

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PART D BENEFICIARIES
WITH QUESTIONABLE
UTILIZATION PATTERNS
FOR HIV DRUGS**



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EXECUTIVE SUMMARY: Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs, OEI-02-11-00170

WHY WE DID THIS STUDY

Under Medicare Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as sponsors, to provide prescription drug coverage. The Office of Inspector General (OIG) has found that Part D is vulnerable to fraud, waste, and abuse. Prior work has focused on questionable practices by pharmacies and prescribers; this report addresses beneficiaries with questionable utilization patterns.

CMS has placed few restrictions on specific beneficiaries, and these restrictions have focused on opioids. For example, CMS's Overutilization Monitoring System provides each sponsor with a list of beneficiaries who are potentially overutilizing opioids. However, opioids are not the only Part D drugs vulnerable to fraud, waste, and abuse. Other types of drugs, including those that treat human immunodeficiency virus (HIV), are also vulnerable because they can be very expensive and can have psychoactive effects.

HOW WE DID THIS STUDY

We based this study on an analysis of Prescription Drug Event records for HIV drugs in 2012. Part D sponsors submit one record to CMS for each drug that is dispensed to a beneficiary enrolled in their plans. Each record contains information about the drug, beneficiary, pharmacy, and prescriber. We developed six measures to identify beneficiaries with questionable utilization patterns on the basis of results of past OIG analyses and fraud investigations and input from CMS staff.

WHAT WE FOUND

Medicare Part D paid \$2.8 billion for HIV drugs in 2012. Almost 1,600 Part D beneficiaries had questionable utilization patterns for HIV drugs. These beneficiaries had no indication of HIV in their Medicare histories, received an excessive dose or supply of HIV drugs, received HIV drugs from a high number of pharmacies or prescribers, or received contraindicated HIV drugs (i.e., HIV drugs that should not be used in combination with one another). In total, Medicare paid \$32 million for HIV drugs for these beneficiaries. While some of this utilization may be legitimate, all of these patterns warrant further scrutiny. These patterns may indicate that a beneficiary is receiving inappropriate drugs and diverting them for sale on the black market. They may also indicate that a pharmacy is billing for drugs that a beneficiary never received or that a beneficiary's identification number was stolen.

WHAT WE RECOMMEND

We recommend that CMS (1) expand sponsors' drug utilization review programs, (2) expand the Overutilization Monitoring System to include additional drugs susceptible to fraud, waste, and abuse, (3) expand sponsors' use of beneficiary-specific controls, (4) restrict certain beneficiaries to a limited number of pharmacies or prescribers, (5) limit the ability of certain beneficiaries to switch plans, (6) increase monitoring of beneficiaries' utilization patterns, and (7) follow up on questionable utilization patterns. CMS concurred with all but the second and fifth recommendations.

TABLE OF CONTENTS

Objectives	1
Background.....	1
Methodology	7
Findings.....	13
Medicare Part D Paid \$2.8 Billion for HIV drugs in 2012... ..	13
Almost 1,600 Part D Beneficiaries Had Questionable Utilization Patterns for HIV Drugs	14
Conclusion and Recommendations.....	21
Agency Comments and Office of Inspector General Response.....	24
Appendix.....	26
A: HIV Drugs.....	26
B: Most Common HIV Drugs and Combinations.....	28
C: Agency Comments	30
Acknowledgments.....	34

OBJECTIVES

1. To determine the extent to which beneficiaries received human immunodeficiency virus (HIV) drugs paid for by Medicare Part D in 2012.
2. To determine the extent to which beneficiaries had questionable utilization patterns for HIV drugs in 2012.

BACKGROUND

Medicare Part D provides an optional prescription drug benefit to Medicare beneficiaries.¹ The Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as Part D sponsors, to provide drug coverage to beneficiaries who choose to enroll in the program.² In 2012, 37 million beneficiaries were enrolled in Part D.³

In the 9 years since Part D began, the Office of Inspector General (OIG) and others have raised concerns about Part D billing. OIG has found that the program has limited safeguards and is vulnerable to fraud, waste, and abuse. Recent OIG reports have focused on questionable practices by pharmacies and prescribers. This report addresses beneficiaries with questionable utilization patterns.

CMS has placed few restrictions on specific beneficiaries in Part D. These restrictions have focused on opioids, as this type of drug is especially vulnerable to fraud, waste, and abuse. However, opioids are not the only Part D drugs that are vulnerable. Other types of drugs are also susceptible to fraud, waste, and abuse, particularly if they are very expensive or have psychoactive effects. For example, antipsychotic drugs and certain respiratory and cardiac drugs are susceptible.

In addition, antiretroviral drugs that treat HIV⁴ are a target for fraud, waste, and abuse because they can be very expensive and can have psychoactive effects. For example, one common HIV drug costs about \$1,700 for a month's supply. Also, when certain HIV drugs and commonly abused painkillers are taken together, the HIV drugs can enhance the effects of the

¹ 42 U.S.C. § 1395w-101(a).

² 42 U.S.C. § 1395w-112(b)(1).

³ The Boards of Trustees, *Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, pp. 151 and 157. Accessed at <http://downloads.cms.gov/files/TR2013.pdf> on November 26, 2013.

⁴ For the purposes of this report, we refer to antiretroviral drugs that treat HIV as "HIV drugs."

painkillers.⁵ Further, one study reported that another HIV drug is used by HIV-negative individuals for its intoxicating effects.⁶

A number of recent fraud cases have involved HIV drugs. In one case, Medicare paid over \$8.5 million for medications for HIV/AIDS patients that either were medically unnecessary or were never provided.⁷ In another case, a pharmacy owner was charged with fraudulently billing Medicaid for HIV drugs that he never filled or only partially filled.⁸ He is accused of paying cash and other kickbacks to beneficiaries in exchange for their HIV drugs.

In a third case, 48 people were charged with defrauding Medicaid of \$108 million.⁹ They are accused of trafficking hundreds of millions of dollars' worth of prescription drugs, including HIV drugs. In this scheme, Medicaid beneficiaries allegedly filled their prescriptions for HIV drugs using their Medicaid benefits and then sold the medication for cash. The medication was repackaged and resold to pharmacies that then dispensed the drugs to unsuspecting customers. In a similar case, four people were charged with a scheme to distribute HIV drugs on the black market and defraud Medicaid of \$155 million.¹⁰

This study focuses on beneficiaries who have questionable utilization patterns for HIV drugs. Although the report addresses HIV drugs, the issues that it raises are relevant to other Part D drugs susceptible to fraud, waste, and abuse. This report is part of a larger body of work examining Part D. Two other

⁵ T.H. Nieminen et al., "Oxycodone Concentrations Are Greatly Increased by the Concomitant Use of Ritonavir or Lopinavir/Ritonavir." *European Journal of Clinical Pharmacology*, August 10, 2010. For a list of HIV drugs' brand names, see Appendix A.

⁶ James A. Inciardi et al., "Mechanisms of Prescription Drug Diversion Among Drug-Involved Club- and Street-Based Populations," *Pain Medicine*, March 2007; 8(2): 171–183. Accessed at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879025/> on February 21, 2014.

⁷ Federal Bureau of Investigation, *Manhattan Doctor Pleads Guilty to \$8.5 Million Medicare Fraud Scheme*, February 25, 2013. Accessed at <http://www.fbi.gov/newyork/press-releases/2013/manhattan-doctor-pleads-guilty-to-8.5-million-medicare-fraud-scheme> on September 5, 2013.

⁸ Kings County District Attorney's Office, *Kings County District Attorney Charles J. Hynes, NYC Human Resources Administration Commissioner Robert Doar and U.S. Department of Health and Human Services, Special Agent In Charge, Thomas O'Donnell Announce the Indictment of the Owner of a Williamsburg Pharmacy for Illegally Receiving Nearly \$800,000 in Medicaid Payments*, August 29, 2013. Accessed on September 5, 2013 (link no longer works).

⁹ United States of America -v- Juan Carlos Viera et al., S1 11 Cr. 1072 (DLC), July 17, 2012. Accessed at <http://www.justice.gov/usao/nys/pressreleases/July12/drugs/vierajoseetals1indictment.pdf> on October 22, 2013.

