exists, establish an NCD or develop LCDs with more consistent requirements for drug testing services.

SECOND RECOMMENDATION: CLEAR POLICY ON DETERMINING THE NUMBER OF DRUG CLASSES

CMS Comments

CMS stated that LCDs are not the proper venue for billing or coding requirements and that these requirements are not directly related to the reasonable and necessary standard. CMS also stated that while billing or coding requirements can be discussed in LCAs, LCAs that are related to an LCD are intended to support an LCD policy. 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.

Office of Inspector General Response

Determining the number of drug classes is directly related to using the correct procedure codes to bill for drug testing services. Our report shows that if there is no clear policy (e.g., a policy in LCDs or LCAs) on drug testing services specifically related to determining the number of drug classes tested, providers may not understand how to correctly submit claims.⁴⁴

⁴⁴ See footnote 16.

As noted in our report, six of the seven Medicare contractors stated that they considered the CPT guidance as the most appropriate source for determining the number of drug classes for the purpose of billing definitive drug testing services. Because the AMA developed the CPT guidance, CMS and the Medicare contractors may be able to obtain from the AMA the needed clinical evidence for drug classes.

After reviewing CMS's comments, we refined the first part of our second recommendation by adding that CMS can indicate in other instructions (in addition to LCDs or LCAs) how laboratories should determine the number of drug classes.

THIRD RECOMMENDATION: IMPLEMENTING A SYSTEM EDIT OR PROCEDURE FOR FREQUENCY OF DRUG TESTING SERVICES

CMS Comments

CMS stated there is no clinical evidence to suggest that testing frequency should be linked to a certain number of days of abstinence or that a certain number of tests per year is reasonable and necessary for all individuals.

Office of Inspector General Response

As stated in our report, 1 of the Medicare contractors had a prepayment edit limiting the frequency for each type of drug test (i.e., presumptive and definitive) to 12 per year per beneficiary. Further, five contractors had LCDs stating that payment was limited based on a certain frequency of drug testing services. The maximum allowable frequency of drug testing services based on the number of days of abstinence for beneficiaries with substance use disorders was 1 per week. We suggest that CMS discuss with the Medicare contractors how they determined these frequency limits, including any clinical evidence used to make those determinations. Although we understand that a limit on the number of tests per year may not be appropriate for all beneficiaries, a system edit or procedure, such as postpayment reviews, for beneficiaries that exceed a certain frequency may identify drug testing services that are not reasonable and necessary.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered Medicare Part B claims for drug testing services for beneficiaries with a diagnosis of substance use disorder (excluding claims for beneficiaries with a diagnosis of alcohol use disorder) provided from January 1 through December 31, 2019.⁴⁵ Medicare paid \$179,945,457 on behalf of 274,042 beneficiaries with substance use disorders for 1,713,493 drug testing services.

We did not perform an overall assessment of the internal control structures of CMS or its Medicare contractors. Rather, we limited our review to those internal controls (i.e., program safeguards) related to Medicare reimbursement requirements for drug testing services. We focused on reviewing four of the five components of internal controls: control environment, risk assessment, control activities, and information and communication.⁴⁶ Because our audit was designed to provide only reasonable assurance that the internal controls we reviewed were effective, it would not necessarily have detected all internal control deficiencies.

We conducted our audit from March 2020 to March 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed Medicare contractors' LCDs covering our audit period;
- interviewed officials from CMS and Medicare contractors to obtain an understanding of Medicare reimbursement requirements and their established program safeguards, if any, for drug testing services;
- reviewed written responses that the seven Medicare contractors provided to our questions related to their program safeguards;

⁴⁵ We also excluded procedure code G0659 from our audit because the total amount of paid claims was immaterial, and this procedure code (for one of the definitive drug tests) was not dependent on the number of drug classes tested.

