DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC - 1 2016

The Honorable Edward J. Markey
United States Senate
Washington, DC 20510

Dear Senator Markey:

Thank you for your letter concerning Medicare Part D coverage of prescription fentanyl, in particular coverage of Subsys for off-label uses. The Centers for Medicare & Medicaid Services (CMS) is engaging in a variety of efforts to curb the impact of the national opioid abuse epidemic by combatting non-medical prescription opioid use, dependence, and overdose through safe and appropriate opiate utilization while promoting evidence-based practices for acute and chronic pain management. In your letter, you asked about CMS's efforts as they relate to Subsys.

The CMS has taken clear steps to address potential inappropriate reimbursement by the Part D program for Subsys. Beginning for contract year 2015, CMS instructed Part D plans to implement point-of-sale (POS) edits for prior authorization (PA) on Transmucosal Immediate Release Fentanyl (TIRF) drugs, including Subsys. The 2015 Call Letter established criteria for which CMS would expect plan sponsors to implement POS edits for PA on qualifying drugs and/or drug classes that pose the greatest risk for non-Part D covered uses. As a result of these efforts, the use of PA for Subsys has increased over time. For CY 2013, 66% of formularies with Subsys had a PA for the drug. For CY 2014, 88% of formularies with Subsys had a PA for the drug. For CY 2015, 2016, and 2017, 100% of formularies with Subsys had or have a PA requirement for the drug.

Through the PA process, Part D plans can determine in consultation with the prescriber whether the beneficiary's use of the drug is approved by the Food and Drug Administration (FDA) or supported by one or more citations in specified drug compendia. The labeled indications and compendia citations for TIRF drugs only support their use for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent pain. Plan sponsors also have the option to use the PA process to confirm that the prescribers of Subsys claims for Medicare beneficiaries meet the criteria and training requirement outlined in the FDA-approved Risk Evaluation and Mitigation Strategy.

Since Subsys entered the market in 2012, in total, Part D sponsors paid for 223 Subsys claims in 2012; 4,253 claims in 2013; 11,133 claims in 2014; and 15,497 claims in 2015. In order to identify any improper payments, CMS has included Subsys in broader program integrity projects focused on TIRF drugs, discussed in greater detail below. In addition to Subsys, the TIRF drugs include Abstral, Actiq, Fentanyl Citrate, Fentanyl Oralet, Fentora, Lazanda, and Onsolis. Similar

to Subsys, all of these drugs contain fentanyl and are only indicated for the management of breakthrough pain in adults with cancer.

The CMS requires plan sponsors to submit a prescription drug event (PDE) record for each Part D prescription that is dispensed in order to receive payment. CMS analyzed Part A and Part B data for enrollees in stand-alone prescription drug plans (PDPs) and conducted audits of Medicare Advantage prescription drug plans (MA-PDs) with PDE records indicating use of fentanyl products to identify off-label use of these drugs. In order to recover Medicare Trust Fund dollars, CMS instructed plan sponsors to delete the identified PDE records submitted to CMS for payment for TIRF drugs, including Subsys, if they could not confirm the medically-accepted indication. CMS also instructed plan sponsors to ensure that downstream and related entities have policies and procedures in place to prevent members from receiving TIRF drugs without an FDA-approved indication or compendia-supported indication.

The following is a summary of these TIRF-related program integrity projects. Deleted PDEs represent TIRF drugs dispensed without a confirmed medically-accepted indication at the point-of-sale and later reversed after further analysis by the plan.

In September 2013, CMS conducted our first assessment of medically accepted indications for TIRF drugs dispensed across PDPs from January 1, 2010 through June 30, 2013. This initial review of PDPs resulted in 22,848 deleted PDEs and $77 million dollars recovered. In July 2014, we conducted our first assessment of medically accepted indications for TIRF drugs dispensed across MA-PDs from January 1, 2010 through December 31, 2013. This initial review of MA-PDs resulted in 7,783 deleted PDEs and $21 million dollars recovered. In November 2015, we completed a subsequent review of medically accepted indications for TIRF drugs dispensed across PDPs, from July 1, 2013 through June 30, 2015. This follow-on assessment of PDPs shows a significant decrease in TIRF drugs dispensed for non-medically-accepted indications, with 2,991 deleted PDEs and $19 million dollars recovered.

In addition, CMS has expanded plan sponsor self-audit reviews to include TIRF drugs. Plan sponsors have been instructed to conduct a review of TIRF drugs submitted for Part D payment and report findings. When a dispensing event happened but the event was in error, such as when the drug is a non-Part D drug, the sponsor should recoup the claim, delete the PDE, and adjust the beneficiary's benefit-specific accumulators around covered drug costs.

The CMS does not have the authority under Medicare Part D rules to recoup payments under Part D from Insys based on its marketing tactics.

Combating non-medical prescription opioid use, opioid use disorders, and overdose continues to be a priority for CMS. We are dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically appropriate care. CMS is committed to working with Part D sponsors to make certain they are in compliance with requirements that protect beneficiaries and can prevent and address opioid overutilization. As part of these efforts, CMS has broadened its focus from ensuring that beneficiaries have access to prescribed drugs to

also ensuring that sponsors implement effective safeguards and provide coverage for medically necessary drug therapies that meet standards for safety and efficacy. Although there is still work that needs to be done, CMS is confident that our initiatives will maintain beneficiary access to appropriate medications for pain control while decreasing inappropriate opioid prescribing patterns and reducing the rate of opioid use disorders and overdoses. We look forward to continuing to work with Congress on these efforts. Thank you again for your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator