

January 2008

MEDICARE PART D

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



G A O

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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.

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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.

Contents

Letter		1
	Results in Brief	6
	Background	9
	Coverage Determination Processes Allow for Prompt Decisions, Apply a Range of Criteria, and Have Resulted in Approvals for the Majority of Requests	12
	Appeals Processes Allow for Better Informed Decisions, Have Often Resulted in Coverage Approvals, and Are Impeded by AOR Requirement	18
	CMS Efforts to Inform Beneficiaries about Sponsors' Performance Have Improved; Oversight Hindered by Poorly Defined Reporting Requirements	25
	Conclusions	34
	Recommendations for Executive Action	35
	Agency Comments and Our Evaluation	35
Appendix I	Steps and Time Frames for Part D Coverage Determination and Appeals	38
Appendix II	Comments from the Centers for Medicare & Medicaid Services	39
Appendix III	GAO Contact and Staff Acknowledgments	42
Tables		
	Table 1: Requests Addressed in Coverage Determinations and Appeals	11
	Table 2: CMS's Revised Metric on IRE Appeals Decisions, as of November 2007	28
	Table 3: Audit Elements Found Deficient at Four or More Sponsors in CMS's Audits of Five PDP Sponsors, as Reported in October 2007	33

Figures

Figure 1: IRE Disposition of Part D Appeals, July 2006 through June 2007	21
Figure 2: IRE Decisions by Issue Addressed in the Request, July 2006 through June 2007	22

Abbreviations

AOR	appointment of representative
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
IRE	independent review entity
MA-PD	Medicare Advantage prescription drug
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
PDP	prescription drug plan

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United States Government Accountability Office
Washington, DC 20548

January 22, 2008

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable John D. Rockefeller IV
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Subcommittee on Health Care
Committee on Finance
United States Senate

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a voluntary outpatient drug benefit, known as Medicare Part D, that provides prescription drug coverage for nearly 25 million beneficiaries—seniors and individuals with disabilities—enrolled in the program.¹ Beneficiaries may obtain the drug benefit, which began on January 1, 2006, by enrolling in plans offered by Part D sponsors—private companies, such as health insurance companies and pharmacy benefit managers.² The Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—is responsible for contracting with and overseeing the sponsors that provide the drug benefit. Among its many functions, the agency is responsible for monitoring sponsor compliance with program rules and publicly reporting information on certain aspects of sponsor performance.

The MMA and CMS's implementing regulations established specific requirements for Part D sponsors. Sponsors' formularies—lists of plan-

¹Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101—1395w-152). Part D enrollment is as of September 2007.

²Typically, pharmacy benefit managers manage prescription drug benefits for third-party payers. In Medicare, some pharmacy benefit managers have contracted directly with Medicare to offer the Part D benefit.

covered drugs—must include “all or substantially all” drugs within six designated drug categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs. For each of the other therapeutic drug categories and classes, sponsors’ formularies generally must include at least two Part D drugs.³ However, formularies generally cannot include drugs or their uses that the MMA excluded from Medicare Part D coverage.⁴ In addition, MMA promotes the use of generic drugs, which are generally cheaper than most brand-name drugs. The MMA states that a Part D sponsor must require a pharmacy to inform a beneficiary of any differential between the price of a drug and the price of its lowest-priced generic version.⁵

Beyond the minimum formulary requirements, the MMA gives sponsors discretion in designing their formularies to keep costs low. Because Part D plan sponsors share financial risk with the Medicare program, they have an incentive to control beneficiaries’ drug spending.⁶ To do so, sponsors negotiate discounted prices with drug manufacturers and design their formularies to encourage the use of cost-saving prescription drugs. As long

³This requirement does not apply when there is only one drug in the category and class or when CMS has given the sponsor approval to have fewer than two. In general, a drug category includes drugs of different types used to treat similar conditions. A drug class is a subset of drugs within a drug category that has similar properties or mechanisms of action. In some instances, there are no drug classes within a drug category.

⁴The 10 excluded categories of drugs are (1) agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of coughs or colds; (5) prescription vitamins and minerals, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) covered outpatient drugs for which the manufacturer seeks to require associated tests or monitoring be purchased from the manufacturer or their designee as a condition of sale; (8) barbiturates; (9) benzodiazepines; and (10) agents when used for the treatment of sexual or erectile dysfunction unless used to treat another condition as approved by the Food and Drug Administration (FDA)—the agency responsible for approving drugs for sale in the United States. These are the same drug categories that state Medicaid programs, which provide health care coverage to certain low-income individuals, may restrict.

