Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# MEDICARE PART D PLAN SPONSORS AND CMS DID NOT ENSURE THAT TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL DRUGS WERE DISPENSED ONLY TO BENEFICIARIES WHO HAD A CANCER DIAGNOSIS

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

Amy J. Frontz
Deputy Inspector General
for Audit Services

February 2023
A-09-20-03033

# *Office of Inspector General*

https://oig.hhs.gov

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

## *Office of Audit Services*

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

## *Office of Evaluation and Inspections*

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

## *Office of Investigations*

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

## *Office of Counsel to the Inspector General*

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

# *Notices*

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

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

**OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

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

**Report in Brief**
Date: February 2023
Report No. A-09-20-03033

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

# Medicare Part D Plan Sponsors and CMS Did Not Ensure That Transmucosal Immediate-Release Fentanyl Drugs Were Dispensed Only to Beneficiaries Who Had a Cancer Diagnosis

## Why OIG Did This Audit

OIG has been tracking opioid use in Medicare during the opioid crisis and has identified providers with questionable prescribing practices and beneficiaries at serious risk of misuse or overdose of opioids. Transmucosal immediate-release fentanyl (TIRF) drugs are high-potency, prescription opioid pain relievers that are approved solely to manage breakthrough cancer pain. Because of known improper off-label use of TIRF drugs that can impact the health and safety of beneficiaries, for this audit we reviewed Medicare Part D plan sponsors' (plan sponsors') prescription drug event (PDE) data to determine whether these drugs were dispensed in compliance with Medicare requirements.

Our objective was to determine whether plan sponsors and the Centers for Medicare & Medicaid Services (CMS) ensured that TIRF drugs were dispensed in accordance with Medicare requirements.

## How OIG Did This Audit

Our audit covered 45,776 PDEs for TIRF drugs dispensed to 5,034 beneficiaries from July 2015 through December 2019, for which the Medicare Part D total cost was $513.9 million. We analyzed Medicare claims data to determine whether beneficiaries who received TIRF drugs had a cancer diagnosis. We selected a judgmental sample of 51 beneficiaries who did not have a cancer diagnosis in their Medicare claims history and reviewed plan sponsor documentation to determine why TIRF drugs were approved.

## What OIG Found

Plan sponsors and CMS did not ensure that all TIRF drugs were dispensed in accordance with Medicare requirements. Medicare requires that TIRF drugs be dispensed only for the medically accepted indication of breakthrough cancer pain. For 7,552 PDEs, plan sponsors approved TIRF drugs dispensed to 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history to support a medically accepted indication for the use of these drugs. As a result, plan sponsors paid $86.2 million in unallowable Medicare Part D total costs. Plan sponsors also approved 2,023 PDEs totaling $19.7 million for TIRF drugs for 176 beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed. Although we did not determine these PDEs to be unallowable, they were at high risk of being unallowable. In addition, for 65 of the 810 beneficiaries, plan sponsors continued to approve TIRF drugs after the beneficiaries' PDEs had been determined to be unallowable during CMS's assessments of medically accepted indications.

For another 409 beneficiaries included in the CMS assessments, CMS determined PDEs to be allowable for 333 beneficiaries and was inconsistent in its determinations of whether 76 beneficiaries had medically accepted indications for TIRF drugs even though these beneficiaries did not have a cancer diagnosis in their Medicare claims history.

## What OIG Recommends and CMS Comments

We recommend that CMS work with its plan sponsors to: (1) delete the PDEs related to the $86.2 million of unallowable Medicare Part D total costs and determine after reconciliation the impact to the Federal Government; and (2) identify and delete any unallowable PDEs related to the $19.7 million of Medicare Part D total costs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government. The report contains three other recommendations.

CMS did not concur with four of our five recommendations. CMS did not explicitly state that it concurred or did not concur with our fifth recommendation but stated that it will continue conducting data analyses to identify potentially improper PDEs for TIRF drugs. After reviewing CMS's comments, we maintain that our recommendations are valid.

The full report can be found at https://oig.hhs.gov/oas/reports/region9/92003033.asp.

**TABLE OF CONTENTS**


INTRODUCTION ..... 1

Why We Did This Audit ..... 1

Objective ..... 1

Background ..... 1

Medicare Part D Prescription Drug Program ..... 1

Medicare Payments to Plan Sponsors ..... 2

Medicare Part D Covered Drugs ..... 3

Transmucosal Immediate-Release Fentanyl Drugs ..... 4

FDA's Risk Evaluation and Mitigation Strategy for TIRF Drugs ..... 5

CMS Assessments of Medically Accepted Indications for TIRF Drugs ..... 6

How We Conducted This Audit ..... 8

FINDINGS ..... 9

Medicare Part D Requirements ..... 11

Plan Sponsors Did Not Ensure That All TIRF Drugs Were Dispensed in Accordance With Medicare Requirements ..... 11

Plan Sponsors Approved TIRF Drugs for Beneficiaries Who Did Not Have a Cancer Diagnosis in Their Medicare Claims History ..... 12

Plan Sponsors Approved TIRF Drugs for Beneficiaries Whose Most Recent Cancer Diagnosis in Their Medicare Claims History Was More Than 1 Year Before the Drugs Were Dispensed ..... 13

Plan Sponsors Approved TIRF Drugs for Beneficiaries Whose Prescription Drug Events Had Been Previously Determined To Be Unallowable During CMS's Assessments of Medically Accepted Indications ..... 14

CMS Assessments Did Not Ensure That All TIRF Drugs Were Dispensed in Accordance With Medicare Requirements ..... 15

CMS Allowed Prescription Drug Events for Beneficiaries Who Did Not Have a Cancer Diagnosis in Their Medicare Claims History ..... 15

CMS Was Inconsistent in Its Determinations of Whether Beneficiaries Had Medically Accepted Indications for TIRF Drugs ..... 16

Plan Sponsors' Prior Authorization Processes Were Not Adequate ..... 17

RECOMMENDATIONS ..... 19

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE ..... 19

Recommendations 1 and 2: Delete Unallowable Prescription Drug Event Records ..... 19
CMS Comments ..... 19
Office of Inspector General Response ..... 20

Recommendation 3: Ensure That Plan Sponsors Obtain Sufficient Information During the Prior Authorization Process ..... 20
CMS Comments ..... 20
Office of Inspector General Response ..... 20

Recommendation 4: Expand the Required Prescription Drug Event Data Elements To Include Diagnosis Codes ..... 21
CMS Comments ..... 21
Office of Inspector General Response ..... 21

Recommendation 5: Conduct Data Analysis ..... 22
CMS Comments ..... 22
Office of Inspector General Response ..... 22

APPENDICES

A: Audit Scope and Methodology ..... 23

B: Prescriber-Related Information ..... 25

C: CMS Comments ..... 26

# INTRODUCTION

## WHY WE DID THIS AUDIT

The United States currently faces a nationwide public health emergency due to the opioid crisis. The Office of Inspector General (OIG) has been tracking opioid use in Medicare during this crisis and has identified providers with questionable prescribing practices and beneficiaries at serious risk of misuse or overdose of opioids.[1] Transmucosal immediate-release fentanyl (TIRF) drugs are high-potency, prescription opioid pain relievers that are approved by the Food and Drug Administration (FDA) solely to manage breakthrough cancer pain.[2] Because of known improper off-label use of TIRF drugs that can impact the health and safety of beneficiaries, for this audit we reviewed Medicare Part D plan sponsors' (plan sponsors') prescription drug event (PDE) data (submitted to the Centers for Medicare & Medicaid Services (CMS)) to determine whether TIRF drugs were dispensed in compliance with Medicare requirements.[3, 4]

## OBJECTIVE

Our objective was to determine whether plan sponsors and CMS ensured that TIRF drugs were dispensed in accordance with Medicare requirements.

## BACKGROUND

### Medicare Part D Prescription Drug Program

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D voluntary prescription drug benefit. Under Part D, which went into effect on January 1, 2006, individuals who are entitled to benefits under Medicare Part A or are enrolled in Medicare Part B may obtain voluntary coverage for outpatient prescription drugs.

---

[1] OIG reports related to opioid prescribing, use, and misuse can be accessed at Combating the Opioid Epidemic | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov).

[2] Breakthrough cancer pain is an episode of severe pain that "breaks through" a period of persistent pain at least partly controlled by a stable opioid regimen. (Sebastiano Mercadante and Russell K. Portenoy, "Breakthrough cancer pain: twenty-five years of study," *Pain,* vol. 157, Dec. 2016, pp. 2657–2663. Accessed at https://doi.org/10.1097/j.pain.0000000000000721 on Sept. 12, 2022.)

[3] Off-label use of a drug is defined as a use for an indication that is not approved by the FDA and is not listed in the drug's official prescribing information.

[4] When a beneficiary has a prescription filled for a drug under Medicare Part D, a plan sponsor must submit to CMS a summary record, referred to as a "PDE record." This record contains cost data as well as information about the drug. A PDE record is not the same as an individual drug claim transaction but is a summary extract using CMS-defined standard fields.

CMS, which administers Medicare, contracts with private insurers (also known as plan sponsors) to offer prescription drug benefits to eligible individuals who choose to enroll in Medicare Part D. Medicare beneficiaries have the option of enrolling in stand-alone prescription drug plans, or they may receive prescription drug coverage as part of managed-care plans. The managed-care plans (known as Medicare Advantage plans) also include medical benefits.

