

## Report in Brief

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



### 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.

## 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

### 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.