¹⁰ Attorney General Eric Schneiderman, *A.G. Schneiderman Announces Arrests In \$274 Million Black Market Prescription Drug Operation*, April 4, 2012. Accessed at <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-274-million-black-market-prescription-drug-operation> on November 14, 2013.

reports identified pharmacies and prescribers with questionable billing patterns.¹¹ A third report identified inappropriate Part D payments for Schedule II drugs billed for as refills.¹² A fourth report identified Part D drugs ordered by individuals who do not have the authority to prescribe.¹³ All of these reports are part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) Initiative, which focuses on detecting health care fraud through innovative data analysis and enhanced cooperation between the Department of Justice, OIG, and CMS.

Medicare Part D

Medicare beneficiaries have the option of enrolling in stand-alone prescription drug plans, or they may receive prescription drug coverage as a part of managed care plans. The managed care plans (known as Medicare Advantage plans, or Medicare Part C) also include medical benefits. They are offered as an alternative to traditional Medicare (known as Medicare Parts A and B).¹⁴

Most beneficiaries are responsible for certain costs under Part D, which may include a monthly premium, an annual deductible, and coinsurance. However, certain low-income beneficiaries are eligible to receive assistance to pay some or all of these Part D costs. The portion that is paid by Medicare is referred to as the low-income subsidy.¹⁵

Medicare beneficiaries are generally not allowed to switch prescription drug plans during the year. However, those who qualify for the low-income subsidy are allowed to change plans every month. Other beneficiaries may also switch under special circumstances. For example, they may switch if they move out of their plan's service area. They may also switch if they have a severe or disabling condition, such as HIV, and if there is a Medicare Chronic Care Special Needs Plan that serves that condition.¹⁶

¹¹ Office of Inspector General (OIG), *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012, and OIG, *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.

¹² Schedule II drugs are controlled substances with the highest potential for abuse of any prescription drugs legally available in the United States. OIG, *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed As Refills*, OEI-02-09-00605, September 2012.

¹³ OIG, *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority*, OEI-02-09-00608, June 2013.

¹⁴ Medicare Part A covers services such as inpatient hospitalizations and skilled nursing care, while Medicare Part B covers physician and outpatient services.

¹⁵ 42 CFR § 423.315(d).

¹⁶ For more information about the circumstances under which a beneficiary may switch plans, see CMS, *Special Circumstances (Special Enrollment Periods)*. Accessed at <http://www.medicare.gov/sign-up-change-plans/when-can-i-join-a-health-or-drug-plan/special-circumstances/join-plan-special-circumstances.html#collapse-3206> on December 23, 2013.

Medicare Part D covers drugs prescribed for medically accepted indications.¹⁷ For each plan, sponsors develop a list of covered drugs, known as a formulary. A formulary often gives preference to certain drugs over other drugs that treat the same condition. Each formulary must include at least two drugs within each category or class. Sponsors can also use utilization management tools, such as requiring prior authorization or establishing quantity limits, to place restrictions on the use of certain drugs on their formularies.

Under Part D, HIV drugs are considered a protected class, which helps to ensure that beneficiaries have access to them.¹⁸ As such, CMS requires that each formulary include “all or substantially all” HIV drugs. Further, unlike they may for most drugs, sponsors may not use certain utilization management tools, such as prior authorization, for HIV drugs.

Monitoring of Medicare Part D

CMS contracts with the National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse. Its responsibilities include identifying and investigating potential fraud and abuse, referring cases, and fulfilling requests for information from law enforcement. The MEDIC is required to identify potential fraud and abuse through external sources, such as tips, as well as proactive methods, such as data analysis.¹⁹

CMS also relies on sponsors to help safeguard the Part D program. CMS requires sponsors to have compliance plans that contain measures to detect, prevent, and correct fraud, waste, and abuse.²⁰ CMS recommends that sponsors use data analysis and specifically calculate the total number of prescriptions each beneficiary received—both overall and within certain classes of drugs—to identify possible fraud, waste, or abuse.

CMS also requires sponsors to have a drug utilization review program to assist in preventing overutilization of prescribed medications and to reduce fraud, waste, and abuse.²¹ These programs should include concurrent reviews, which

¹⁷ 42 U.S.C. § 1395w-102(e)(1).

¹⁸ The six protected classes are immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. See 42 CFR § 423.120(b)(2)(i); CMS, *Prescription Drug Benefit Manual*, ch. 6 § 30.2.5.

¹⁹ See OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.

²⁰ 42 CFR § 423.504(b)(4)(vi).

²¹ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012. Accessed at <http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf> on October 4, 2012. See also CMS, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*, August 31, 2012.

are claim-level edits at the point of sale. These edits commonly include three types.²² They include “refills too soon,” which can prevent the refilling of a drug before a certain date. They include “maximum therapeutic dose exceeded,” which can prevent prescriptions with unsafe doses from being dispensed. Lastly, these edits include “therapeutic duplication,” which can prevent beneficiaries from receiving multiple concurrent drugs in the same class. Sponsors’ drug utilization review programs should also include retrospective reviews, which occur after the drug is dispensed.

CMS has stated that sponsors need to employ more effective drug utilization review programs and outlined three levels of improvements that it expected sponsors to apply in 2013.²³ Specifically, CMS stated that sponsors should (1) improve their concurrent claims edits for all drugs (e.g., limit dosage at the point of sale to the maximum allowable dose on the Food and Drug Administration (FDA)-approved label); (2) improve their formulary utilization design (e.g., implement quantity limits based on the FDA-approved label); and (3) for opioids, improve retrospective reviews and case management.

CMS recommended that sponsors take several steps to improve their retrospective review and case management for opioids.²⁴ First, sponsors should use data analysis to identify patterns of apparent duplicative drug use. Next, when warranted, clinical staff should communicate with prescribers and beneficiaries to ascertain medical necessity. When the prescriber agrees that the beneficiary may be overutilizing the drugs or when the prescriber does not respond to the sponsor’s inquiries, sponsors may place point-of-sale edits on beneficiaries. These edits are specific to the beneficiary and can vary on the basis of the situation. For example, they may prevent a beneficiary from receiving any drug in a certain class or an excessive dose of a particular drug ingredient.

In July 2013, CMS implemented the Overutilization Monitoring System to ensure that sponsors have reasonable and appropriate drug utilization

²² CMS, *Improving Drug Utilization Review Controls in Part D*, September 28, 2011.

²³ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012. Accessed at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNoticeA.pdf> on October 15, 2013.

²⁴ CMS, *Medicare Advantage and Prescription Drug Plan Fall Conference: Medicare Part D Overutilization Monitoring System Update and Lessons Learned*, September 4, 2013. Accessed at http://www.cms.gov/Outreach-and-Education/Training/CTEO/Event_Archives.html#CMS%20Medicare%20Advantage%20Prescription%20Drug%20Plan%20Fall%20Conference%20%28Webcast%29 on November 14, 2013. (Also online at <http://www.ustream.tv/recorded/38234985>.)

management programs.²⁵ On a quarterly basis, CMS provides each sponsor with a list of beneficiaries with potential issues regarding overutilization of opioids or acetaminophen.²⁶ Sponsors are required to review these beneficiaries and report the status of these reviews to CMS.

Guidelines for the Use of HIV Drugs

The Department of Health and Human Services (HHS) has published guidelines for practitioners on the use of HIV drugs.²⁷ The March 2012 guidelines recommended, among other things, that all patients taking HIV drugs receive certain laboratory tests regularly. These tests include a CD4 count and a measure of the patient's viral load. The CD4 count measures immune function and can help to determine how well the patient is progressing with the treatment and whether the treatment needs to be changed. The measure of viral load indicates how well the patient is responding to the drugs. The guidelines recommend that these two tests be performed at the beginning of care when a patient is first diagnosed and every 3 to 6 months thereafter.²⁸ A third laboratory test, which tests for drug resistance, is recommended when care begins and if treatment does not seem to be working.²⁹

Related Work

A recent OIG report found that 2,637 retail pharmacies had questionable billing in 2009.³⁰ These pharmacies had extremely high billing for at least one of eight measures we developed. For example, many pharmacies billed extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber, which could mean that a pharmacy is billing for drugs that are not medically necessary or were never provided to the beneficiary. Among other things, the report recommended that CMS strengthen its monitoring of

²⁵ CMS, *Medicare Part D Overutilization Monitoring System*, July 5, 2013. Accessed at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMS-memo-Medicare-Part-D-Overutilization-Monitoring-System-07-05-13-.pdf> on December 23, 2013.