CMS requires that plan sponsors develop a network of pharmacies to dispense drugs to beneficiaries enrolled in their plans (42 CFR § 423.120(a)). Pharmacies submit claims to plan sponsors (or to plan sponsors' Pharmacy Benefit Managers (PBMs)) for drugs they dispense to beneficiaries.[5]

Plan sponsors then submit PDE records to CMS for all covered drugs that are dispensed to beneficiaries throughout the year. These records contain cost data as well as information about each drug, including the date of service, payment fields, the pharmacy that dispensed the drug, and the beneficiary who received the drug.[6] PDE records do not contain information related to beneficiaries' medical diagnoses. (In this report, we refer to PDE records as "PDEs.")

**Medicare Payments to Plan Sponsors**

CMS makes estimated monthly payments to plan sponsors for each enrolled Medicare beneficiary. These payments are based on bids that plan sponsors submit before the beginning of the subsequent calendar year. Each bid estimates the plan sponsor's anticipated drug costs as well as its administrative costs (42 CFR § 423.265(c)(1)). CMS uses the approved bids in establishing the premium amounts that beneficiaries pay and the estimated monthly payments that it makes to each sponsor (42 CFR §§ 423.286 and 423.315(b)).

After the coverage year, CMS reconciles these estimated monthly payments with the actual costs incurred by plan sponsors to determine at the end of the year whether CMS owes money to the plan sponsors or the plan sponsors owe money to CMS (42 CFR § 423.343). CMS

[5] PBMs are organizations that help manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers.

[6] The payment fields in the PDE records include the: (1) ingredient cost paid, (2) dispensing fee paid, (3) amount attributed to sales tax, and (4) vaccine administration fee. The sum of these fields, referred to as the "gross covered drug cost" (total cost), is the amount that a drug plan incurs for covered Part D drugs. (CMS, *2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide.* Available online at https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCPDEParticipantGuide%20cameraready%20081811.pdf/$FILE/PDEParticipantGuide%20cameraready%20081811.pdf. Accessed on Sept. 12, 2022.)

determines each plan sponsor's actual costs based on the PDEs that the plan sponsor submits and direct and indirect remuneration (DIR) reported by the plan sponsor.[7]

When a plan sponsor determines that a drug was dispensed for a nonmedically accepted indication during a retrospective review of claims data, the PDE should be deleted (CMS's *Prescription Drug Benefit Manual*, chapter 6, § 10.6.1). According to plan sponsors, when CMS or a plan sponsor identifies PDEs to be deleted, the plan sponsor will delete or direct its claim processor to delete those PDEs. The plan sponsor then submits the PDE file to CMS, and the file has a record of these deletions.

If a plan sponsor submits PDEs for drugs that should not have been covered by Medicare Part D, the plan sponsor may be overpaid for the drugs. To determine the estimated impact to the Federal Government of an identified overpayment, CMS uses an impact calculation, which determines the effect of the overpayment on reinsurance and low-income cost-sharing amounts.[8] CMS performs a reconciliation based on corrected payments, and that reconciliation is compared with the initial reconciliation to determine the total overpayment. CMS uses a reopening process, during which adjustments or deletions to PDEs may result in adjustments to the plan sponsor's final payment determination, to determine the impact of identified overpayments.[9] Following this process, CMS recoups the calculated amount of the impact to the Federal Government through an adjustment to the plan sponsor's estimated monthly payment.

**Medicare Part D Covered Drugs**

Medicare Part D covers only drugs that are dispensed pursuant to a prescription; are approved for safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic (FD&C) Act; and are for a medically accepted indication. A medically accepted indication is any use of a covered outpatient drug that is approved under the FD&C Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia (the Act

[7] DIR comprises fees, payments, or payment adjustments that change the cost of Medicare Part D covered drugs for plan sponsors or PBMs. DIR results from payment arrangements negotiated independently of CMS—between plan sponsors, PBMs, network pharmacies, drug manufacturers, and other parties involved in administering the Part D benefit. Manufacturer rebates make up a significant share of all DIR reported to CMS.

[8] Reinsurance and low-income cost-sharing amounts are two mechanisms that Medicare Part D provides to pay plan sponsors for Part D basic benefits. The reinsurance subsidy is a Federal subsidy for 80 percent of allowable drug costs above a beneficiary's out-of-pocket threshold. Reinsurance reduces the risk of participating in Part D by guaranteeing plans a certain amount of payment for beneficiaries who have high drug costs. Low-income cost-sharing subsidies are payments on behalf of certain beneficiaries based on their income and asset levels (42 CFR § 423.329).

[9] CMS may reopen and revise an initial or reconsidered final payment determination: (1) for any reason, within 12 months from the date of the notice of the final determination to the plan sponsor; (2) after that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the plan sponsor upon establishment of good cause for reopening; or (3) at any time, in instances of fraud or similar fault of the Medicare Part D plan sponsor or any subcontractor of the Part D plan sponsor (42 CFR § 423.346(a)).

§ 1860D-2(e); the Act §§ 1927(g)(1)(B)(i) and (k)(6)).[10] Plan sponsors are responsible for ensuring that drugs dispensed are only for medically accepted indications (CMS's *Prescription Drug Benefit Manual,* chapter 6, § 10.6).

Plan sponsors should consistently utilize prior authorization for those drugs with the highest likelihood of non-Part D covered uses, such as when a drug is: (1) covered under Medicare Parts A or B, (2) excluded from Part D coverage, or (3) prescribed for a nonmedically accepted indication (CMS's *Prescription Drug Benefit Manual,* chapter 6, § 30.2.2.3). According to plan sponsors, when a prescriber submits a prior authorization request for a drug, the prescriber provides answers to questions designed by the plan sponsor, which helps the plan sponsor decide whether to approve coverage of the drug, in accordance with Medicare requirements. For example, a prescriber must indicate the diagnosis associated with the requested drug for the plan sponsor to verify that the drug is being used for a medically accepted indication. If the prior authorization request is inaccurate or lacking sufficient information, the plan sponsor contacts the prescriber to obtain necessary information to make a decision on coverage of the drug.

**Transmucosal Immediate-Release Fentanyl Drugs**

TIRF drugs are Schedule II controlled substances that are 100 times more potent than morphine and have a high potential for abuse, similar to other opioid analgesics.[11] FDA approved these drugs solely for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid


[10] The compendia are summaries of drug information used to determine the appropriate use of drugs. The two compendia used by Medicare Part D are the American Society of Health System Pharmacists, Inc.'s American Hospital Formulary Service Drug Information and Thomson Reuters' DrugDEX Information System (CMS's *Prescription Drug Benefit Manual*, chapter 6, § 10.6).

[11] Schedule II drugs are drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.

therapy for their underlying persistent cancer pain.[12, 13] TIRF drugs are sold under the following brand names (some have generic equivalents):

- Abstral sublingual tablet
- Actiq oral transmucosal lozenge[14]
- Fentora buccal tablet
- Lazanda nasal spray
- Onsolis buccal soluble film
- Subsys sublingual spray

"Transmucosal" refers to the route that the drug enters the body, through or across a mucosal membrane. These routes include under the tongue (sublingual), through the nose (nasal), and through the buccal cavity (above a rear molar, between the upper cheek and gum).

**FDA's Risk Evaluation and Mitigation Strategy for TIRF Drugs**

Under the FDA Amendments Act of 2007, FDA has the authority to require a manufacturer to develop a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of certain drugs with serious safety concerns outweigh the risks. Each REMS focuses on preventing, monitoring, and managing specific serious risks by informing, educating, and reinforcing safe use of a drug by key participants (i.e., patients, health care providers, pharmacists, and health care settings that dispense or administer the drug) to reduce the frequency and severity of an adverse drug experience.[15]

[12] Cancer is a disease in which some of the body's cells grow uncontrollably and spread to other parts of the body. These cells may form tumors (also known as neoplasms), which are lumps of tissue. Tumors can be cancerous (malignant) or not cancerous (benign).

[13] Patients are considered opioid tolerant if they are on an around-the-clock daily opioid regimen for 1 week or longer, consisting of at least: 60 milligrams (mg) of oral morphine per day, 25 micrograms per hour of transdermal fentanyl, 30 mg of oral oxycodone per day, 8 mg of oral hydromorphone per day, 25 mg of oral oxymorphone per day, 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. (An equianalgesic dose is a dose of one opioid that is equivalent in pain-relieving effects to that of another opioid.) Patients must remain on around-the-clock opioids while taking TIRF drugs. (FDA, "Risk Evaluation and Mitigation Strategy (REMS) Document TIRF Shared System REMS Program." Available online at https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2021_12_03_REMS_Full.pdf. Accessed on Feb. 8, 2022.)

[14] Actiq and its generic equivalent are approved for cancer patients 16 years of age and older.

[15] Section 505-1(b)(4) of the FD&C Act defines an adverse drug experience as serious if it results in death, immediate risk of death, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect (or, based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent the above-described outcomes).