⁵Although some drugs are protected by patents and are manufactured by only one company, when the patent expires, other manufacturers can produce its generic version. Currently, about half the drug sales in the United States are generics.

⁶Medicare pays sponsors a monthly amount per enrollee independent of each enrollee’s drug use, therefore creating an incentive to manage costs. Payments to prescription drug plan sponsors are adjusted according to each beneficiary’s risk factors, including diagnoses and demographic factors. However, sponsors still have an incentive to control costs so that they are less than the adjusted payment received from CMS and payments received from the beneficiary.

as they meet the minimum formulary requirements, sponsors may exclude particular drugs from their formularies. For drugs included on the formulary, sponsors may assign drugs to tiers that correspond to different levels of cost sharing. In general, they encourage the use of generic medications by putting them on a cost-sharing tier that requires the lowest out-of-pocket costs for beneficiaries and discourage the use of expensive drugs by putting them on tiers that require higher out-of-pocket spending by beneficiaries. A national survey of noninstitutionalized seniors conducted in the fall of 2006 found that 25.7 percent of beneficiaries reported switching to a cheaper medication after they enrolled in a Part D plan.⁷

Sponsors can also lower drug spending by applying various utilization management restrictions to drugs on their formularies.⁸ Utilization management restrictions typically include (a) prior authorization, which requires the beneficiary to obtain the sponsor's approval before a drug is covered for that individual; (b) quantity limits, which restrict the dosage or number of units of a drug provided within a certain period of time; and (c) step therapy, which requires that a beneficiary try lower-cost drugs before a sponsor will cover a more costly drug.

Beneficiaries who attempt to fill a prescription for a nonformulary drug or a restricted formulary drug will have coverage withheld unless the beneficiary receives special permission from the plan sponsor. In a 2006 national survey of seniors, 11.3 percent of respondents reported needing special permission to get a prescription filled.⁹ When coverage is withheld, CMS regulations require that pharmacies inform beneficiaries of their right to make a formal request to their plan for coverage—a process known as a coverage determination. Beneficiaries, their appointed representatives,¹⁰ or prescribing physicians can use the coverage determination process to

⁷P. Neuman et al., "Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors," *Health Affairs*, vol. 26, no. 5 (2007): w630-w643, www.healthaffairs.org (accessed Aug. 21, 2007).

⁸For information on how drug utilization management tools contribute to cost savings, see GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, [GAO-03-196](#) (Washington, D.C.: Jan. 10, 2003).

⁹See Neuman et al.

¹⁰Within the scope of this report, we refer to "beneficiaries or their appointed representatives" as beneficiaries.

demonstrate that the sponsor's coverage criteria have been met or that an exception to the formulary,¹¹ cost-sharing requirements, or utilization restrictions should be granted based on the medical needs of the beneficiary. Beneficiaries who receive an unfavorable coverage determination may appeal the decision, first to the sponsor—a process known as a redetermination—and then to an independent review entity (IRE)¹²—a process known as a reconsideration.¹³

As a beneficiary protection, MMA and CMS regulations require that sponsors have procedures in place to make coverage determination and appeal decisions in a timely manner. CMS established priority levels for coverage determinations and appeal requests as either standard or expedited (for requests thought to be urgent, based on the beneficiary's or physician's judgment).¹⁴ Prescribing physicians may initiate coverage determinations and expedited redeterminations on behalf of a beneficiary without permission from the beneficiary, but to initiate a standard appeal on a beneficiary's behalf, they must have a completed appointment of representative (AOR) form.¹⁵ Sponsors must make standard coverage determination decisions within 72 hours and expedited coverage determination decisions within 24 hours. Decisions at the redetermination level must be made within 7 days for a standard request and within 72 hours for an expedited request. If the sponsor fails to notify the beneficiary of its decision within the established time frames, the decision is deemed an automatic denial, at which point the sponsor must forward the case to the IRE. At the reconsideration level—the second level of appeal—the IRE has 7 days to decide a standard request and 72 hours for

¹¹A request for a Part D drug that is not on the sponsor's formulary would be considered a request for an exception to the formulary.

¹²To handle reconsiderations, CMS contracted with MAXIMUS Federal Services to serve as the IRE. MAXIMUS Federal Services also serves as the IRE for appeals for medical services in Medicare Advantage, Medicare's managed care program.

¹³Subsequent levels of appeals are a hearing before an administrative law judge, a Medicare Appeals Council review, and, finally, a federal district court review. However, these subsequent levels are outside the scope of this report.