⁴⁶ The Government Accountability Office's (GAO's) *Standards for Internal Control in the Federal Government: September 2014* (GAO-14-704G), known as the Green Book, sets the internal control standards for Federal entities. The Green Book defines internal control as the plans, methods, policies, and procedures used by management to fulfill the mission, strategic plan, goals, and objectives of the entity. The Green Book approaches internal control through a hierarchal structure made up of five components: (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

- judgmentally selected seven laboratories in three States and for each laboratory:⁴⁷
 - interviewed staff to obtain an understanding of how they perform and bill for drug testing services and
 - reviewed supporting documentation obtained during our interviews;
- reviewed HFPP’s publication *Examining Clinical Laboratory Services*, issued in May 2018, and interviewed HFPP officials about the publication to obtain an understanding of industrywide issues related to drug testing services that were previously identified;
- obtained Medicare claims data for drug testing services for dates of service for our audit period and analyzed these data to identify:
 - the number of tests and the amounts paid for procedure codes for definitive drug testing services,
 - beneficiaries with more than one presumptive or definitive drug test on the same date of service,
 - the amounts paid and the number of beneficiaries with claims processed by more than one Medicare contractor,
 - the amounts paid and the number of beneficiaries with more than one definitive drug test in 1 week, and
 - the number of tests and the amounts paid for potential direct-to-definitive drug tests and definitive drug tests paired with presumptive tests on the same date of service; 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.

⁴⁷ We selected laboratories in three different jurisdictions and then narrowed our selection to laboratories whose billing practices varied significantly from their peers (e.g., a laboratory that had 82 percent of the claims for procedure code G0483, which had the highest Medicare fee schedule amount).

APPENDIX B: GLOSSARY OF TERMS⁴⁸

abstinence: A method of addiction treatment that involves the patient's complete avoidance of substance use.

benzodiazepines: A class of drugs most commonly used to treat insomnia and anxiety.

concentration of drug: The amount of a drug typically reported in nanograms per milliliter.

definitive drug testing: Identifies specific medications, illicit substances, and metabolites in the blood, urine, or oral fluids and reports the results in concentrations of drugs within a drug class.

direct-to-definitive drug testing: The performing of a definitive drug test without first performing a presumptive drug test.

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

metabolite: A substance that results from the process of a drug being chemically altered by the body (i.e., metabolized).

presumptive drug testing: Provides a negative, positive, or numerical result indicating the presence or absence of drugs or drug classes in a sample.

procedure codes for definitive drug testing: For CY 2019, the procedure codes for definitive drug testing were G0480, G0481, G0482, G0483, and G0659. Procedure codes G0480 through G0483 were based on the number of drug classes tested using drug identification methods able to identify individual drugs utilizing universally recognized internal standards, calibration, and quality control materials. Procedure code G0659 was based on any number of drug classes tested using a simple method of definitive drug testing.

procedure codes for presumptive drug testing: For CY 2019, the procedure codes for presumptive drug testing were 80305,⁴⁹ 80306, and 80307 and were based on the complexity of the test. For example, code 80305 was used for presumptive drug testing using direct optical observation (e.g., using a cup or dipstick test), and code 80307 was used for presumptive drug testing using a chemical analyzer (e.g., using laboratory instruments).

⁴⁸ The terms and definitions in this glossary come from various sources, including LCDs, and are for the purposes of this report only. They may not be the same terms and definitions used in Federal regulations and CMS guidance.

⁴⁹ **The five character codes and descriptions included in this report 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.**

synthetic drug: A drug with properties and effects similar to a known hallucinogen or narcotic but having a slightly altered chemical structure, especially a drug created to evade restrictions against illegal substances.

APPENDIX C: CMS COMMENTS



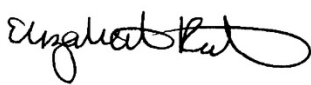
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: April 9, 2021

TO: Amy Frontz
Deputy Inspector General for Audit Services

FROM: Elizabeth Richter
Acting Administrator 

SUBJECT: Office of Inspector General (OIG) Draft Report: 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)

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.

