



Highlights of [GAO-08-47](#), a report to congressional requesters

## Why GAO Did This Study

Under the Medicare Part D program, prescription drug coverage is provided through plans sponsored by private companies. Beneficiaries, their appointed representatives, or physicians can ask sponsors to cover prescriptions restricted under their plan—a process known as a coverage determination—and can appeal denials to the sponsor and the independent review entity (IRE). GAO was asked to review (1) the processes for sponsors' coverage determination decisions and the approval rates, (2) the processes for appealing coverage denials and the approval rates at the sponsor and IRE levels, and (3) the Centers for Medicare & Medicaid Services' (CMS) efforts to inform the public about sponsors' performance and oversee sponsors' processes. GAO visited seven sponsors that account for over half of Part D enrollment. GAO also interviewed and obtained data from CMS and IRE officials.

## What GAO Recommends

GAO recommends that CMS (1) reduce the need for an AOR form by requiring that sponsors and the IRE, upon receipt of standard appeal requests submitted by prescribing physicians without AOR forms, telephone beneficiaries to see if they wish to initiate the appeal, and (2) provide specific definitions for data that sponsors must report to CMS. The agency supports the intent of our first recommendation and is considering it in light of current legal requirements. CMS has taken steps to implement the second recommendation.

To view the full product, including the scope and methodology, click on [GAO-08-47](#). For more information, contact Kathleen M. King at (202) 512-7114 or [kingk@gao.gov](mailto:kingk@gao.gov).

## MEDICARE PART D

### Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could Be Improved

#### What GAO Found

Sponsors in our study address coverage requests for drugs with restrictions using processes that allow for prompt decisions, apply a range of criteria, and have resulted in approvals of most cases. To minimize the amount of time needed to make a determination, study sponsors use automated systems to compare the patient information they receive from prescribing physicians against preset coverage criteria. The coverage criteria for specific drugs incorporate Medicare requirements—such as whether the drug use is excluded from coverage under Medicare Part D—and discretionary components—such as whether a less expensive alternative drug has been tried and failed. Some study sponsors indicated they feel pressure to make decisions within the CMS-required time frames even when all pertinent patient information from physicians is not at hand. In reviewing a sample of 421 case files, GAO found that overall, study sponsors approved about 67 percent of the coverage determination requests, ranging from 57 percent to 76 percent.

The process for conducting appeals allows staff not involved in the previous case review to make better-informed decisions by considering additional supporting evidence. At the first level of appeal, sponsor staff evaluate any corrected or augmented evidence to see if coverage criteria have been met. At the second level of appeal, IRE staff consider the information the sponsor reviewed, along with any additional support that may be available. In many cases, appeals result in new interpretations of whether the requested drug should be covered. CMS appeals data show that, from July 2006 through December 2006, the median approval rate across all Part D sponsors was 40 percent; from July 2006 through June 2007, appeals to the IRE received full or partial approval in 28 percent of cases. For some standard appeals, missing appointment of representative (AOR) documentation contributed to delays in sponsor-level appeals decisions and dismissals of IRE appeals cases. Some study sponsors have developed “workarounds” to eliminate the need for the completed AOR form.

CMS has improved its efforts to inform beneficiaries about sponsors' performance, but its oversight of sponsors is hindered by poorly defined reporting requirements. CMS developed two performance metrics on sponsors' timeliness and the outcomes of their coverage decisions. The agency improved the way it displays this information on the Medicare Web site in late 2007. In addition, CMS requires that sponsors report data on various measures of coverage requests and approvals. However, the agency has provided minimal guidance on the types of cases to be included in each coverage determination measure. As a result, our study sponsors reported data differently to CMS, hindering the agency's ability to adequately monitor sponsors' activities. Finally, CMS has conducted several audits and found that sponsors were noncompliant with a number of specific requirements. Areas of sponsor noncompliance ranged from incomplete written policies and procedures to delays in authorizing drug coverage after the IRE approved an urgent request.