²⁶ The list can also include other beneficiaries identified by CMS. See CMS, *Medicare Part D Overutilization Monitoring System—Updates*, October 25, 2013.

²⁷ HHS Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents*, pp. C1–C10. March 27, 2012. Accessed at <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL003093.pdf> on August 26, 2013.

²⁸ A CD4 count is also known as a CD4+ T-cell count, and a viral load test is also known as an HIV RNA plasma test. According to the guidelines, in certain clinically stable patients, the CD4 count can be monitored every 6 to 12 months, rather than every 3 to 6 months.

²⁹ Drug resistance occurs when the drug is no longer effective in stopping the virus from replicating.

³⁰ OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012.

pharmacies, provide additional guidance to sponsors on monitoring pharmacy billing, and further strengthen its compliance plan audits.

Another recent report found that 736 general-care physicians had questionable prescribing patterns.³¹ Each of these physicians prescribed extremely high amounts for at least one of five measures we developed. For example, many of these physicians prescribed extremely high numbers of prescriptions per beneficiary or high percentages of Schedule II drugs, which may indicate that these prescriptions are medically unnecessary. The report recommended that CMS instruct the MEDIC to expand its analysis of prescribers and provide sponsors with additional guidance on monitoring prescribing patterns.

Another recent OIG report found that Part D inappropriately paid \$25 million for Schedule II drugs billed as refills in 2009.³² Sponsors should not have paid for any of these drugs because Federal law prohibits refills on prescriptions for Schedule II drugs; such drugs require a new prescription.³³ Among other things, the report recommended that CMS issue guidance to sponsors to prevent billing of Schedule II refills and to exclude Schedule II refills when calculating payments to sponsors.

A fourth report found that Part D inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists, athletic trainers, home contractors, interpreters, and transportation companies.³⁴ This raises concerns about the appropriateness of Part D payments and about patient safety. The report recommended that CMS require sponsors to verify that prescribers have the authority to prescribe drugs and ensure that Medicare does not pay for prescriptions from individuals without prescribing authority.

METHODOLOGY

We based this study on an analysis of prescription drug event (PDE) records for HIV drugs in 2012. Part D sponsors submit a PDE record to CMS for each time that a drug is dispensed to a beneficiary enrolled in their plans. Each record contains information about the drug and beneficiary, as well as the identification numbers for the pharmacy and the prescriber. We matched these records to beneficiaries' Part A and B claims from CMS's National

³¹ OIG, *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.

³² OIG, *Inappropriate Part D Payments for Schedule II Drugs Billed as Refills*, OEI-02-09-00605, September 2012.

³³ Federal law permits partial refills under certain circumstances. It is possible some of these drugs may have been inaccurately billed as refills when they were partial fills.

³⁴ OIG, *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority*, OEI-02-09-00608, June 2013.

Claims History File to determine whether beneficiaries had an indication of HIV in their medical histories. For each HIV drug, we also reviewed the FDA-approved label to identify the drug's indications, recommended dose, and contraindications.

Analysis of HIV Drugs

We first identified all PDE records for HIV drugs with dates of service from January 1 to December 31, 2012. To do this, we matched FDA's list of HIV drugs to First Databank and Red Book to identify the National Drug Codes (NDCs) for HIV drugs.³⁵ In total, we identified 654 NDCs. For a list of HIV drugs and their generic names, see Appendix A.

We identified 3,177,937 PDE records with these NDCs. Using the Health Insurance Claims Number (HICN), we matched the PDE records to the National Claims History File and obtained Part A and B claims for each beneficiary for 2011 and 2012. Using the HICN, we also matched the PDE records to the Beneficiary Enrollment Database (EDB). For the purposes of this review, we excluded 174,504 PDE records for beneficiaries who appeared to be taking HIV drugs as pre- or post-exposure prophylaxis or for hepatitis B.³⁶

We analyzed these data to determine the total amount Medicare paid for HIV drugs, the most common drugs, and the most common combinations of HIV drugs.³⁷ We also analyzed the demographics of the beneficiaries receiving HIV drugs. Specially, we looked at their age, sex, and Medicare status.

Analysis of Questionable Utilization Patterns

We developed six measures to identify beneficiaries with questionable utilization patterns that warrant further scrutiny for fraud, waste, or abuse.³⁸ We developed these measures on the basis of the results of past OIG analyses and fraud investigations related to HIV drugs, as well as input from CMS staff. These measures focused on beneficiaries' Medicare histories, doses of HIV drugs, supplies of HIV drugs, the number of pharmacies per beneficiary,

³⁵ FDA, *Antiretroviral Drugs Used in the Treatment of HIV Infection*, August 2013. Accessed at <http://www.fda.gov/ForConsumers/byAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm> on November 12, 2013.

³⁶ We excluded a total of 10,566 beneficiaries. For beneficiaries with Parts A and B claims, we assumed that those who received Truvada only and had an HIV test in 2011 and 2012 were taking the drug for pre-exposure prophylaxis. Next, we assumed that beneficiaries with a diagnosis of V0179 ("contact with or exposure to other viral diseases") were taking HIV drugs as post-exposure prophylaxis. Lastly, we assumed that beneficiaries who received Viread only and had a diagnosis of hepatitis B were taking the drug for hepatitis B.

³⁷ To calculate the total amount that Part D paid, we summed three fields on the PDE records that represent the total gross drug costs: ingredient cost, dispensing fee, and sales tax.

³⁸ These measures are not intended to be clinical standards for treatment.

the number of prescribers per beneficiary, and contraindicated drugs. We developed these measures to address a variety of concerns so each measure is independent of the others. As a result, we considered beneficiaries to have questionable utilization patterns if they had extreme results on one or more measures.

Below is a description of each measure and how we identified beneficiaries with questionable utilization patterns.

Medicare history had no indication of HIV. The beneficiary's Medicare claims history (1) did not show a diagnosis of HIV, (2) did not include any of three laboratory tests that are used to monitor the use of HIV drugs, and (3) did not show that the beneficiary received any medical services from any of his or her HIV drug prescribers.

For this measure, we identified beneficiaries who received HIV drugs and were enrolled in Medicare Parts A and B for all of 2012.³⁹ We reviewed the Part A and B claims from January 1, 2011, to December 31, 2012 for each of these beneficiaries. We first determined whether any of the beneficiary's Part A or B claims from this 2-year period had any of the following HIV diagnosis codes:

- 042 (human immunodeficiency virus (HIV-1⁴⁰) disease);
- V08 (asymptomatic human immunodeficiency virus), which indicates that the patient tested positive for HIV, but has no symptoms;
- 079.53 or 07953 (HIV-2); and
- 795.71 or 79571 ("nonspecific serologic evidence of human immunodeficiency virus," which indicates an inconclusive HIV test).

We then determined whether there were claims for the beneficiary for any of the three laboratory tests that monitor the use of HIV drugs. Specifically, we reviewed the Healthcare Common Procedure Coding System (HCPCS) codes in the claims to determine whether each beneficiary received at least 1 CD4 count, viral load test, or drug resistance test during the 2-year period.

Next, we analyzed the claims data to determine whether beneficiaries received a medical service during the 2-year period from any of the prescribers of their HIV drugs. Using the prescriber's National Provider Identifier (NPI), we searched the beneficiary's Part A and B claims to determine whether the

³⁹ For this measure, we analyzed claims for 90,351 beneficiaries who were enrolled in Medicare Parts A and B for all of 2012.