In December 2011, FDA approved the TIRF REMS Access program for the entire class of TIRF drugs to reduce the risk of misuse and abuse of, addiction to, and overdose with these drugs.[16] Prescribers and pharmacies are required to enroll in the program and successfully complete a knowledge assessment every 2 years. Patients who are prescribed a TIRF drug on an outpatient basis must also sign a patient-prescriber agreement with a health care provider and are asked to read the medication guide provided to them by the prescriber.

### History of Unlawful Marketing Practices for TIRF Drugs

In September 2008, Cephalon, a biopharmaceutical company, pleaded guilty to the unlawful practice of off-label marketing related to three drugs, including Actiq, the first TIRF drug that FDA approved (in November 1998).[*] The company targeted noncancer physicians to prescribe Actiq for uses other than cancer pain. Cephalon paid $40 million in criminal fines and $375 million, plus interest, to resolve False Claims Act allegations arising from claims submitted to Medicaid, Medicare, and other Federal programs.

Another TIRF drug, Subsys, was approved by FDA in January 2012. By the end of 2015, Subsys accounted for at least 75 percent of Medicare Part D total costs for TIRF drugs, or $155 million. In June 2019, Insys Therapeutics admitted to illegal conduct in promoting Subsys. In addition to a $225 million global resolution, Insys executives were convicted of crimes related to illegal marketing of Subsys. Insys used speaker programs to pay bribes and kickbacks to physicians to increase the number of Subsys prescriptions and the dosage prescribed.[†] Insys also set up a reimbursement center dedicated to obtaining prior authorizations by misleading insurers regarding patients' true diagnoses.[‡]

[*] Department of Justice (DOJ), "Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing." Available online at https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html. Accessed on Sept. 12, 2022.

[†] DOJ, "Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations." Available online at https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal. Accessed on Sept. 12, 2022.

[‡] DOJ, "Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy." Available online at https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy. Accessed on Sept. 12, 2022.

**CMS Assessments of Medically Accepted Indications for TIRF Drugs**

In October 2016, Senator Edward J. Markey expressed concerns to CMS that Medicare Part D paid for improper off-label use of Subsys, which may have contributed to the opioid abuse

[16] FDA, "Risk Evaluation and Mitigation Strategy (REMS) Document TIRF Shared System REMS Program." Available online at https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2021_12_03_REMS_Full.pdf. Accessed on Feb. 8, 2022.

epidemic.[17] In December 2016, in response to Senator Markey's concerns, CMS described its efforts related to TIRF drugs, including Subsys.[18] CMS informed Senator Markey that it had begun conducting assessments of medically accepted indications for TIRF drugs in September 2013. As of the response date, CMS had completed assessments for TIRF drugs dispensed to beneficiaries from January 1, 2010, through June 30, 2015, which resulted in plan sponsors' deletion of more than 33,600 unallowable PDEs, totaling $117 million, from CMS's integrated data repository (IDR).[19] CMS completed subsequent assessments through December 31, 2017, and deleted from the IDR more than 1,600 unallowable PDEs totaling $13 million. Because of the significant decrease in the number of PDEs for TIRF drugs dispensed to beneficiaries without a cancer diagnosis, CMS discontinued performing additional assessments.

Beginning in 2015, CMS instructed plan sponsors to implement point-of-sale edits for prior authorization of qualifying drugs or drug classes, or both, that pose the greatest risk for non-Part D covered uses, including the high likelihood of use for nonmedically accepted indications as defined in section 1860D-2(e)(4) of the Act.[20] CMS specifically cited TIRF drugs as an example.[21]

Federal efforts to help reduce the off-label prescribing and use of TIRF drugs may have resulted in a decrease in unallowable total costs and Medicare Part D total costs. From January 2010 through December 2019, the Medicare Part D total cost for TIRF drugs prescribed to beneficiaries nationwide was $912.6 million. Figure 1 on the following page shows total costs for TIRF drugs for every year during this 10-year period and the decrease in costs from 2016 through 2019.

[17] Available online at https://www.markey.senate.gov/imo/media/doc/2016-10-11-CMS-Letter-Fentanyl.pdf. Accessed on May 16, 2022.

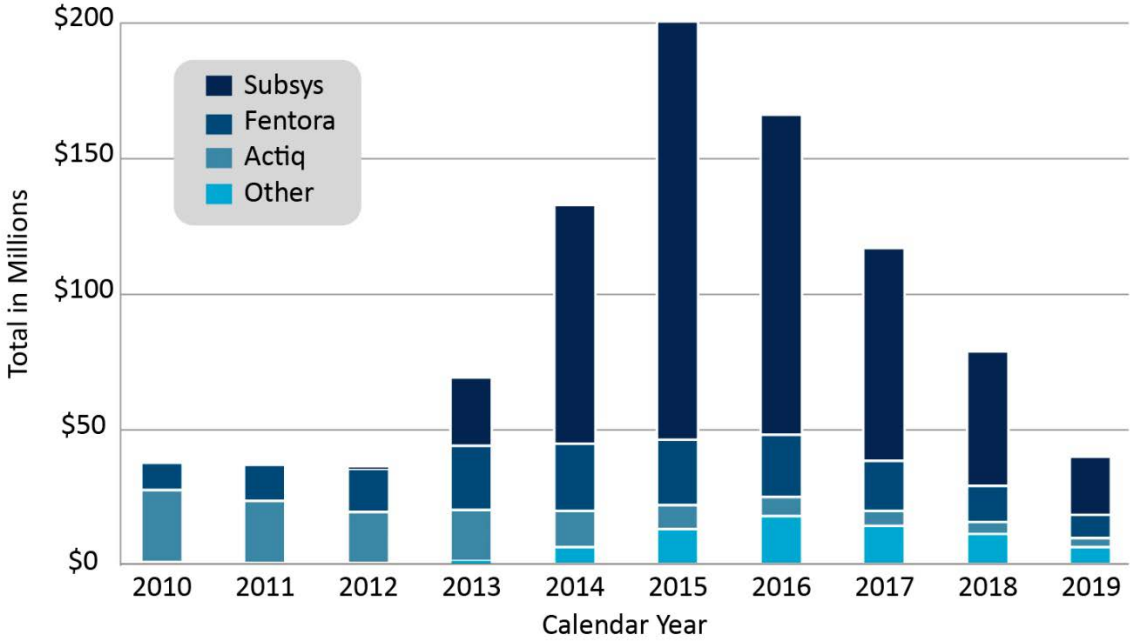
[18] Available online at https://www.markey.senate.gov/imo/media/doc/2016-12-01-Slavitt-Letter.pdf. Accessed on May 16, 2022.

[19] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D claims; beneficiary and provider data sources; and ancillary data, such as contract information and risk scores.

[20] One purpose of point-of sale edits is to prompt prescribers and pharmacists to conduct additional reviews to determine whether a beneficiary's use of a drug is for a medically accepted indication.

[21] CMS, 2015 Final Call Letter (Apr. 7, 2014). Available online at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf. Accessed on May 16, 2022.

**Figure 1: Medicare Part D Total Costs for TIRF Drugs From 2010 Through 2019**




## HOW WE CONDUCTED THIS AUDIT

Our audit covered 45,776 PDEs submitted by plan sponsors for TIRF drugs dispensed to 5,034 beneficiaries from July 1, 2015, through December 31, 2019 (audit period), for which the Medicare Part D total cost was $513.9 million. We analyzed Medicare claims data to determine whether beneficiaries who received TIRF drugs during our audit period had a cancer diagnosis in their Medicare claims history.[22] We considered PDEs for beneficiaries who did not have a cancer diagnosis in their Medicare claims history as unallowable because breakthrough cancer pain is the only medically accepted indication for Medicare reimbursement of TIRF drugs.[23] It is not reasonable for a beneficiary to be prescribed TIRF drugs for breakthrough cancer pain without having had a cancer diagnosis.

[22] We determined that a beneficiary did not have a cancer diagnosis if there was not a malignant neoplasm diagnosis code (*International Classification of Diseases* (ICD), 9th revision, codes 140 through 209; and ICD, 10th revision, codes C00 through C96) on any Medicare fee-for-service or managed-care claim from January 1, 2006, through December 31, 2019, or within 1 year after the TIRF drug's PDE date. We determined that a beneficiary had a cancer diagnosis if there was a malignant neoplasm code on any Medicare claim before or within 1 year after the TIRF drug's PDE date.

[23] On inpatient claims, providers must report the principal diagnosis, which is the condition established after study to be chiefly responsible for the admission. Other diagnosis codes are required on inpatient claims and are used in determining the appropriate Medicare Severity Diagnosis Related Group. The provider reports up to 24 additional diagnoses if they coexisted at the time of admission or developed subsequently, and which had an effect on the treatment or length of stay (CMS's *Medicare Claims Processing Manual*, chapter 23, § 10.2). For outpatient claims, providers report the principal diagnosis, which is the diagnosis shown to be chiefly responsible for the outpatient services and up to 24 other diagnoses that coexisted (CMS's *Medicare Claims Processing Manual*, chapter 23, § 10.3).

We identified 7 plan sponsors that had high Medicare Part D total costs for TIRF drugs during our audit period for beneficiaries who did not have a cancer diagnosis in their Medicare claims history, and we selected a judgmental sample of 51 beneficiaries. (Appendix A describes our audit scope and methodology.) For the 51 beneficiaries, we reviewed documentation provided by their plan sponsors to determine why TIRF drugs were approved for beneficiaries who did not have a cancer diagnosis. In addition, we reviewed medical records from providers who did not prescribe TIRF drugs (i.e., nonprescribing providers) for 28 of the 51 beneficiaries, primarily those for which plan sponsor documentation showed a specific cancer diagnosis, to determine whether the medical records included a cancer diagnosis.[24] We relied on information in the medical records and information provided by the nonprescribing providers to make our determinations. We did not use medical review to determine whether the beneficiaries had cancer.

