May 2019

PRESCRIPTION OPIOIDS

Voluntary Medicare Drug Management Programs to Control Misuse

GAO Highlights

Highlights of GAO-19-446, a report to congressional committees

Why GAO Did This Study

Misuse and abuse of prescription opioids can lead to overdose and death. According to the Centers for Disease Control and Prevention (CDC), 47,600 overdose deaths in the United States in 2017 involved an opioid. GAO and other federal entities have raised concerns about opioid misuse and abuse in Medicare. The Comprehensive Addiction and Recovery Act of 2016 (CARA) authorized CMS and Medicare plan sponsors to establish voluntary DMPs that may limit access to frequently abused prescription drugs, such as opioids, for Medicare beneficiaries who are identified as being at risk for prescription drug abuse. DMPs will become mandatory in Medicare starting in January 2022.

CARA included a provision for GAO to review DMPs under Medicare. This report: 1) describes how Medicare identifies beneficiaries at risk of opioid misuse and abuse and how it attempts to mitigate that risk; and 2) identifies the factors likely to affect the success of Medicare DMPs.

GAO reviewed CDC's *Guideline for Prescribing Opioids for Chronic Pain*, CMS regulations, and other relevant CMS guidance. GAO also interviewed officials from CMS, the five largest Medicare Part D prescription drug plan sponsors, and officials from six other stakeholder organizations representing Medicare plan sponsors, physicians (including pain specialists), pharmacy benefit managers, state Medicaid programs, and patients.

View GAO-19-446. For more information, contact James Cosgrove at (202) 512-7114 or CosgroveJ@gao.gov.

What GAO Found

Medicare's drug management programs (DMP) identify beneficiaries at risk of opioid misuse or abuse, and attempt to mitigate that risk through the use of case management and coverage limitations. DMPs are overseen by the Centers for Medicare & Medicaid Services (CMS) and voluntarily implemented by Medicare Part D prescription drug plan sponsors (private health plans). CMS established a two-step framework for identifying at-risk beneficiaries under DMPs. First, CMS identifies potentially at-risk beneficiaries based on key factors, such as beneficiaries' daily dosage of opioids and the number of prescribers and pharmacies from which they receive opioids, with higher numbers possibly putting the beneficiary at more risk. Second, Medicare Part D prescription drug plan sponsors' clinicians coordinate the provision of care among prescribers and pharmacists (referred to as case management) to determine if those potentially at-risk beneficiaries are actually at risk. If a patient is deemed to be at risk, coverage limitation tools—such as limiting a beneficiary to a selected prescriber or pharmacy, and implementing point-of-sale restrictions on certain drugs or amounts—can be used to limit the at-risk beneficiary's access to opioids. Beneficiaries have an opportunity to appeal an at-risk designation. None of the five plan sponsors GAO interviewed expressed concerns about beneficiaries not receiving clinically appropriate doses of opioids under the Medicare DMPs.

Medicare Part D prescription drug plan sponsors and other stakeholders GAO interviewed reported several factors beyond the case management process that could contribute to the success of DMPs. These factors included communication among sponsors, opioid prescribers, and pharmacies dispensing opioids to reduce potential resistance to participating in DMPs by opioid prescribers or beneficiaries.

- According to plan sponsors and stakeholders, plan sponsors could communicate with stakeholders to ensure that DMPs are not viewed as a punitive tool by beneficiaries, but rather as tools for keeping them safe.
- Plan sponsors and stakeholders noted that it is important for plan sponsors to have flexibility in varying coverage limitation features to fit regional and other differences in population groups. They noted that CMS should periodically reassess and adjust the elements of the DMP program where appropriate, to incorporate evidence from the outcomes of the DMP—such as how at-risk beneficiaries are identified, or which drugs are selected as frequently abused drugs.

Finally, CMS officials told GAO that they are taking steps to assess the DMPs and gather the information required to make periodic changes to the DMP program. For example, CMS officials plan to analyze data for at-risk beneficiaries that DMPs are required to report to CMS, update their Medicare Part D audit protocol, and obtain feedback from plan sponsors about how the DMPs are working.

The Department of Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.