⁴⁰ HIV-1 is the most common strain of the virus. HIV-2 is not widely seen outside Africa.

beneficiary received any medical services, such as office visit or surgery, from the prescriber.⁴¹

Excessive doses of an HIV drug. The beneficiary received greater than two times the daily recommended dose of an active ingredient.

For this measure, we first reviewed the FDA-approved labels for each HIV drug and identified the recommended dose for each active ingredient of the drug.⁴² Using the PDE records, we calculated the average daily dose that each beneficiary received for each HIV drug ingredient. We did this by summing the total amount dispensed and dividing it by the number of unique days the beneficiary had a prescription for that drug. If the beneficiary's average daily dose over the entire year was more than two times the recommended dose on the FDA-approved label, we considered it to be questionable.

Excessive supply of an HIV drug. The beneficiary received more than a 16-month (480-day) supply of an HIV drug.

For each drug and strength, we calculated the total number of days supplied using the PDE records.⁴³ If the total was more than 480 days, we considered it to be questionable.

High number of pharmacies. The beneficiary received HIV drugs from six or more pharmacies.

For this measure, we used the pharmacies' NPIs to calculate the total number of pharmacies for each beneficiary.⁴⁴ We used a standard technique, known as the Tukey method, to identify the beneficiaries who were outliers (i.e., those who were above the 75th percentile plus three times the interquartile range). Using this method, we determined that beneficiaries who received HIV drugs from six or more pharmacies were extremely different from their peers, and we considered this to be questionable.⁴⁵

⁴¹ To do this analysis, we also checked whether the prescriber was listed on the claims as the rendering provider, attending provider, operating provider, or other provider. For records that did not contain an NPI for the prescriber, we used a "crosswalk" developed by OIG analysts to identify the prescriber's NPI. We excluded from this analysis any PDE records for which we were unable to identify the prescriber's NPI.

⁴² In cases in which the recommended dose varied on the basis of the beneficiaries' weight, age, or health status, we identified the dose that was for an average adult, without special circumstances or comorbidities. When doses varied on the basis of past HIV drug use, we used the higher of the two doses.

⁴³ For this analysis, we combined brand-name drugs with their generic equivalents.

⁴⁴ Most PDE records included an NPI for the pharmacy. In cases in which we were unable to identify the NPI, we used the provider identifier on the PDE record for this analysis.

⁴⁵ See J.W. Tukey, *Exploratory Data Analysis*. Addison-Wesley, 1977. The interquartile range is calculated by subtracting the value at the 25th percentile from the value at the 75th percentile.

High number of prescribers. The beneficiary received HIV drugs from six or more prescribers.

For this measure, we used the prescribers' NPIs to calculate the total number of prescribers for each beneficiary.⁴⁶ As we did with the pharmacies, we used the Tukey method to identify the beneficiaries who were outliers. We determined that beneficiaries with six or more prescribers were extremely different from their peers. For each beneficiary with six or more prescribers, we then reviewed the prescribers' addresses and phone numbers to determine whether they appeared to be from the same group practice or institution.⁴⁷ If a beneficiary had six or more prescribers who did not appear to be from the same group practice or institution, we considered it to be questionable. For example, if a beneficiary had a total of seven prescribers, but four of the seven were in the same practice, we did not consider it questionable.

Contraindicated combination of HIV drugs. The beneficiary received a contraindicated combination of HIV drugs for more than 60 days during the year.

The labels for two HIV drugs state that the drug is contraindicated with another HIV drug. Specifically, the label for Lexiva states that it is contraindicated with delavirdine.⁴⁸ The label for Reyataz states that it is contraindicated with indinavir. To determine whether beneficiaries took these drugs at the same time, we used the dispensing date and number of days supplied to determine the approximate dates the beneficiary took the drugs. For example, if a 30-day supply of drug was dispensed on January 1, 2012, we assumed the beneficiary took the drug from January 1, 2012, to January 30, 2012. If the PDE records indicated that the beneficiary took the same combination of contraindicated drugs for more than 60 days of the year, we considered it to be questionable.

Analysis of Beneficiaries With Questionable Utilization Patterns

We analyzed the characteristics of the beneficiaries who had one or more questionable utilization patterns. We determined the total amount that Part D paid for HIV drugs for these beneficiaries. We determined the proportion of these beneficiaries that were located in each Core Base Statistical Area

⁴⁶ Most PDE records included an NPI for the prescriber. In cases in which the PDE record included a different identifier, we used a crosswalk developed by OIG staff to identify the NPI. If we could not identify the NPI, we used the prescriber identifier on the PDE for this analysis.

⁴⁷ We obtained the addresses and phone numbers from the National Plan and Provider Enumeration System.

⁴⁸ For a full list of HIV drugs' brand names, see Appendix A. (Many HIV drugs are currently available only in brand-name form.)

(CBSA). A CBSA is a region around an urban center that has at least 10,000 people.⁴⁹ We also determined the number of times that these beneficiaries changed Part D plans during the year. We then determined the extent to which these beneficiaries received HIV drugs from any of the 2,637 retail pharmacies or 736 general-care physicians with questionable Part D patterns that we identified in two earlier reports.⁵⁰

Limitations

We designed this study to identify utilization patterns that warrant further scrutiny. None of the measures we analyzed independently confirm that a particular beneficiary is engaging in fraud, waste, or abuse.

We did not independently verify the accuracy of the PDE records or the Medicare Part A and B claims data. In addition, our review was limited to medical services paid for by Medicare. In some cases, beneficiaries may have received services that were not included in this review, such as services from free clinics or services for which the beneficiary paid out of pocket.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

⁴⁹ CBSAs include the entire metropolitan area, not just the urban center. See U.S. Census Bureau, *Metropolitan and Micropolitan Statistical Areas*. Accessed at <http://www.census.gov/population/www/metroareas/aboutmetro.html> on November 21, 2013.

⁵⁰ OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012. OIG, *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.

FINDINGS

Medicare Part D Paid \$2.8 Billion for HIV Drugs in 2012

In 2012, 135,554 beneficiaries received HIV drugs that were paid for by Medicare Part D. On average, Medicare paid \$20,989 per beneficiary for these drugs, totaling \$2.8 billion for the year.⁵¹ Typically, each beneficiary had one or two prescribers and used one pharmacy for their HIV drugs. On average, beneficiaries received 23 1-month supplies of HIV drugs.

Beneficiaries typically received more than one type of HIV drug

A full treatment regimen usually includes multiple drugs because different classes of HIV drugs fight the disease differently. The most common combination of drugs was Norvir, Reyataz, and Truvada. Norvir and Reyataz work by interfering with the enzymes that HIV uses to produce viral particles. Truvada interferes with the building of the HIV DNA.

Some beneficiaries took certain drugs known as multiclass combination drugs instead of taking separate HIV drugs. These HIV drugs contain active ingredients from multiple classes and are considered a full treatment regimen. Atripla was the most commonly used multiclass combination drug, followed by Complera and then Stribild. For more information about the most common drugs and most common combinations of drugs, see Appendix B.

Beneficiaries who received HIV drugs were more likely to be younger and male

Beneficiaries who received HIV drugs were more likely to be younger and male than the Medicare Part D population as a whole.⁵² Eighty-two percent of beneficiaries who received HIV drugs were under the age of 65. In contrast, 15 percent of all Part D beneficiaries were under 65. This may be because many of the beneficiaries who received HIV drugs qualified for Medicare because of disability, rather than age. Beneficiaries who received HIV drugs were predominantly male—75 percent—compared to 40 percent of all Part D beneficiaries. In addition, beneficiaries who received HIV drugs were much

⁵¹ This includes the amount paid by sponsors, by the Government, and by or on behalf of beneficiaries.

⁵² The estimates for age and sex for the entire Part D population are taken from CMS, *Chronic Conditions Data Warehouse: Medicare Part D Charts*, September 2013. Accessed at https://www.ccwdata.org/web/guest/medicare-charts/medicare-part-d-charts#f1_age_2011 on November 7, 2013.

more likely to receive the low-income subsidy; 82 percent received a subsidy compared to 29 percent of all Part D beneficiaries.⁵³

Almost 1,600 Part D Beneficiaries Had Questionable Utilization Patterns for HIV Drugs

In 2012, a total of 1,578 Medicare Part D beneficiaries had questionable utilization patterns for HIV drugs. Eighty-three percent of these beneficiaries received the low-income subsidy, meaning that they paid little or no cost-sharing to receive drugs under Part D.