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.

## FINDINGS

Plan sponsors and CMS did not ensure that all TIRF drugs were dispensed in accordance with Medicare requirements. Medicare requires that TIRF drugs be dispensed only for the medically accepted indication of breakthrough cancer pain.

Specifically, plan sponsors did not ensure that all TIRF drugs were dispensed in accordance with Medicare requirements as follows:

- **Plan sponsors approved TIRF drugs for beneficiaries who did not have a cancer diagnosis in their Medicare claims history.** Of the 45,776 PDEs that plan sponsors submitted, plan sponsors approved 7,552 PDEs for TIRF drugs dispensed to 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history to support a medically accepted indication for the use of these drugs.[25] As a result, plan

[24] We reviewed medical records from nonprescribing physicians for 24 beneficiaries whose prior authorizations included diagnosis codes related to malignant or benign neoplasms and for 4 beneficiaries whose prior authorizations noted that the beneficiaries had breakthrough pain due to cancer. We did not obtain documentation from nonprescribing providers for the 23 remaining beneficiaries, whose prior authorization documentation generally did not include information regarding a specific diagnosis code related to a malignant or benign neoplasm.

[25] The 45,776 PDEs submitted by plan sponsors for TIRF drugs were dispensed to 5,034 beneficiaries. Although 4,265 of these beneficiaries had a cancer diagnosis, the number of beneficiaries who did not have a cancer diagnosis totals 810, not 769, because 41 beneficiaries had PDEs with service dates more than 1 year before the earliest cancer diagnosis in the Medicare claims data, which we considered to be unallowable, and had other PDEs with service dates within 1 year of or after the date of their earliest cancer diagnosis.

sponsors paid $86.2 million in unallowable Medicare Part D total costs.[26] The remaining 38,224 PDEs were for TIRF drugs dispensed to 4,265 beneficiaries who had a cancer diagnosis in their Medicare claims history.

- **Plan sponsors approved TIRF drugs for beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed.** Of the 38,224 PDEs for TIRF drugs dispensed to beneficiaries who had a cancer diagnosis, 2,023 totaling $19.7 million were for TIRF drugs dispensed to 176 beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed.[27] Although we did not determine the PDEs to be unallowable—because the beneficiaries had a cancer diagnosis in their Medicare claims history before TIRF drugs were dispensed—these PDEs totaling $19.7 million were at high risk of being unallowable.

- **Plan sponsors approved TIRF drugs for beneficiaries whose PDEs had been previously determined to be unallowable.** Of the 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history, 479 were included in the CMS assessments of medically accepted indications for TIRF drugs. For 70 of the 479 beneficiaries, CMS determined that the beneficiaries' PDEs were unallowable during its assessments because it identified that the beneficiaries did not have a cancer diagnosis; CMS instructed plan sponsors to delete the PDEs. However, after the CMS assessments, plan sponsors still submitted 889 unallowable PDEs totaling $7.7 million (of the $86.2 million) for TIRF drugs dispensed to 65 of the 70 beneficiaries identified by CMS as not having a cancer diagnosis.[28]

In addition, CMS's assessments did not ensure that all TIRF drugs were dispensed in accordance with Medicare requirements. Specifically, for 409 of the 479 beneficiaries included in the CMS assessments, CMS determined PDEs to be allowable for 333 beneficiaries and was inconsistent in its determinations of whether 76 beneficiaries had medically accepted indications for TIRF drugs. Of the $86.2 million in unallowable Medicare Part D total costs, the 333 beneficiaries were associated with 3,232 PDEs and $38.3 million, and the 76 beneficiaries were associated with 843 PDEs and $11 million.[29]

We determined that plan sponsors approved TIRF drugs for beneficiaries who did not have a cancer diagnosis because plan sponsors' prior authorization processes were not adequate.

[26] The unrounded amount was $86,247,325.

[27] The unrounded amount was $19,704,602.

[28] The unrounded amount for the 889 PDEs was $7,652,409. Although plan sponsors submitted PDEs for the five remaining beneficiaries before the CMS assessments, they did not submit any PDEs after the assessments were completed. The CMS assessments covered PDEs that occurred from January 1, 2010, through December 31, 2017.

[29] The unrounded amounts were $38,326,052 and $11,022,935, respectively.

Specifically, these authorization processes did not always require verification of the diagnosis or followup to confirm that the beneficiaries had a cancer diagnosis. In addition, during its assessments, CMS determined PDEs to be allowable for beneficiaries who did not have a cancer diagnosis because CMS relied on plan sponsors' prior authorization documentation.

## MEDICARE PART D REQUIREMENTS

Medicare Part D covered drugs are available only by prescription, approved by FDA (or is a drug described under sections 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act) (the Act § 1860D-2(e)). For TIRF drugs to qualify for Medicare Part D reimbursement, they must be for a medically accepted indication, i.e., the management of breakthrough pain in cancer patients.

Plan sponsors are responsible for ensuring that covered Part D drugs are dispensed for medically accepted indications by using the tools and data available to them to make such determinations (CMS's *Prescription Drug Benefit Manual,* chapter 6, § 10.6). In addition, plan sponsors should consistently use prior authorization for those drugs with the highest likelihood of non-Part D covered uses because of the high likelihood of use for nonmedically accepted indications (CMS's *Prescription Drug Benefit Manual,* chapter 6, § 30.2.2.3). Plan sponsors use standard prior authorization forms to facilitate the collection of information during the prior authorization process.[30] When a plan sponsor determines that a drug was dispensed for a nonmedically accepted indication during a retrospective review of claims data, the PDE should be deleted (CMS's *Prescription Drug Benefit Manual,* chapter 6, § 10.6.1).

## PLAN SPONSORS DID NOT ENSURE THAT ALL TIRF DRUGS WERE DISPENSED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Plan sponsors approved TIRF drugs for beneficiaries who did not have a cancer diagnosis in their Medicare claims history. Plan sponsors also approved TIRF drugs for beneficiaries whose most recent cancer diagnosis in their Medicare claims history was for services provided more than 1 year before the drugs were dispensed. For some of the beneficiaries who did not have a cancer diagnosis in their Medicare claims history, plan sponsors continued to approve TIRF drugs after the beneficiaries' PDEs had been determined to be unallowable during CMS's assessments of medically accepted indications.

[30] In explaining the prior authorization process, selected plan sponsors told us that a prescriber must indicate the diagnosis associated with the requested drug so that the plan can determine whether the drug is being used for a medically accepted indication. If the diagnosis provided does not meet the requirements for prescribing a TIRF drug, the prior authorization will be denied.

**Plan Sponsors Approved TIRF Drugs for Beneficiaries Who Did Not Have a Cancer Diagnosis in Their Medicare Claims History**

During our audit period, plan sponsors submitted 7,552 PDEs for TIRF drugs dispensed to 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history and paid $86.2 million in unallowable Medicare Part D total costs.

For all 51 judgmentally sampled beneficiaries from the group of 810 beneficiaries, plan sponsors approved TIRF drugs even though the beneficiaries did not have a cancer diagnosis in their Medicare claims history to support a medically accepted indication for the use of these drugs. The TIRF drugs were approved during the plan sponsors' prior authorization processes. For example, for 1 beneficiary, the plan sponsor submitted 40 PDEs totaling $1 million for the TIRF drug Subsys, dispensed from September 2014 through October 2017 and prescribed by a neurologist.[31] In 2014 and 2015, for the question "What is the indication or diagnosis?" on the prior authorization questionnaire, the prescriber responded, "breakthrough cancer pain." In 2016, for the question "Is the intended indication for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain?" the prescriber responded "yes." However, the plan sponsor did not have documentation to support that the beneficiary had a cancer diagnosis during that period.

In November 2017, the same prescriber submitted a prior authorization request to renew the Subsys prescription for this beneficiary. The plan sponsor denied the renewal because it was not prescribed for management of breakthrough cancer pain; this time, the prescriber noted that the beneficiary was a spinal cord paraplegic who was functional on Subsys. The PDE data did not include any additional PDEs for this beneficiary after this period.

For 28 of the 51 judgmentally selected beneficiaries, medical records from nonprescribing providers confirmed that the beneficiaries were not actively being treated for cancer when the TIRF drugs were dispensed. For example, for 1 beneficiary, the plan sponsor submitted 78 PDEs totaling $1.1 million for the TIRF drug Fentora, dispensed from March 2014 through December 2019 and prescribed by a pain management physician.[32] The prescriber's response differed in questionnaires completed for multiple prior authorization requests submitted to the plan sponsor for that beneficiary. Specifically, for the question "What diagnosis are you treating with this prescription?" some requests indicated "malignant pain," some requests indicated "breakthrough cancer pain," and one request indicated "history of breast cancer." However, the beneficiary did not have a cancer diagnosis in the Medicare claims history.