¹⁴CMS requires a sponsor to expedite a request if it determines, or the beneficiary's prescribing physician indicates, that applying the standard time frame could seriously jeopardize the health of the beneficiary.

¹⁵The AOR documentation requirement in Part D was modeled on that used in traditional Medicare and Medicare Advantage. In applying this rule to Part D, CMS guidance states that prescribing physicians can only act on behalf of beneficiaries in requesting standard redeterminations or any type of reconsiderations if they are appointed representatives.

an expedited request. (See app. I for an illustration of the coverage determination and appeals levels and time frames.)

Questions have been raised about how coverage determination and appeals processes work to safeguard beneficiaries' access to the Part D-covered drugs they need. Little is known about how decisions are made, the outcomes of coverage requests, and how CMS oversees sponsors' coverage determination and appeals processes. You asked us to review Part D coverage determination and appeals processes at the sponsor and IRE levels. This report provides information on (1) the processes for sponsors' coverage determination decisions and the approval rates, (2) the processes for appealing coverage denials and the coverage approval rates at the sponsor and IRE levels, and (3) CMS's efforts to inform beneficiaries about sponsors' performance and to oversee sponsors' coverage determination and appeals processes.

To review the processes for sponsors' coverage determination decisions and approval rates, we conducted site visits to seven sponsors offering Part D plans in 2006, and interviewed officials about how coverage determinations are made. The seven sponsors were chosen because they varied on a number of measures, including size of enrollment and their market presence across the country. As of September 1, 2006, the seven sponsors we interviewed enrolled about 13 million beneficiaries, about 54 percent of all Part D enrollees. In addition, at each sponsor we reviewed a randomly selected sample of coverage determination case files from October 2006 to verify the information sponsor officials told us.¹⁶ In total, we reviewed 421 coverage determination case files—at least 34 from each sponsor. Information from these sponsors is illustrative and cannot be generalized to the entire sponsor community. We also reviewed relevant documents, including the MMA and Part D implementing regulations, to understand sponsor requirements. Also, we obtained the views of beneficiary advocates and physician association representatives about the Part D coverage determination process. Physician association representatives included both general and specialty practitioners.

To examine appeals processes, we interviewed management staff from the seven selected sponsors and the IRE about their policies and procedures.

¹⁶Case file documentation typically includes a log indicating when the request was initiated and when it was completed, the request form or letter, supporting evidence, and copies of the decision notice.

We reviewed randomly selected samples of October 2006 appeals case files at each sponsor and the IRE to verify information obtained from our interviews. In total, we reviewed 458 redetermination case files—at least 43 from each sponsor—and 100 reconsideration case files. To learn about coverage approval decisions at the redetermination level, we analyzed data reported by sponsors to CMS on the number of redeterminations made from July 2006 through December 2006. To assess the reliability of these sponsor-reported data, we interviewed CMS officials responsible for the collection and analysis of the data, and we reviewed the CMS data reporting requirements for redeterminations. We determined that the data were sufficiently reliable for purposes of this report. To learn about coverage approval decisions at the reconsideration level, we analyzed IRE workload data reported to CMS, including data on the results of IRE decision making. To assess the reliability of the IRE data, we conducted interviews with IRE staff to learn about how the data are compiled. We determined the data were sufficiently reliable for the purposes of this report.

To determine how CMS informs beneficiaries about sponsors' performance, we examined information posted on the Medicare Prescription Drug Plan Finder tool and discussed planned changes to the Web site with CMS officials. To determine how CMS oversees the coverage determination and appeals processes, we interviewed agency officials responsible for policy development and oversight of the Part D program. We also examined data CMS collected to monitor sponsors' activities and compared the reporting practices of our study sponsors. Finally, we reviewed CMS's compliance audit reports.

In conducting our work, we did not examine how beneficiaries are informed about their rights to request a coverage determination, or the appropriateness of sponsors' coverage criteria or coverage decisions. In addition, we did not examine the extent to which beneficiaries use the coverage determination process because the CMS data needed to do so were inadequate. Although beneficiaries may pursue appeals beyond the reconsideration level, reviewing these additional levels is beyond the scope of this report. We performed our work from July 2006 through January 2008 in accordance with generally accepted government auditing standards.