These 1,578 beneficiaries had no indication of HIV in their Medicare claims histories, received an excessive dose or supply of HIV drugs, received HIV drugs from a high number of pharmacies or prescribers, and/or received contraindicated HIV drugs. See Table 1 for the number of beneficiaries with each questionable utilization pattern.

Table 1: Number of Beneficiaries With Questionable Utilization Patterns for HIV Drugs, 2012

	Number of Beneficiaries
No Indication of HIV	888
Excessive Dose	226
Excessive Supply	206
High Number of Pharmacies	213
High Number of Prescribers	179
Contraindicated HIV Drugs	10
Total	1,578*

*Sum does not equal 1,578 because a number of beneficiaries had more than 1 questionable utilization pattern. Source: OIG analysis of Part D data, 2013.

In total, Medicare paid \$32 million for HIV drugs for beneficiaries with questionable utilization patterns. While some of this utilization may be legitimate, all of these patterns warrant further scrutiny. These patterns

⁵³ Estimates of the percentage of all beneficiaries receiving the low-income subsidies in 2012 are calculated from data in The Boards of Trustees, *Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, p. 151. Accessed at <http://downloads.cms.gov/files/TR2013.pdf> on November 26, 2013.

indicate that a beneficiary may be receiving inappropriate or unnecessary drugs. The HIV drugs for beneficiaries with questionable patterns were ordered by 2,698 prescribers and billed by 2,221 pharmacies. Of these, 183 pharmacies and 25 prescribers were previously identified by OIG as having questionable Part D billing.⁵⁴

Beneficiaries with questionable patterns were more likely to live in or near Miami or New York. Twenty-four percent of the beneficiaries with questionable patterns lived in or near Miami, while just 2 percent of all beneficiaries who received HIV drugs lived there. Fourteen percent of beneficiaries with questionable patterns lived in the New York area, while 10 percent of all beneficiaries who received HIV drugs lived there.

Five Part D sponsors accounted for more than three-quarters of the beneficiaries with questionable patterns. These sponsors were also the most common among all beneficiaries who received HIV drugs. Two of these sponsors, however, had a disproportionate number of beneficiaries with questionable patterns enrolled in their plans. These sponsors had 54 percent of the beneficiaries with questionable patterns enrolled in their plans but had 43 percent of all beneficiaries who received HIV drugs enrolled.

Almost 900 beneficiaries had no indication of HIV in their Medicare histories

As Table 1 shows, 888 beneficiaries received HIV drugs paid for by Medicare Part D but did not have Medicare histories that indicated they had HIV. According to their Medicare claims from 2011 and 2012, these beneficiaries had none of the following three indicators of HIV:

- a diagnosis of HIV,
- any of the laboratory tests that monitor the use of HIV drugs, and
- a service from any of the providers who prescribed them HIV drugs.

In total, Medicare paid \$6.5 million for HIV drugs for beneficiaries who had no indications of HIV in their Medicare histories. Eighty-three percent of these beneficiaries received the low-income subsidy.

When Medicare pays for HIV drugs and there is no indication in the Medicare history that the beneficiary has HIV, it raises concerns about fraud and abuse. The beneficiary may have received the drugs and diverted them for sale on the black market. Another possibility is that the beneficiary never received the

⁵⁴ For more information, see OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012, and OIG, *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.

drugs. For example, the pharmacy could have submitted claims for drugs that were never dispensed, or the beneficiary's identification number could have been stolen. These drugs were dispensed by 556 pharmacies.

Two of these pharmacies stand out. These two pharmacies—both located in Miami—billed for HIV drugs for more than one-third (321 of 888) of the beneficiaries who had no indication of HIV. These 321 beneficiaries had characteristics different from those of the beneficiaries who typically received HIV drugs. Most of the beneficiaries associated with the two pharmacies were women and their average age was 74, which is 21 years older than the average for beneficiaries who received HIV drugs in 2012. In addition, they typically received just over a 1-month supply of HIV drugs. Medicare paid these two pharmacies a total of \$359,456 for HIV drugs for beneficiaries who had no indication of HIV.

The remaining two-thirds of the beneficiaries with no indication of HIV (567 of 888) also received drug supplies for fewer months than average. They typically received 12 1-month supplies of HIV drugs, whereas the average for all beneficiaries receiving HIV drugs was 23 1-month supplies.⁵⁵ The difference in these patterns raises further concern that pharmacies may be billing for drugs that beneficiaries are not receiving or do not need. Interestingly, 1 pharmacy in Pennsylvania billed for 19 of these beneficiaries.

Example of a Beneficiary With No Indication of HIV

In 2012, Medicare paid \$33,536 for HIV drugs for a 77-year old Detroit woman who had no indication of HIV in her Medicare claims history. She had prescriptions for 10 different types of HIV drugs prescribed by 6 different doctors. There is no evidence that she visited any of these doctors.

About 230 beneficiaries received an excessive dose of an HIV drug; about 210 received an excessive supply

A total of 226 Part D beneficiaries received an excessive dose of at least 1 HIV drug in 2012. Each of these beneficiaries received an average daily dose that was more than twice the recommended dose for an active ingredient. Thirteen of these beneficiaries received an average daily dose that was more than five times the recommended dose. For example, 1 beneficiary received

⁵⁵ As noted earlier, a full treatment regimen usually includes multiple drugs because different classes of HIV drugs fight the disease differently.

30 times the recommended dose of lopinavir. Four beneficiaries received five or more times the recommended dose of zidovudine.

More than half of the 226 beneficiaries had excessive doses because they received multiple drugs containing the same ingredient. When added together, the dose for the ingredient was excessive. In one example, a New York beneficiary received three different HIV drugs containing tenofovir almost every month, resulting in five times the recommended dose of tenofovir.

Although a higher dose may sometimes be appropriate, excessive doses over long periods of time raise questions about whether these drugs are medically necessary. Such high dosages may mean that the drugs are being diverted or that claims were submitted for drugs that were never dispensed. It may also mean that the beneficiary's drugs are not being properly monitored and, as a result, the beneficiary is taking potentially dangerous levels of drugs.

Example of a Beneficiary With Excessive Doses

One beneficiary received \$17,509 of HIV drugs in a single day and no other HIV drugs the rest of the year. On that single day, she received more than twice the recommended dose for five different HIV drug ingredients. Further, two of the drugs, Atripla and Complera, are complete drug regimens that do not need to be taken with other HIV drugs.

A total of 206 Part D beneficiaries received an excessive supply of HIV drugs in 2012. Each of these beneficiaries received more than a 16-month supply of at least one HIV drug. An excessive supply may indicate that the beneficiary is receiving drugs that are not medically necessary or that the beneficiary or pharmacy is diverting these drugs and selling them for profit. It also may indicate that the beneficiary's drugs are not being properly monitored for safety.

Nearly one-third of these beneficiaries received excessive supplies of multiple HIV drugs. This includes three beneficiaries who each received excessive supplies of four different drugs. In one case, the beneficiary received supplies that were more than a 480-day supply each of Prezista, Norvir, Intelence, and Selzentry. Another beneficiary received a 600-day supply of Atripla, a 600-day supply of Isentress, and a 510-day supply of Lexiva.

Example of a Beneficiary With an Excessive Supply

One beneficiary from New York received a 720-day supply of Norvir 100 mg. Almost every month in 2012, this beneficiary received this drug from two different pharmacies and two different prescribers. Recent research indicates that when ritonavir—the active ingredient in Norvir—is mixed with some illicit drugs, including ecstasy, it heightens the psychoactive effects of the drugs.