[31] This example includes PDEs and costs outside our audit period to provide a complete picture of the events that occurred. During our audit period, the plan sponsor submitted 27 PDEs totaling $800,486 from July 2015 through October 2017 for the beneficiary.

[32] This example includes PDEs and costs outside our audit period to provide a complete picture of the events that occurred. During our audit period, the plan sponsor submitted 61 PDEs totaling $948,636 from July 2015 through December 2019 for the beneficiary.

In addition, medical records we obtained from nonprescribing providers confirmed that this beneficiary was not being actively treated for cancer during the period that the beneficiary was prescribed Fentora. The medical records showed that the beneficiary was under the care of pain management physicians for persistent and increasing back pain following a lumbar fusion 20 years earlier, and one nonprescribing provider diagnosed the beneficiary with "narcotic abuse for over 10 years." According to the notes in the medical records, the nonprescribing provider spoke at length with the beneficiary about narcotic use and abuse and recommended that the beneficiary "call [the beneficiary's] pain management physician and wean off narcotics." The nonprescribing provider noted that when the beneficiary was completely weaned off narcotics, the beneficiary could come back to discuss surgical options.

**Plan Sponsors Approved TIRF Drugs for Beneficiaries Whose Most Recent Cancer Diagnosis in Their Medicare Claims History Was More Than 1 Year Before the Drugs Were Dispensed**

During our audit period, plan sponsors submitted 38,224 PDEs for TIRF drugs dispensed to 4,265 beneficiaries who had a cancer diagnosis in their Medicare claims history. Of the 38,224 PDEs, 2,023 were for TIRF drugs dispensed to 176 beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed. Although we did not determine the PDEs to be unallowable—because the beneficiaries had a cancer diagnosis in their Medicare claims history before TIRF drugs were dispensed—these PDEs totaling $19.7 million were at a high risk of being unallowable.

For example, for 1 beneficiary, plan sponsors submitted 40 PDEs totaling $1.1 million for the TIRF drug Fentora, dispensed from January 2017 through December 2019, even though the most recent Medicare claim with a cancer diagnosis was for services provided almost 10 years before the beneficiary began receiving TIRF drugs. The beneficiary's Medicare claims history showed a diagnosis of unspecified malignant neoplasm of breast (female) included on claims from August 2006 through January 2007. No additional cancer diagnosis appeared in the beneficiary's Medicare claims history. Therefore, the 40 PDEs totaling $1.1 million were at a high risk of being unallowable.

We are setting aside the 2,023 PDEs totaling $19.7 million for CMS to work with its plan sponsors to identify and delete any unallowable PDEs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government.

## Quality of Care Concerns Related to TIRF Drugs

When TIRF drugs are dispensed to beneficiaries who do not have a medically accepted indication, it can lead to misuse of the drugs, which can impact the health and safety of the beneficiaries. During our audit period, 446 beneficiaries who did not have a cancer diagnosis to support the use of TIRF drugs had at least 1 Medicare claim indicating an opioid overdose or opioid misuse during the time they were receiving TIRF drugs.

In addition, during our audit period, 395 beneficiaries who received TIRF drugs without a cancer diagnosis received extreme amounts of opioids—i.e., an average daily morphine equivalent dose (MED) greater than 240 milligrams (mg) for 12 months during a year.[*] For example, three beneficiaries received an average daily MED of greater than 1,000 mg every year from 2015 through 2019. Seventeen physicians prescribed TIRF drugs to at least five beneficiaries who received extreme amounts of opioids in multiple years. (See Appendix B for additional prescriber-related information.)

[*] MED, which is also known as morphine milligram equivalent, is a measure that converts all strengths for the various opioids into one standard value. The Centers for Disease Control and Prevention (CDC) recommends that clinicians avoid prescribing, or carefully justify an increase of dosage of, a daily MED of more than 90 mg. (CDC, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.* Available online at https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf. Accessed on Sept. 12, 2022.) We defined beneficiaries who received extreme amounts of opioids as those that received more than two and a half times 90 mg, or more than 240 mg per day.

### Plan Sponsors Approved TIRF Drugs for Beneficiaries Whose Prescription Drug Events Had Been Previously Determined To Be Unallowable During CMS's Assessments of Medically Accepted Indications

CMS's assessments of medically accepted indications for TIRF drugs included 479 of the 810 beneficiaries who we determined did not have a cancer diagnosis in their Medicare claims history to support the use of these drugs. CMS determined that PDEs for 70 of the 479 beneficiaries were unallowable and instructed plan sponsors to delete them. However, after the CMS assessments, plan sponsors still submitted 889 unallowable PDEs totaling $7.7 million for TIRF drugs dispensed to 65 of those beneficiaries.

CMS identified beneficiaries as not having a medically accepted indication for TIRF drugs during its assessments, which indicated that the beneficiaries' future PDEs were at a higher risk of being noncompliant with Medicare requirements. Plan sponsors did not always use information from the CMS assessments when determining whether subsequent TIRF drugs should be approved or whether plan sponsor staff were obtaining sufficient information during the prior authorization process.

For example, for one beneficiary, whose PDEs were determined to be unallowable when CMS conducted its initial assessment, the plan sponsor continued to approve PDEs for TIRF drugs.[33] Specifically, the plan sponsor submitted 89 PDEs totaling $350,000 for TIRF drugs dispensed from June 2013 through December 2015. Plan sponsor prior authorization documentation showed the diagnosis as "management of breakthrough cancer pain." However, the plan sponsor did not have documentation to support that the beneficiary had cancer. In addition, documentation from two hospitals where the beneficiary was seen during this period confirmed that the beneficiary was not actively being treated for cancer.

## CMS ASSESSMENTS DID NOT ENSURE THAT ALL TIRF DRUGS WERE DISPENSED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

During its assessments of medically accepted indications for TIRF drugs for 409 beneficiaries, CMS allowed PDEs for 333 beneficiaries who did not have a cancer diagnosis in their Medicare claims history to support the use of these drugs and was inconsistent in its determinations of whether 76 beneficiaries had medically accepted indications.

### CMS Allowed Prescription Drug Events for Beneficiaries Who Did Not Have a Cancer Diagnosis in Their Medicare Claims History

During its assessments, CMS allowed PDEs for TIRF drugs for 333 of the 810 beneficiaries who we determined did not have a cancer diagnosis in their Medicare claims history to support the use of these drugs. The 333 beneficiaries were associated with 3,232 PDEs and $38.3 million of the $86.2 million in unallowable Medicare Part D total costs that we identified. Our review of medical records from nonprescribing providers for 12 of these beneficiaries confirmed that the beneficiaries were not being treated for cancer at the time they received TIRF drugs.[34]

For example, for 1 beneficiary, the plan sponsor submitted 19 PDEs totaling $297,000 for the TIRF drug Subsys, dispensed from December 2013 through December 2015.[35] For the question "Please provide diagnosis" on the prior authorization questionnaire, the prescriber gave different responses to this question on prior authorization requests for this beneficiary, but the plan sponsor approved all of the requests. The response from 2013 indicated "diagnosis of chronic pain syndrome and dysphagia," and the responses from 2014 and 2015 indicated

[33] This example includes PDEs and costs outside our audit period to provide a complete picture of the events that occurred. During our audit period, the plan sponsor submitted 33 PDEs totaling $200,646 from July through December 2015.

[34] These 12 beneficiaries were part of the group of 28 beneficiaries whose medical records we reviewed from nonprescribing providers. The remaining 16 beneficiaries: (1) were not included in CMS's assessments or (2) were included in CMS's assessments, and CMS determined the beneficiaries' PDEs to be unallowable or was inconsistent in its determinations.

[35] This example includes PDEs and costs outside our audit period to provide a complete picture of the events that occurred. During our audit period, the plan sponsor submitted 6 PDEs totaling $142,414 from July through December 2015.

"malignant neoplasm vagina and malignant neoplasm endocervix." Because the diagnosis from 2013 was not for a medically accepted indication for TIRF drugs, the prior authorization request should not have been approved. In addition, the beneficiary did not have a cancer diagnosis in the Medicare claims history. A hospital where the beneficiary was seen during this period stated that there were no records with a diagnosis of cancer from November 2011 through May 2021.

Of the 19 PDEs for this beneficiary, 6 PDEs were included in one of CMS's assessments of medically accepted indications for TIRF drugs. CMS determined that the six PDEs, which occurred from July through December 2015, were allowable based on plan sponsor documentation of a medically accepted indication (e.g., a statement by the prescribing physician) even though the Medicare claims did not indicate a diagnosis of cancer.

### CMS Was Inconsistent in Its Determinations of Whether Beneficiaries Had Medically Accepted Indications for TIRF Drugs

During its assessments, CMS was inconsistent in its determinations of whether beneficiaries had medically accepted indications for TIRF drugs. For 76 beneficiaries who did not have a cancer diagnosis in their Medicare claims history, CMS determined PDEs for the same beneficiary to be:

- allowable in some assessments and unallowable in other assessments,
- allowable for one plan sponsor and unallowable for another plan sponsor during the same assessment, or
- allowable for one TIRF drug and unallowable for a different TIRF drug for one plan sponsor during the same assessment.