Results in Brief

The sponsors we studied 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, sponsors we visited obtain patient information needed to make their decisions using drug-specific coverage determination request forms. Information on the forms is entered into a computer for analysis of whether coverage criteria—the conditions that need to be met for the requested drug to be covered—have been met. These drug-specific coverage criteria incorporate Medicare requirements—such as whether the drug use is excluded from coverage under Medicare Part D—and sponsor-developed components—such as whether a less expensive alternative drug has been tried and failed. When a request cannot be approved by technical staff, sponsors' clinical staffs make the final determination. However, the pressure to make a coverage determination within the CMS-mandated time frames increases the likelihood that sponsors may deny requests when complete information is not at hand or cannot be obtained quickly. In reviewing a sample of 421 case files, we found that study sponsors approved about 67 percent of the coverage determination requests. Overall, the approval rate for standard requests in our sample was 67 percent, compared to 53 percent for expedited requests.

Appeals decisions at the study sponsors and the IRE typically involve the review of more information than was available at the previous level and different decision makers. For redeterminations—the first level of appeal—we found that, generally, sponsor staff often consider additional supporting patient information provided by prescribing physicians that was not available for the coverage determination. The redetermination staff evaluate the corrected or augmented evidence to see whether coverage criteria have been met. In conducting reconsiderations—the second level of appeal—IRE officials review the information the sponsor reviewed, along with any additional support that may be available or that they solicit from the prescribing physician. In many cases, new interpretations of the evidence resulted in approval for coverage of the requested drug. CMS appeals data show that, from July 2006 through December 2006, the median approval rate for all Part D sponsors was 40 percent. For the period from July 2006 through June 2007, the IRE either fully or partially approved coverage of the drug in 28 percent of reconsideration cases. We found that, for some standard appeals, missing AOR documentation contributed to delays in study sponsor redeterminations and dismissals of IRE reconsiderations. Most sponsors in our study, as well as IRE officials, reported that the AOR requirement—that prescribing physicians be appointed beneficiary representatives with a signed AOR form in order to initiate standard appeals—impedes the process. 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 has developed two sponsor performance metrics in the area of coverage determinations and appeals: the rate at which sponsors met required time frames for decision making and the rate at which the IRE concurs with sponsors' redetermination decisions. As of November 2007, the agency changed the manner in which it calculates and displays these performance metrics on its Medicare Web site to improve the information available to beneficiaries. In its efforts to monitor sponsors' coverage determinations and appeals activities, we found that CMS is hindered by inconsistent data. The agency requires that sponsors report data quarterly on various measures of coverage requests and approvals. However, CMS has provided minimal guidance on the types of cases to be included in each coverage determination measure. As a result, for 2006, our study sponsors reported measures differently—for instance, some sponsors double counted cases in separate measures while other sponsors omitted certain types of cases from any of the measures. In addition, CMS audited several prescription drug plan (PDP) sponsors for their adherence to coverage determination and appeals requirements and found that each audited sponsor was noncompliant for 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 expedited request. CMS required these sponsors to submit corrective action plans to address the identified deficiencies.

To improve the Medicare Part D coverage determination and appeals processes, we are making two recommendations. First, we recommend that CMS require sponsors and the IRE, upon receipt of standard appeal requests submitted by prescribing physicians without completed AOR forms, to telephone beneficiaries to determine whether they wish to initiate the appeal. Second, we recommend that CMS provide specific definitions for data sponsors report to CMS that the agency uses for monitoring coverage determination and appeals activities. In commenting on a draft of this report, the agency wrote that it is considering the first recommendation in light of current legal requirements. CMS also stated that it is in the process of implementing the report's second recommendation and has already modified its Part D reporting requirements guidance.

Background

The Medicare Part D Program

The Medicare Part D benefit is provided through private organizations that offer one or more drug plans with different levels of premiums, deductibles, and cost sharing. Plan sponsors must offer the standard Part D benefit established under MMA or an actuarially equivalent benefit. The standard benefit includes an annual deductible, coverage up to a level of spending, a coverage gap—the period when beneficiaries pay all of the costs of their drugs—and catastrophic coverage above a specified out-of-pocket limit. Sponsors may also offer enhanced benefit plans that provide a lower deductible and coverage in the coverage gap in exchange for higher premiums. Certain low-income beneficiaries are eligible for subsidies to defray most of their out-of-pocket costs.

Part D sponsors offer drug coverage either through stand-alone PDPs for those in traditional fee-for-service Medicare, or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare's managed care program. As of September 2007, CMS had contracts with 101 PDPs and 461 MA-PDs.¹⁷ The majority of Part D enrollees, about 71 percent, are in PDPs. PDP enrollment across contracts varies widely, ranging from fewer than 20 enrollees to more than 3.3 million enrollees, and is highly concentrated—the four largest contracts account for about 53 percent of total PDP enrollment in September 2007.