Over 210 beneficiaries obtained HIV drugs from a high number of pharmacies; nearly 180 beneficiaries had a high number of prescribers

Two hundred thirteen Part D beneficiaries obtained HIV drugs from a high number of pharmacies in 2012. Each of these beneficiaries went to six or more pharmacies for their HIV drugs during the year. Twenty beneficiaries each went to more than 10 pharmacies. When a beneficiary obtains HIV drugs from many pharmacies, it could mean the beneficiary is seeking drugs to divert for profit or the beneficiary's identification number was stolen. Another concern is that the beneficiary is getting excessive doses or supplies. About one-third of the beneficiaries who went to a high number of pharmacies were from the Miami or New York areas.

A total of 179 beneficiaries had a high number of prescribers for their HIV prescriptions, raising concerns about “doctor-shopping.”⁵⁶ Each of these beneficiaries had at least six prescribers for HIV drugs. Twenty-nine beneficiaries had 10 or more prescribers. When a beneficiary goes to a high number of prescribers to obtain HIV drugs, it could indicate that the beneficiary is acquiring drugs with the intention of diverting them. It might also signal that the beneficiary's care is not being monitored or coordinated properly. Forty-five percent of the beneficiaries who had a high number of prescribers were from the Miami or New York areas.

Beneficiaries with a high number of pharmacies or prescribers were far more likely to change their Part D prescription drug plans two or more times during the year, meaning they were enrolled in three or more plans. These beneficiaries were at least 10 times more likely to change their plans multiple

⁵⁶ “Doctor-shopping” occurs when a beneficiary consults a number of doctors for the purpose of inappropriately obtaining prescriptions.

times compared to all beneficiaries taking HIV drugs. Specifically, 12 percent of the beneficiaries with a high number of pharmacies switched plans more than once in 2012, and 16 percent with a high number of prescribers switched more than once. In contrast, 1 percent of all beneficiaries taking HIV drugs changed their plans more than once. Notably, eight beneficiaries were enrolled in six or more plans during 2012.

The patterns of 61 beneficiaries are of particular concern. Each of these beneficiaries obtained HIV drugs from a high number of pharmacies and a high number of prescribers.

Example of a Beneficiary With a High Number of Pharmacies and Prescribers

A 48-year-old from Miami went to 28 pharmacies and had 16 prescribers for HIV drugs, which included 15 different types of drugs. The beneficiary received excessive doses and excessive supplies during the year. In total, Medicare paid \$198,272 for the HIV drugs for this beneficiary.

Ten beneficiaries received contraindicated HIV drugs

Ten beneficiaries each received a potentially dangerous combination of HIV drugs for at least 60 days in 2012. According to the FDA-approved labels for these drugs, these combinations are contraindicated, meaning the risks of using the drug combination clearly outweigh any potential therapeutic benefit.⁵⁷ One of the beneficiaries received contraindicated HIV drugs for almost the entire year. These drugs were often dispensed on the same date by the same pharmacy, despite warning labels. Even though the number of beneficiaries who received such combinations is small, these combinations should not happen at all, as taking such combinations could put beneficiaries at great risk.

Over 100 beneficiaries had questionable utilization patterns for more than 1 measure

One hundred two beneficiaries had questionable utilization patterns for multiple measures. Ninety-three beneficiaries had questionable patterns for two or three measures, while nine beneficiaries had questionable patterns for

⁵⁷ See FDA, *Guidance of Industry: Warning and Precautions, Contraindications, and Black Box Warning Sections of Labeling for Human Prescription Drugs and Biological Products – Content and Format*, October 2011. Accessed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf> on May 14, 2013.

four or more measures. See the text box below for examples of beneficiaries with several questionable patterns.

Examples of Beneficiaries With Several Questionable Patterns

- Medicare paid \$349,854 in 2012 for one Florida beneficiary's HIV drugs. This beneficiary received 20 different HIV drugs from 32 prescribers and 20 different pharmacies. In total, he received 284 HIV drugs. This resulted in excessive doses of seven HIV drugs and an excessive supply of three drugs. He was enrolled in five different Part D plans during the year.
- Medicare paid \$146,160 for HIV drugs for a 37-year-old Miami beneficiary. In 1 month alone, he received 16 HIV drugs. Several times during the year, he received these drugs from two different pharmacies on the same day. He had prescriptions from nine physicians and was enrolled in two Part D plans during the year.
- Medicare paid \$154,549 for HIV drugs for a 44-year-old beneficiary in Miami who had 12 prescribers. The beneficiary used 19 pharmacies and received more than 3 times the recommended doses of emtricitabine and tenofovir.

CONCLUSION AND RECOMMENDATIONS

Various types of Part D drugs can be targets for fraud, waste, and abuse, particularly if they are expensive or have psychoactive effects. HIV drugs are an example of such Part D drugs. They are costly and can be profitable to beneficiaries and others who choose to sell them on the black market.

We found that almost 1,600 Part D beneficiaries who received HIV drugs had questionable utilization patterns in 2012. While some of this utilization may be legitimate, all of these patterns warrant further scrutiny. These patterns indicate that beneficiaries may be receiving inappropriate or unnecessary drugs. Other possibilities include that the pharmacy submitted claims for drugs never dispensed or that the beneficiary's identification was stolen. Almost 900 of the 1,600 beneficiaries had no indication of HIV in their Medicare histories. Others received an excessive dose or excessive supply of HIV drugs, obtained HIV drugs from a high number of pharmacies, had a high number of prescribers, or received contraindicated HIV drugs.

CMS has placed few restrictions on specific beneficiaries in Part D. These restrictions have focused on opioids. This report addresses another group of drugs that is susceptible to fraud, waste, and abuse. It shows that CMS needs to increase its program integrity efforts focused on beneficiaries beyond opioids and limit certain beneficiaries from receiving other potentially inappropriate or unnecessary drugs. CMS needs to do this while also maintaining beneficiaries' access to needed drugs.

We recommend that CMS:

Expand Sponsors' Drug Utilization Review Programs

The purpose of drug utilization review programs is to address inappropriate utilization to protect beneficiaries and to reduce fraud, waste, and abuse. CMS required sponsors to improve these programs beginning in 2013. Specifically, it required that sponsors make improvements to the concurrent claims review and formulary design for all drugs. However, improvements to retrospective reviews and case management were required only for opioids.

CMS should require sponsors to improve retrospective reviews and case management for other drugs susceptible to fraud, waste, and abuse, including HIV drugs. As they do with opioids, sponsors should use data analysis to identify beneficiaries who may be overutilizing these drugs and to identify possible fraud, waste, and abuse. CMS should require sponsors to contact the prescribing physicians to determine whether utilization is appropriate.

Expand the Overutilization Monitoring System To Include Additional Drugs Susceptible to Fraud, Waste, and Abuse

CMS should ensure that sponsors have made the necessary changes to improve their drug utilization review programs. As part of its efforts, CMS should expand the Overutilization Monitoring System—which currently focuses on opioids and acetaminophen—to include other drugs susceptible to fraud, waste, and abuse, such as HIV drugs. Specifically, CMS should—on a quarterly basis—identify beneficiaries who are receiving excessive amounts of certain drugs, including HIV drugs; provide a list of these beneficiaries to sponsors; and require sponsors to review each beneficiary and report on the status of these reviews.

Expand Sponsors' Use of Beneficiary-Specific Controls

Under certain conditions, CMS allows sponsors to implement edits at the point of sale for beneficiaries identified as overutilizing opioids. The goal of these edits is to prevent these beneficiaries from receiving inappropriate and unsafe drugs and to prevent fraud, waste and abuse. CMS should encourage sponsors to develop similar controls for other drugs. As a part of this effort, CMS should provide additional guidance to sponsors about the circumstances under which they can use point-of-sale edits and similar controls for beneficiaries identified as overutilizing other drugs susceptible to fraud, waste, and abuse, including HIV drugs.

CMS should balance the need for these controls with maintaining access to needed drugs. CMS should closely monitor the sponsors to ensure that they use these controls only after appropriate case management and communication with the prescriber and beneficiary.