The 76 beneficiaries were associated with 843 PDEs and $11 million of the $86.2 million in unallowable Medicare Part D total costs. The following example describes a beneficiary for whom CMS determined the PDEs to be allowable in one assessment and unallowable in another assessment but for whom we determined PDEs to be unallowable because the beneficiary did not have a cancer diagnosis in the Medicare claims history.[36]

In December 2013, a plan sponsor denied a Medicare prescription TIRF drug coverage request for a beneficiary who was prescribed the drug by an anesthesiology physician for abdominal pain management, not for breakthrough cancer pain. The beneficiary requested that the plan sponsor reconsider its decision, explaining that they had been taking fentanyl for over 8 years and that the only change was decreasing the strength from 1,200 to 800 micrograms. The plan sponsor denied the request in January 2014; however, based on the PDE data, the plan sponsor

[36] This example includes PDEs outside our audit period to provide a complete picture of the events that occurred. During our audit period, a plan sponsor submitted 37 PDEs totaling $1,164,434 from July 2015 through July 2018.

continued to submit PDEs from February through June 2014. In late 2014, another plan sponsor approved the beneficiary's prescription for 800 micrograms of Subsys through the end of 2015. According to the prior authorization documentation, a physical medicine and rehabilitation physician prescribed the beneficiary Subsys for "breakthrough cancer pain." In 2018, the plan sponsor again approved Subsys for the beneficiary, noting that the prescribing physician stated over the phone that the beneficiary had a "diagnosis of breast cancer" and that the drug was for "breakthrough pain for the diagnosis."

During its first assessment, CMS determined that 47 PDEs dispensed from January 2010 through May 2013 were unallowable because the beneficiary did not have a medically accepted indication in the Medicare claims history. During its second assessment, CMS determined that 21 PDEs for TIRF drugs dispensed from July 2013 through June 2015 were allowable based on plan sponsor documentation of a medically accepted indication even though the Medicare claims did not indicate a diagnosis of cancer. In addition, medical records from nonprescribing providers confirmed that the beneficiary was not actively being treated for cancer while receiving TIRF drugs. According to PDE records for the beneficiary, TIRF drugs continued to be dispensed through July 2018.

## PLAN SPONSORS' PRIOR AUTHORIZATION PROCESSES WERE NOT ADEQUATE

Plan sponsors approved TIRF drugs for beneficiaries who did not have a cancer diagnosis because the plan sponsors' prior authorization processes did not require verification of a cancer diagnosis or followup to confirm that the beneficiaries actively had the cancer diagnosis that was reported. Specifically, when a prescriber requested a coverage determination or redetermination for a TIRF drug from a plan sponsor, the prescriber submitted a completed written questionnaire to the plan sponsor or gave responses to the questionnaire over the phone. The questionnaire included questions such as "What diagnosis are you treating with this prescription?" or "Will the [drug] be used to manage breakthrough pain due to a current cancer condition or cancer related complication?" However, for the prior authorizations we reviewed for the 51 judgmentally sampled beneficiaries, plan sponsor staff did not obtain additional or clarifying information when the questions were not answered in enough detail to determine whether beneficiaries were actively being treated for cancer.

For the 51 judgmentally sampled beneficiaries, plan sponsors approved TIRF drugs for:[37]

- 45 beneficiaries based solely on questions answered by prescribers or prescribers' offices on the prior authorization questionnaires,

- 5 beneficiaries based on prior authorization questionnaires and prescribers' medical records that did not support a cancer diagnosis for the beneficiaries, and

[37] The number of beneficiaries totals more than 51 because 2 beneficiaries had PDEs approved by more than 1 plan sponsor.

- 3 beneficiaries without any documentation of a medically accepted indication (according to the plan sponsors).

Although plan sponsors used data mining techniques to identify patterns and utilization outliers (e.g., the number of prescribers, pharmacies, and claims associated with a beneficiary) that indicated fraud, waste, or abuse related to PDEs for TIRF drugs, plan sponsors were not able to use data mining to confirm a beneficiary's medically accepted indication specified by a prescriber because they did not have access to all Medicare claims data.[38] Furthermore, PDE records do not contain diagnosis codes. If diagnosis codes had been a required element of the PDE records, plan sponsor staff could have used the prior authorization process to obtain additional information (e.g., medical records) from the prescribing physician to confirm that TIRF drugs were prescribed for a medically accepted indication.[39, 40]

Plan sponsors continued to use the same prior authorization process for beneficiaries who were identified as not having a medically accepted indication during the CMS assessments, which indicated that the beneficiaries' future PDEs were at a higher risk of being noncompliant with Medicare requirements. If plan sponsors had used known beneficiary information identified during the CMS assessments, plan sponsors could have prevented additional TIRF drugs from being dispensed to beneficiaries who did not have a cancer diagnosis.

In addition, during its assessments, CMS determined PDEs to be allowable for beneficiaries who did not have a cancer diagnosis because CMS relied on plan sponsor documentation.

[38] Beginning in plan year 2020, a plan sponsor may submit a request to CMS for claims data under Medicare Part A and Part B for items and services furnished to beneficiaries who are enrolled in a plan offered by the plan sponsor; however, the plan sponsor may not use the data to inform coverage determinations or conduct retroactive reviews of medically accepted indications (42 CFR § 423.153(g)). CMS commented that the criteria limitation "does not preclude the [plan] sponsor from reassessing prior determinations for future approvals."

[39] Prior OIG reports recommended adding diagnosis codes to PDE records as an expansion of the required data elements to help drug plan sponsors and CMS ensure that a drug meets the definition of a Medicare Part D covered drug (*Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), issued May 2011, and *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), issued November 2022).

[40] In an online article in *STAT,* OIG officials stated that, from March to July 2020, there was a dramatic increase in the number of prescriptions written for hydroxychloroquine; however, because neither prescriptions nor Medicare claims include diagnosis codes, the reason for the spike in prescribing was difficult to determine. Hydroxychloroquine is approved for use by the FDA for malaria, lupus, and rheumatoid arthritis and was temporarily granted emergency use authorization to treat COVID-19 from March through June 2020, when the use was revoked based on new data. (Christi A. Grimm and Julie K. Taitsman, "Why drug prescriptions should include diagnoses," *STAT,* Mar. 1, 2021. Accessed at https://www.statnews.com/2021/03/01/why-drug-prescriptions-should-include-diagnoses/ on June 27, 2022.)

## RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services work with its plan sponsors to:

- delete the PDEs related to the $86,247,325 of unallowable Medicare Part D total costs and determine after reconciliation the impact to the Federal Government;

- identify and delete any unallowable PDEs related to the $19,704,602 of Medicare Part D total costs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government;

- ensure that plan sponsors obtain sufficient information during the prior authorization process so that TIRF drugs are dispensed only to beneficiaries with a medically accepted indication of breakthrough cancer pain;

- expand the required PDE data elements to include diagnosis codes to enable plan sponsors to confirm that TIRF drugs are prescribed for a medically accepted indication; and

- conduct data analysis and follow up on information that is inconsistent between the Medicare claims data and prior authorization information obtained for TIRF drug prescriptions.

## CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS did not concur with our first four recommendations. CMS did not explicitly state that it concurred or did not concur with our fifth recommendation but stated that it will continue conducting data analyses to identify potentially improper PDEs for TIRF drugs. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix C.

After reviewing CMS's comments and for the reasons detailed below, we maintain that our recommendations are valid. A summary of CMS's comments and our responses follow.

### RECOMMENDATIONS 1 AND 2: DELETE UNALLOWABLE PRESCRIPTION DRUG EVENT RECORDS

#### CMS Comments

CMS stated that it did not concur with our first and second recommendations because our determination of the amount of unallowable costs was not based on the applicable statute, regulations, or guidance. CMS stated that we did not determine whether prior authorizations

had been obtained from prescribing providers confirming that a medication was for a medically accepted indication, nor what clinical information was provided by prescribers via the prior authorization process. CMS also stated that it disagrees with the position that every Medicare Part D claim without a corresponding cancer diagnosis, or a recent cancer diagnosis, demonstrates that a TIRF drug was used for a nonmedically accepted indication. CMS stated that, although it disagrees with our methodology, it continues to take misuse of TIRF drugs seriously and is therefore undertaking an additional TIRF audit using a methodology aligned with legal requirements for plan sponsors.

**Office of Inspector General Response**

Our audit methodology was based on the medically accepted indication requirements as defined in section 1860D-2(e) of the Act. We maintain that it is not reasonable for a beneficiary to be prescribed TIRF drugs for breakthrough cancer pain without having had a cancer diagnosis in the Medicare claims data. As part of our review of the judgmental sample, we reviewed prior authorizations to determine why TIRF drugs were approved for beneficiaries who did not have a cancer diagnosis. Those prior authorizations showed that when physicians did not answer questions in sufficient detail to determine whether beneficiaries were actively being treated for cancer, plan sponsor staff did not obtain additional or clarifying information. For beneficiaries for which plan sponsor documentation showed that the prescribing physician indicated a specific cancer diagnosis, we also reviewed medical records from providers who did not prescribe the TIRF drugs to confirm that the beneficiaries did not have a cancer diagnosis. The results of our judgmental sample confirmed that the Medicare claims data were reliable and that beneficiaries were not actively being treated for cancer when the TIRF drugs were dispensed. We appreciate that CMS will undertake an additional TIRF audit because when TIRF drugs are dispensed to beneficiaries without a medically accepted indication, it can lead to misuse, which can impact the health and safety of the beneficiaries.