For example, nationally, all Medicare Administrative Contractors (MACs) have an edit in place to limit Medicare payment to one presumptive drug test (to identify the presence or absence of drugs or drug classes) and one definitive drug test (to identify specific substances) per day per beneficiary. In addition, CMS leverages tools like the Fraud Prevention System to alert MACs of providers who bill at an anomalous rate.

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.

In addition, while MACs have the authority to make local coverage determinations (LCDs) within their jurisdictions under sections 1869(f)(2)(B) and 1862(l)(5)(D) of the Social Security Act, CMS has also taken a number of steps to achieve more consistency among LCDs when appropriate. CMS convenes regular meetings with the MACs to collaborate on LCD evidentiary development and discuss development processes to the extent permitted by their contracts. These meetings foster in-depth coverage discussions and collaboration on Medicare coverage policy. Additionally, in order to measure, incentivize, and ensure increased collaboration among the MACs, CMS has added a metric related to LCD collaboration to the MAC Award Fee, which MACs can earn if their performance exceeds basic requirements.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should work with its Medicare contractors to establish an NCD or develop LCDs with more consistent requirements for drug testing services.

CMS Response

CMS does not concur with this recommendation. Requirements placed in NCDs and LCDs must be based on medical evidence and provide coverage policies based on the reasonable and necessary standard. Per the definition of LCDs in section 1869(f)(2)(B) of the Social Security Act, LCDs only address the reasonable and necessary standard (and thus would not cover other topics that may be relevant to fraud, waste, and abuse). At this time, there is no clinical evidence to support a single, specific reasonable and necessary standard for drug testing services, which would be necessary to establish an NCD. In addition, LCDs are not required to be consistent across MAC jurisdictions. However, as stated above, CMS has already taken a number of steps to achieve more consistency among LCDs when appropriate.

OIG Recommendation

CMS should work with its Medicare contractors to clearly indicate in LCDs or LCAs how laboratories should determine the number of drug classes when identifying which procedure code to bill for definitive drug testing services (e.g., using CPT guidance as a specific source).

CMS Response

CMS does not concur with this recommendation. The purpose of LCDs is for contractors to state whether a particular item or service is covered on a contractor-wide basis under the reasonable and necessary standard found in section 1862(a)(1)(A) of the Social Security Act. LCDs are not the proper venue for billing or coding requirements, which are not directly related to the reasonable and necessary standard. While billing or coding requirements can be discussed in LCAs, LCAs that are related to an LCD are intended to support an LCD policy. At this time, there is 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 LCD. As such, it would not be appropriate to discuss billing or coding related to drug classes in an LCA.

OIG Recommendation

CMS should work with its Medicare contractors to implement a system edit or procedure to identify and limit the frequency of drug testing services per beneficiary across all Medicare jurisdictions. System edits or procedures that CMS and its contractors could consider include: (1) adding a modifier to claims that represents the number of days of abstinence to track frequency or (2) determining the number of reasonable and necessary drug tests per calendar year per beneficiary and performing postpayment reviews of those tests that exceed the number.

CMS Response

CMS does not concur with this recommendation. At present, there is no clinical evidence to suggest that testing frequency should be linked to a certain number of days of abstinence, or that a certain number of tests per year is reasonable and necessary for all individuals.

OIG Recommendation

CMS should work with its Medicare contractors to determine whether a postpayment medical review is necessary for laboratories that have been paid for excessive definitive drug tests (e.g., more than one test) in a 1-week period for the same beneficiary.

CMS Response

CMS concurs with this recommendation. CMS will share this audit report with the MACs for their consideration in adding medical review activities on potentially excessive definitive drug testing services to their improper payment review strategies.

OIG Recommendation

CMS should work with its Medicare contractors to consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test so that Medicare contractors can identify for follow-up those laboratories that routinely bill direct-to-definitive drug testing for a large number of drug classes.

CMS Response

CMS concurs with this recommendation. MACs can already determine whether there was a presumptive test by searching claims history. CMS will determine whether adding a modifier to claims would be feasible and whether it would be helpful to MACs in following up with identified laboratories.

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