Restrict Certain Beneficiaries to a Limited Number of Pharmacies or Prescribers

We found that a number of beneficiaries received similar drugs from extremely high numbers of pharmacies or prescribers. CMS should seek legislative authority, if necessary, to restrict certain beneficiaries to a limited number of pharmacies or to a limited number of prescribers, a practice commonly referred to as “lock-in.” This practice is currently used by some State Medicaid programs. CMS would need to balance these restrictions with ensuring access to quality care for these beneficiaries. Restricting certain beneficiaries to a limited number of pharmacies or prescribers could reduce program costs and inappropriate utilization. It could also improve coordination of services and quality of care for these beneficiaries.

Limit the Ability of Certain Beneficiaries To Switch Plans

We found that a number of beneficiaries with questionable utilization patterns switched their Part D plans multiple times during the year. CMS should seek legislative authority to restrict the ability of certain beneficiaries to switch plans multiple times during the year. Currently, beneficiaries who receive the low-income subsidy are allowed to switch plans every month. While CMS needs to continue to allow beneficiaries to switch plans under certain circumstances, it needs to implement some restrictions. Sponsors cannot effectively monitor the drugs that beneficiaries are receiving when beneficiaries frequently switch plans. Limiting certain beneficiaries' ability to switch plans could save taxpayer dollars and improve the quality of care for these beneficiaries.

Increase Monitoring of Beneficiaries' Utilization Patterns

CMS should instruct the MEDIC to routinely monitor beneficiaries' utilization patterns. CMS should focus on drugs susceptible to fraud, waste, and abuse, including HIV drugs. To do this, CMS should use the measures in this report or other methods that it deems appropriate. It should use claims data from Medicare Parts A and B to identify beneficiaries who do not have a history, such as a diagnosis, that supports the use of the drugs. CMS should then identify the pharmacies and prescribers that are associated with these beneficiaries.

Follow Up on Questionable Utilization Patterns

In a separate memorandum, we will refer to CMS the beneficiaries with questionable utilization patterns. CMS or the MEDIC should further assess these utilization patterns by using other methods, such as reviewing medical records and supporting documentation. CMS should then determine the most appropriate actions.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on our draft report, CMS concurred with five of our seven recommendations. CMS concurred with our first recommendation (to expand sponsors' drug utilization review programs), stating that it has indicated that Part D sponsors may adapt its guidance with respect to opioids and nonopioid medications. It also said that it will reiterate and clarify this guidance with respect to the potential overutilization, misuse, and safety issues identified in this report related to HIV drugs.

CMS did not concur with our second recommendation (to expand the Overutilization Monitoring System). It stated that the system is not functionally designed to be a comprehensive safety and/or fraud-identification tool. Instead, it is primarily a tool focused on medication safety to ensure that Part D sponsors adequately address the overutilization of opioids and acetaminophen. While we understand that the Overutilization Monitoring System's primary focus is opioids and acetaminophen, we see benefits in expanding it to include other drugs to ensure that sponsors are improving their drug utilization review programs.

CMS concurred with our third and fourth recommendations (that it expand sponsors' use of beneficiary-specific controls and that it restrict certain beneficiaries to a limited number of pharmacies or prescribers). It noted that current guidance states that sponsors may expand their use of beneficiary-specific controls to drugs other than opioids and acetaminophen, as long as they use the same level of diligence and internal documentation that the agency expects with respect to opioids and acetaminophen. With respect to restricting certain beneficiaries to a limited number of pharmacies or prescribers, CMS stated it would be receptive to legislative authority for "lock-in" in Part D.

CMS said that it did not concur with our fifth recommendation (to limit the ability of certain beneficiaries to switch plans) at this time. The agency said that it believes that new legislative authority to limit prescribers or pharmacies and the implementation of OIG's other recommendations are more likely to effectively address OIG's intent to limit an individual's ability to commit fraud or obtain more than necessary doses of Part D drugs. Further, CMS said that it is concerned about the potential unintended consequences from creating limitations for certain beneficiaries receiving the low-income subsidy. While we share CMS's concern about the vulnerability of this population, we believe this recommendation can be implemented with minimal impact on these beneficiaries. It could be used in only the most extreme cases, where other steps have failed to prevent potential abuse or overutilization.

CMS concurred with the sixth and seventh recommendations (that it increase monitoring of beneficiaries' utilization patterns and that it follow up on questionable utilization patterns). It stated that it will conduct future analysis that will use Medicare Part A and B claims data to identify beneficiaries, as well as the pharmacies and prescribers linked to these beneficiaries, to monitor fraud, waste, and abuse in Medicare Parts C and D. CMS further stated that it will review the OIG data and take appropriate actions. The full text of CMS's comments is provided in Appendix C.

APPENDIX A

HIV Drugs

Brand Name	Generic Name
Multiclass Combination Products	
Atripla	efavirenz, emtricitabine and tenofovir disoproxil fumarate
Complera	emtricitabine, rilpivirine, and tenofovir disoproxil fumarate
Stribild	elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	
Combivir	lamivudine and zidovudine
Emtriva	emtricitabine, FTC
EpiVir	lamivudine, 3TC
Epzicom	abacavir and lamivudine
Retrovir	zidovudine, azidothymidine, AZT, ZDV
Trizivir	abacavir, zidovudine, and lamivudine
Truvada	tenofovir disoproxil fumarate and emtricitabine
Videx EC	enteric coated didanosine, ddi EC
Videx	didanosine, dideoxyinosine, ddi
Viread	tenofovir disoproxil fumarate, TDF
Zerit	stavudine, d4T
Ziagen	abacavir sulfate, ABC
Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)	
Eduvant	rilpivirine
Intelence	etravirine
Rescriptor	delavirdine, DLV
Sustiva	efavirenz, EFV
Viramune (Immediate Release)	nevirapine, NVP
Viramune XR (Extended Release)	nevirapine, NVP

(continued on next page)

HIV Drugs (continued)

Brand Name	Generic Name
Protease Inhibitors (PIs)	
Agenerase	amprenavir, APV (no longer marketed)
Aptivus	tipranavir, TPV
Crixivan	indinavir, IDV,
Fortovase	saquinavir (no longer marketed)
Invirase	saquinavir mesylate, SQV
Kaletra	lopinavir and ritonavir, LPV/RTV
Lexiva	fosamprenavir calcium, FOS-APV
Norvir	ritonavir, RTV
Prezista	darunavir
Reyataz	atazanavir sulfate, ATV
Viracept	nelfinavir mesylate, NFV
Fusion Inhibitors	
Fuzeon	enfuvirtide, T-20
Entry Inhibitors - CCR5 Co-Receptor Antagonist	
Selzentry	maraviroc
HIV Integrase Strand Transfer Inhibitors	
Isentress	raltegravir

Source: FDA, *Antiretroviral Drugs Used in the Treatment of HIV Infection*, August 2013.

Note: For more information about these drugs, see FDA's full table at <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm118915.htm>.

APPENDIX B

Table B-1: Most Common Combinations of HIV Drugs

Combination of Drugs	Total Number of Beneficiaries	Total Number of Days Taken Together
Norvir, Reyataz, and Truvada	14,311	3,175,807
Norvir, Prezista, and Truvada	10,121	1,848,085
ISENTRESS and Truvada	8,656	1,539,604
Norvir and Truvada	7,980	140,186
Norvir and Prezista	6,853	159,757
Norvir and Reyataz	6,388	144,163
KALETRA and Truvada	5,252	1,099,948
Reyataz and Truvada	4,869	231,498
Isentress, Norvir, and Prezista	4,282	312,290
Isentress, Norvir, Prezista, and Truvada	3,471	651,307

Source: OIG analysis of Part D data, 2013.

Note: For a list of the generic names for these drugs, see Appendix A.