**RECOMMENDATION 3: ENSURE THAT PLAN SPONSORS OBTAIN SUFFICIENT INFORMATION DURING THE PRIOR AUTHORIZATION PROCESS**

**CMS Comments**

CMS stated that it did not concur with our recommendation because the recommendation would be too prescriptive as to how the prescriber should satisfy the prior authorization requirement, which could interfere with the prescriber's ability to make a determination of medical necessity for the beneficiary. CMS stated that it does not mandate the processes that Medicare Part D sponsors utilize to ascertain that TIRF drugs are covered only for medically accepted indications.

**Office of Inspector General Response**

We acknowledge that CMS does not want to be too prescriptive as to how the prescriber should satisfy the prior authorization requirement. However, although none of the

beneficiaries had a cancer diagnosis in their Medicare claims history, prescribers indicated that the beneficiaries had a cancer diagnosis in prior authorization information they submitted to the plan sponsors. Therefore, we maintain that there is a need for plan sponsors to obtain followup information when there are inconsistencies between the Medicare claims data and prior authorization information.

## RECOMMENDATION 4: EXPAND THE REQUIRED PRESCRIPTION DRUG EVENT DATA ELEMENTS TO INCLUDE DIAGNOSIS CODES

### CMS Comments

CMS did not concur with our recommendation and asked that we remove it. CMS stated that to require a diagnosis code on a PDE, CMS would need to require diagnosis codes on prescriptions and that it lacks statutory authority for this requirement and that State laws govern what is required to be included on prescriptions. Additionally, CMS stated that even if it had this authority, it would be concerned that requiring diagnosis codes on Medicare Part D claims in the absence of State requirements for prescribers to include diagnosis codes on prescriptions could lead to significant access concerns due to potential delays in receiving medications related to rejected claims. CMS stated that this would also lead to more prescriber, pharmacy, Part D sponsor, and PBM burden to adjudicate CMS-rejected claims because they lack diagnosis codes.

### Office of Inspector General Response

We understand CMS's concern that CMS does not have statutory authority over issues generally governed by State laws. However, because CMS instructs providers on what they must document to ensure that services are covered by Medicare and to receive payment, CMS could require that Medicare Part D claims include diagnosis codes to be covered by Medicare and receive payment. If CMS were to implement such a requirement, stakeholders in the medical and pharmaceutical professions would identify and implement ways to include diagnosis codes to enable CMS to determine that prescriptions for drugs are covered by Medicare before payment. We continue to urge CMS to expand the required data elements on Part D claims to include diagnosis codes, seeking statutory authority as needed.

We appreciate the importance of maintaining Part D beneficiaries' timely access to needed drugs and ask CMS to take steps to protect access and minimize the burden associated with a requirement to include diagnosis codes on Medicare Part D claims. Without diagnosis codes on Part D claims, CMS and its plan sponsors must rely on prior authorization information to determine whether TIRF drugs are prescribed for a medically accepted indication. However, during our audit, we found that the prior authorization information was not reliable for determining whether beneficiaries had a medically accepted indication. Therefore, a diagnosis code is a critical data element for monitoring the use of TIRF drugs. We understand that this would be a long-term investment that would benefit from a multistep implementation plan. CMS could consider partnering with other entities conducting work in this area (e.g., the

National Council for Prescription Drug Programs (NCPDP), which recently awarded a grant to the University of Arizona, Department of Pharmacy Practice and Science, to demonstrate the impact of including diagnostic information).[41]

**RECOMMENDATION 5: CONDUCT DATA ANALYSIS**

**CMS Comments**

CMS stated that in previous iterations of its TIRF audit, CMS had already conducted data analyses that reviewed Medicare claims data to help identify potentially improper PDE records associated with TIRF drugs that may have been prescribed without a medically accepted indication. CMS also stated that an overpayment was identified for the TIRF drugs that did not have a corresponding prior authorization request that met Medicare payment requirements. CMS stated that it will continue data analyses in upcoming iterations of its TIRF audit.

**Office of Inspector General Response**

We acknowledge that CMS has conducted data analyses to help identify potentially improper PDEs associated with TIRF drugs and that CMS identified an overpayment for the TIRF drugs that did not have a corresponding prior authorization request that met Medicare payment requirements. As stated above, based on our judgmental sample, prior authorization alone was not sufficient to confirm that beneficiaries had a medically accepted indication for the use of TIRF drugs.

[41] NCPDP Foundation, "NCPDP Foundation Awards Grant to University of Arizona R. Ken Coit College of Pharmacy to Identify Barriers to Using Indication/Diagnosis Fields in NCPDP Standards." Available online at https://ncpdpfoundation.org/pdf/Foundation-PR-UA-Grant-062722.pdf. Accessed on Feb. 16, 2023.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 45,776 PDEs submitted by plan sponsors for TIRF drugs dispensed to 5,034 beneficiaries from July 1, 2015, through December 31, 2019, for which the Medicare Part D total cost was $513,937,686.

We identified 7 plan sponsors that had high Medicare Part D total costs for TIRF drugs during our audit period for beneficiaries who did not have a cancer diagnosis in their Medicare claims history, and we reviewed plan sponsor documentation for 51 judgmentally sampled beneficiaries.

We obtained an understanding of CMS's oversight activities related to TIRF drugs and the plan sponsors. We also obtained an understanding of plan sponsors' internal controls and monitoring activities related to dispensing TIRF drugs.

We conducted our audit from June 2020 to October 2022.

### METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws and regulations and CMS guidance;
- obtained PDE records for the TIRF drugs with dates of service during our audit period;
- obtained neoplasm (i.e., cancer) diagnosis information from Medicare fee-for-service and managed-care claims from January 1, 2006, through December 31, 2019, for all 5,034 beneficiaries with a TIRF drug PDE record during our audit period;
- analyzed the PDE records and determined the extent to which plan sponsors covered TIRF drugs for beneficiaries who did not have a cancer diagnosis;
- analyzed Medicare claims data for beneficiaries receiving TIRF drugs without a cancer diagnosis to identify indications of opioid overdose, misuse, or death;
- analyzed CMS assessments to identify beneficiaries with PDEs that CMS determined during its assessments to be unallowable and determined whether those beneficiaries continued to receive TIRF drugs during our audit period;

- held discussions with CMS officials to gain an understanding of CMS's and plan sponsors' responsibilities for ensuring that TIRF drugs were dispensed in accordance with Medicare requirements;

- judgmentally selected 7 plan sponsors that had high Medicare Part D total costs for TIRF drugs during our audit period for beneficiaries who did not have a cancer diagnosis in their Medicare claims history;

- obtained and reviewed information from the 7 selected plan sponsors to gain an understanding of their processes for reviewing prior authorizations, submitting and deleting PDEs, and ensuring that drugs are dispensed in accordance with Medicare requirements;

- judgmentally sampled 51 beneficiaries with PDEs totaling at least $50,000 in unallowable Medicare Part D total costs from the 7 selected plan sponsors and reviewed plan sponsor documentation to determine why TIRF drugs were approved for the beneficiaries who did not have a cancer diagnosis in their Medicare claims history;

- reviewed medical records from nonprescribing providers for 28 of the 51 judgmentally sampled beneficiaries to determine whether the medical records included a cancer diagnosis;[42] 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.

[42] See footnote 24 for an explanation of why we reviewed medical records for only 28 of the 51 judgmentally sampled beneficiaries.

## APPENDIX B: PRESCRIBER-RELATED INFORMATION

### Top States by Prescriber and Top Prescriber Specialties for TIRF Drugs

TIRF drugs prescribed to beneficiaries who did not have a medically accepted indication were prescribed by 552 different prescribers nationwide. Prescribers in California accounted for 22 percent of the 552 prescribers, followed by Florida at 16 percent. Prescribers in New York accounted for 8 percent, closely followed by New Jersey at 7 percent and Texas at 6 percent.

More than half of the unallowable TIRF drugs were prescribed by physicians in three specialties: physical medicine and rehabilitation (20 percent), pain medicine (19 percent), and anesthesiology (17 percent). Figure 2 shows the percentages of unallowable Medicare Part D total costs by prescriber specialty.

**Figure 2:**
**Percentages of Unallowable Medicare Part D Total Costs by Prescriber Specialty**


### Drug Manufacturer Payments to Prescribing Physicians

Each year, drug and medical device companies track payments or other transfers of value they make to health care providers and teaching hospitals and submit the data to CMS. The types of payments include grants and charitable contributions as well as payments for entertainment, food and beverages, research, and travel and lodging. From January 2013 through December 2019, TIRF drug manufacturers paid an estimated $15.9 million to 1,186 providers who prescribed TIRF drugs to Medicare beneficiaries who did not have a cancer diagnosis. Such payments may provide an incentive to physicians to prescribe TIRF drugs for off-label uses.

OIG issued a Special Fraud Alert in November 2020, which highlighted the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration related to speaker programs by pharmaceutical and medical device companies.[43] From 2017 through 2019, drug and medical device companies reported paying nearly $2 billion to health care professionals for speaker-related services.

[43] *Special Fraud Alert: Speaker Programs,* Nov. 16, 2020. Available online at https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf. A speaker program is generally defined as a company-sponsored event at which a physician or other health care professional makes a speech or presentation to other health care professionals about a drug or device product or a disease state on behalf of the company.