Table B-2: Most Common HIV Drugs

HIV Drug	Total Number of Beneficiaries	Total Number of Prescriptions	Total Dollars
Norvir	56,018	471,146	\$170,984,046
Truvada	52,574	441,399	\$545,137,647
Isentress	33,748	282,629	\$306,824,485
Reyataz	28,564	238,718	\$255,817,941
Prezista	28,012	227,405	\$248,064,989
Atripla	27,514	237,458	\$448,889,051
Epzicom	18,408	156,654	\$164,068,263
Viread	14,946	116,203	\$88,529,258
Kaletra	14,886	119,312	\$93,417,187
Intelence	11,178	90,926	\$79,094,787
Sustiva	10,702	92,229	\$60,042,837
Epivir / lamivudine*	10,381	76,477	\$22,419,341
Combivir / lamivudine-zidovudine*	9,665	75,764	\$61,281,517
Ziagen / abacavir*	8,155	61,994	\$34,389,214
Viramune / Viramune XR / nevirapine*	7,648	70,367	\$37,013,755
Lexiva	5,457	45,615	\$47,083,756
Complera	3,908	21,800	\$42,214,282
Retrovir / zidovudine*	3,358	23,284	\$1,414,313
Selzentry	3,210	27,365	\$33,262,235
Emtriva	3,119	22,821	\$9,334,652
Trizivir	3,100	24,634	\$38,571,285
Videx / Videx EC / didanosine*	2,487	19,518	\$4,559,596
Viracept	2,112	18,267	\$15,304,005
Zerit / stavudine*	1,698	12,812	\$1,810,603
Stribild	1,200	2,456	\$6,106,062
Invirase	1,130	9,936	\$9,445,175
Edurant	742	4,437	\$3,150,003
Fuzeon	504	3,816	\$10,685,586
Crixivan	463	3,487	\$1,607,226
Aptivus	431	3,658	\$4,328,383
Rescriptor	102	846	\$288,390

Source: OIG analysis of Part D data, 2013.

*When determining the most common drugs, we considered the drugs listed with slashes (/) between them to be the same.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAY 30 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs" (OEI-02-11-00170)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above-referenced OIG draft report. The purpose of this report was to identify patterns of questionable drug utilization in the Medicare Part D program that may warrant further scrutiny.

The CMS is committed to preventing fraud, waste, and abuse in the Medicare Part D program. To help protect the Medicare Part D program, CMS requires plan sponsors to have compliance programs in place to help detect, prevent, and correct fraud, waste, and abuse. CMS also contracts with a Medicare Drug Integrity Contractor (MEDIC) that is tasked with identifying and investigating potential fraud and abuse, referring such cases to law enforcement, and fulfilling requests for information from law enforcement. We appreciate OIG's efforts in working with CMS to prevent fraud, waste, and abuse in the Medicare Part D program. Our response to each of the OIG recommendations follows.

OIG Recommendation

The OIG recommends CMS expand sponsors' drugs utilization review programs. CMS should require sponsors to improve retrospective reviews and case management for other drugs susceptible to fraud, waste, and abuse, including HIV drugs. Similar to opioids, sponsors should use data analysis to identify beneficiaries who may be over-utilizing these drugs and to identify possible fraud, waste, and abuse. CMS should require that sponsors contact the prescribing physicians to determine whether utilization is appropriate.

CMS Response

The CMS concurs with this recommendation. In guidance since 2012, CMS has repeatedly indicated that Part D sponsors may adapt CMS' guidance with respect to opioids to non-opioid medications. (See September 6, 2012 memorandum, "Supplemental Guidance Related to

Improving Drug Utilization Review Controls in Part D” (FAQ section) and the Final calendar year (CY) 2014 and CY 2015 Call Letters). CMS will reiterate and clarify this guidance with respect to the potential overutilization, misuse, and safety issues identified in this report related to HIV medications after OIG releases this report as final.

OIG Recommendation

The OIG recommends CMS expand the overutilization monitoring system. CMS should ensure that sponsors have made the necessary changes to improve their DUR programs. As part of its efforts, CMS should expand the Overutilization Monitoring System (OMS) which currently focuses on opioid and acetaminophen to include other drugs susceptible to fraud, waste, and abuse, such as HIV drugs. Similar to opioids, on a quarterly basis, CMS should identify beneficiaries who are receiving excessive amounts of certain drugs, including HIV drugs; provide a list of these beneficiaries to sponsors; and require sponsors to review each beneficiary and report on the status of these reviews.

CMS Response

The CMS does not concur that it should expand the OMS, which is primarily a medication safety-focused tool to ensure that Part D sponsors adequately address the overutilization of opioids and acetaminophen in the Part D program. OMS is not functionally designed to be a comprehensive safety and/or fraud identification tool. Moreover, opioid and acetaminophen overutilization has been identified as a national epidemic, which warranted a unique and tailored response by CMS to ensure that Part D sponsors had specific guidance from CMS in the absence of a Food and Drug Administration maximum dose for opioids.

OIG Recommendation:

The OIG recommends CMS expand sponsors’ use of beneficiary specific controls. CMS should provide additional guidance to sponsors about the circumstances under which they can use point-of-sale edits and other similar controls for beneficiaries identified as over-utilizing other drugs susceptible to fraud, waste, and abuse, including HIV drugs. CMS should balance the need for these controls with maintaining access to needed drugs. CMS should closely monitor the sponsors to ensure that they use these controls only after appropriate case management and communication with the prescriber and beneficiary.

CMS Response:

The CMS concurs with this recommendation. Current guidance states that sponsors may expand their use of beneficiary specific controls to non-opioid and non-acetaminophen drugs, as long as they use the same level of diligence and internal documentation that we expect with respect to opioids and acetaminophen.

OIG Recommendation

The OIG recommends CMS restrict certain beneficiaries to a limited number of pharmacies of prescribers. CMS should seek legislative authority, if necessary, to restrict beneficiaries to a limited number of pharmacies, or to a limited number of prescribers, a practice commonly referred to as “lock in.”

CMS Response

The CMS concurs with this recommendation. As stated in the related OIG reports, CMS would need legislative authority for “lock in” in Part D. CMS has indicated that it would be receptive to such legislative authority.

OIG Recommendation

The OIG recommends CMS limit the ability of certain beneficiaries to switch plans. The CMS should seek legislative authority to restrict the ability of certain beneficiaries to switch plans multiple times during the year.

CMS Response

The CMS does not concur with this recommendation at this time. CMS believes that new legislative authority to limit the prescribers or pharmacies and the implementation of the other OIG recommendations are more likely to effectively address OIG’s intent to limit an individual’s ability to commit fraud or obtain more than necessary doses of Part D-covered medicines to treat diagnosed conditions.

The CMS is concerned about the potential unintended consequences from creating limitations for certain Low Income Subsidy (LIS) beneficiaries based on their drug usage within the Part D program. As the LIS population is especially vulnerable, the law currently provides full benefit dual eligible beneficiaries a special election period (SEP) outside of the Annual Election Period each fall. This SEP is in place to ensure that this vulnerable population can get the care they need by enrolling in a different plan.

OIG Recommendation

The OIG recommends CMS increase monitoring of beneficiaries’ utilization patterns. The CMS should instruct the MEDIC to routinely monitor beneficiaries’ utilization patterns. CMS should focus on drugs susceptible to fraud, waste, and abuse, including HIV drugs.

CMS Response

The CMS concurs with this recommendation. The MEDIC currently monitors the utilization patterns of beneficiaries receiving drugs that are susceptible to fraud, waste, and abuse, including HIV drugs, through various on-going and completed projects. Additionally, the MEDIC extracts Medicare Parts A and B claims data to help identify fraud, waste, and abuse in Medicare Parts C

Page 4 – Daniel R. Levinson

and D program. CMS in conjunction with the MEDIC recently conducted an analysis which identified prescription drug event records for Transmucosal Immediate-Release Fentanyl products that were inappropriately paid under Part D for beneficiaries without a medically accepted diagnosis. CMS will conduct future analysis that will use Medicare Parts A and B claims data to identify beneficiaries, as well as the pharmacies and prescribers linked to these beneficiaries, to monitor fraud, waste, and abuse in Medicare Parts C and D.

OIG Recommendation

The OIG recommends CMS follow-up on Questionable Utilization Patterns. In a separate memorandum, we will refer to CMS the beneficiaries with questionable utilization patterns. CMS or the MEDIC should further assess these utilization patterns by using other methods such as reviewing medical records and supporting documentation. CMS should then determine what actions are most appropriate.

CMS Response

After receipt of the OIG data, CMS and/or the MEDIC will review the data and take appropriate actions.

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

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