## APPENDIX C: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*
Washington, DC 20201

**DATE:** December 7, 2022

**TO:** Amy Frontz
Deputy Inspector General for Audit Services

**FROM:** Chiquita Brooks-LaSure
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *Medicare Part D Plan Sponsors and CMS Did Not Ensure That Transmucosal Immediate-Release Fentanyl Drugs Were Dispensed Only to Beneficiaries Who Had a Cancer Diagnosis,* A-09-20-03033

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to ensuring that Medicare beneficiaries receive medically necessary transmucosal immediate-release fentanyl (TIRF) drugs in accordance with Medicare requirements, while taking appropriate action to reduce the risk to those without a medical need for these drugs.

TIRF drugs are potent, fast-acting opioids that are Food and Drug Administration (FDA)-approved only for the treatment of breakthrough cancer pain. While these drugs pose a risk to those for whom they are not medically necessary, they play an important role in the treatment of breakthrough cancer pain—in other words, for beneficiaries whose cancer pain is not adequately controlled by other opioids. Therefore, while CMS has several procedures in place to reduce improper use of these drugs, we are also cognizant of the importance of ensuring access for those for whom TIRF drugs are medically necessary.

Beginning in 2015, CMS instructed plan sponsors to implement point-of-sale edits for prior authorization of certain drugs at risk for improper use, specifically citing TIRF drugs.[1] An enrollee, or a physician or other prescriber, may seek prior authorization for a TIRF drug through the coverage determination and appeals process described at 42 CFR Part 423, Subpart M. The statute provides that enrollees and prescribers have the right to request that a Part D plan sponsor expedite a request for prior authorization (24 hours or less instead of the standard 72 hours) and requires plans to accept verbal requests for expedited and standard coverage determinations and expedited redeterminations. Due to the nature of TIRF drugs, these requests are likely subject to the expedited timeframes. The statute also requires that in the case of a request for an expedited determination or redetermination, the plan must expedite the request if the prescriber indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. Plans may ask the prescriber for supporting medical documentation when adjudicating a coverage determination or appeal, but are permitted to rely on the verbal statement of the prescriber. CMS regulations require Part D plan sponsors to establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the

[1] https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf, 42 CFR 423.153(b)(2), and Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual.

documentation in the case file. If the plan denies the prior authorization request, the enrollee has the right to appeal.

To further ensure that CMS only pays for TIRF drugs that are for a medically accepted indication, CMS has conducted four rounds of audits of Part D plans' payments for TIRF drugs, examining prior authorization records to ensure that dispensed TIRF drugs had a corresponding prior authorization request that met Medicare payment requirements. CMS audits of TIRF drugs dispensed from January 1, 2010 through June 30, 2015 resulted in the recovery of $117 million in improper payments. CMS completed subsequent audits of TIRF drugs dispensed through December 31, 2017, which resulted in an additional $13 million in improper payment recoveries. As a part of these audits, in 2020, CMS issued a memo to plan sponsors regarding the dispensing of TIRF drugs without a medically accepted indication, in addition to sharing recommendations and best practices. CMS plans to conduct a fifth round of the TIRF audits beginning in late 2022 to early 2023.

Lastly, the actions taken by CMS are in addition to safeguards already in place via requirements of the FDA's TIRF Risk Evaluation Mitigation Strategy (REMS) Program. This program requires the enrollment and certification of prescribers and dispensing pharmacies. The FDA states that the purpose of the REMS is to mitigate the misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of TIRF medicines. In 2020, the REMS was further strengthened, requiring that prescribers document opioid tolerance with every TIRF prescription, and pharmacies must assess for a change in patients' opioid tolerance with every dispensing of a TIRF medicine.[2]

OIG's recommendations and CMS' responses are below.

**OIG Recommendation**

CMS should work with its plan sponsors to delete the PDEs related to the $86,247,325 of unallowable Medicare Part D total costs and determine after reconciliation the impact to the Federal Government.

**CMS Response**

CMS does not concur with this recommendation because the determination of the amount of unallowable costs was not based on the applicable statute, regulations, or guidance. A drug is coverable under Part D when used for a medically accepted indication, as defined in 1860D-2(e)(4) of the Act. Due to the potential of TIRF drugs being prescribed for a non-medically accepted indication use, CMS reviews formularies to ensure that all Part D plan sponsors have prior authorizations in place to mitigate this risk.[3] This requires only that the plans obtain prior authorizations from the prescribing provider confirming that the medication is for a medically accepted indication. OIG did not determine whether such prior authorization had been obtained, nor what clinical information was provided by the prescriber via the prior authorization process. Instead, OIG deemed a TIRF prescription unallowable if the beneficiary's Medicare medical claims data did not indicate prior treatment for cancer. CMS disagrees with the position that every Part D claim without a corresponding cancer diagnosis is being used for a non-medically accepted indication. While CMS disagrees with the OIG's methodology, CMS continues to take misuse of TIRF drugs seriously and is therefore undertaking an additional TIRF audit using methodology aligned with legal requirements for plans.

---

[2] https://www.fda.gov/drugs/information-drug-class/transmucosal-immediate-release-fentanyl-tirf-medicines

[3] Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual

**OIG Recommendation**

CMS should work with its plan sponsors to identify and delete any unallowable PDEs related to the $19,704,602 of Medicare Part D total costs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government.

**CMS Response**

CMS does not concur with this recommendation because the determination of the amount of unallowable costs was not based on the applicable statute, regulations, or guidance. A drug is coverable under Part D when used for a medically accepted indication, as defined in 1860D-2(e)(4) of the Act. Due to the potential of TIRF drugs being prescribed for a non-medically accepted indication, CMS reviews formularies to ensure that all Part D plan sponsors have prior authorizations in place to mitigate this risk.[4] This requires only that the plans obtain prior authorizations from the prescribing provider confirming that the medication is for a medically accepted indication. OIG did not determine whether such prior authorization had been obtained, nor what clinical information was provided by the prescriber via the prior authorization process. Instead, OIG deemed a TIRF prescription unallowable if the beneficiary's Medicare medical claims data did not indicate prior treatment for cancer, and flagged those with a cancer diagnosis that was more than one year before the TIRF drugs were dispensed as at high risk of being unallowable. CMS disagrees with the position that every Part D claim without a corresponding cancer diagnosis, or recent cancer diagnosis, is being used for a non-medically accepted indication. While CMS disagrees with the OIG's methodology, CMS continues to take misuse of TIRF drugs seriously and is therefore undertaking an additional TIRF audit using methodology aligned with legal requirements for plans.

**OIG Recommendation**

CMS should work with its plan sponsors to ensure that plan sponsors obtain sufficient information during the prior authorization process so that TIRF drugs are dispensed only to beneficiaries with a medically accepted indication.

**CMS Response**

CMS does not concur with this recommendation because it would be too prescriptive as to how the prescriber should satisfy the prior authorization requirement, which could interfere with the prescriber's ability to make a determination of medical necessity for the beneficiary. Current CMS policy confirms that plan sponsors have prior authorization requirements in place to ensure that TIRF drugs are only covered for medically accepted indications. While CMS reviews and approves the prior authorization criteria for TIRF drugs, we do not mandate the processes that Part D sponsors utilize to ascertain this clinical information. As stated above, plans may ask the prescriber for supporting medical documentation when adjudicating a coverage determination or appeal, but are permitted to rely on the verbal statement of the prescriber, in order to protect beneficiaries' and prescribers' right to make verbal requests for expedited and standard coverage determinations and expedited redeterminations.[5] If only written copies of medical chart notes, for example, were to be required for TIRF and other drugs, Part D beneficiaries could be harmed due to delays in medically necessary therapies.

[4] Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual

[5] 42 CFR Part 423, Subpart M

**OIG Recommendation**

CMS should work with its plan sponsors to expand the required PDE data elements to include diagnosis codes to enable plan sponsors to confirm that TIRF drugs are prescribed for a medically accepted indication.

**CMS Response**

CMS does not concur with this recommendation. In order to require a diagnosis code on a PDE, CMS would need to require a diagnosis code on prescriptions. CMS lacks the statutory authority to require that prescribers include diagnosis codes on prescriptions. State laws govern what is required to be included on prescriptions. Additionally, even if CMS had this authority, we would be concerned that requiring diagnosis codes on Part D claims in the absence of state requirements for prescribers to include diagnosis codes on prescriptions could lead to significant access concerns due to potential delays in receiving medications related to rejected claims. This would also lead to more prescriber, pharmacy, Part D sponsor, and pharmacy benefit manager burden to adjudicate CMS-rejected claims because they lack diagnosis codes. Therefore, we have requested that OIG remove this recommendation.

**OIG Recommendation**

CMS should work with its plan sponsors to conduct data analysis and follow up on information that is inconsistent between the Medicare claims data and prior authorization information obtained for TIRF drug prescriptions.

**CMS Response**

In previous iterations of the TIRF audit, CMS already conducted data analyses that reviewed Medicare claims data to help identify potentially improper PDE records associated with TIRF drugs that may have been prescribed without a medically accepted indication. For TIRF drugs that did not have a corresponding prior authorization request that met Medicare payment requirements, an overpayment was identified. CMS will continue such data analyses in upcoming iterations of the TIRF audit, as it is a standard auditing practice.

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