Sponsors' Use of Formularies and Utilization Management Restrictions

For the drugs included on their formularies, Part D sponsors decide which drugs will have utilization management restrictions and which type of restriction they will apply.¹⁸ Utilization management restrictions may include prior authorization, quantity limits, and step therapy requirements. Sponsors may apply utilization management restrictions to prevent the overuse of expensive medications by requiring lower-tier drugs be tried

¹⁷The count of MA contracts that offered the Part D benefit includes local health maintenance organizations, local preferred provider organizations, local provider-sponsored organizations, regional preferred provider organizations, and private fee-for-service plans.

¹⁸MMA requires that sponsors establish a drug utilization management program for covered Part D drugs.

first.¹⁹ The restrictions may also serve to ensure that proper dosages are dispensed, to protect against adverse drug interactions, and to control the use of medications with potential for abuse. Each sponsor has discretion to decide under which circumstances it will apply utilization restrictions.

Research conducted for The Kaiser Family Foundation has shown that sponsors' use of formularies and utilization management restrictions varies significantly.²⁰ The study reported that the 2007 formularies of the 10 largest PDPs differed in their coverage of a sample of commonly used drugs and their use of utilization management restrictions on those drugs.²¹ Four PDPs included on their formulary all of the 152 sampled drugs commonly used by Medicare beneficiaries. Among the remaining 6 PDPs, 1 covered between 90 and 100 percent, and 5 covered between 70 and 80 percent of the sampled drugs. The authors also found that the 10 PDPs placed prior authorization requirements on between 3 and 14 of the 152 sampled drugs. While 3 of the 10 PDPs did not have a step therapy requirement on any of the 152 drugs, 2 PDPs had the requirement on 8 of the drugs. The number of the 152 sampled drugs with quantity limits ranged from 3 to 62.

Types of Coverage Determinations and Appeals

Beneficiaries can use the coverage determination and appeals processes to challenge a utilization management restriction on a drug on the sponsor's formulary or to request coverage for a Part D drug that is not on the sponsor's formulary. Table 1 describes types of requests.

¹⁹For the period January 1, 2007, through March 31, 2007 (the most recent data available), generics accounted for nearly 62 percent of all drugs dispensed to beneficiaries enrolled in Part D.

²⁰J. Hoadley, E. Hargrave, K. Merrell, J. Cubanski, and T. Neuman, *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings*, (Menlo Park, Calif.: The Henry J. Kaiser Family Foundation, November 2006).

²¹These 10 PDPs had the highest enrollment in 2006.

Table 1: Requests Addressed in Coverage Determinations and Appeals

If the drug is on the plan formulary

Prior authorization request	The beneficiary attempts to gain the sponsor's approval of coverage for a drug with a prior authorization requirement by either meeting the sponsor's coverage criteria or showing that the drug is medically necessary.
Step therapy request	The beneficiary attempts to prove to the sponsor either that they have taken the lower-cost drugs required before a higher-cost drug or taking the higher-cost drug without first trying the lower-cost drugs is medically necessary.
Quantity or dosage limit exception request	The beneficiary attempts to obtain approval from the sponsor to take a drug at higher strength than approved by the sponsor or take more units of a drug than the sponsor will approve per month. ^a
Tiering exception request	The beneficiary attempts to obtain approval to pay the cost-sharing associated with a lower cost-sharing tier than the tier to which the drug is assigned.

If the drug is not on the plan formulary

Formulary exception request	The beneficiary attempts to obtain coverage of Part D drugs that are not included on a sponsor's formulary for reasons of medical necessity.
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Source: GAO analysis of CMS information.

^aQuantity or dosage limits may be based on FDA labeling.

Coverage Determination Processes Allow for Prompt Decisions, Apply a Range of Criteria, and Have Resulted in Approvals for the Majority of Requests

Study sponsors have designed their coverage determination processes to allow for prompt decision making within CMS-required time frames. They obtain patient information needed to make their decisions using drug-specific coverage determination request forms and enter this information into a computer for analysis of whether coverage criteria have been met. When coverage requests cannot be approved by technical staff, they are decided by clinical staff. Sponsors apply drug-specific coverage criteria that incorporate the requirements established by MMA and CMS as well as factors that they have discretion to apply, such as evidence of trial and failure of lower-cost drugs. In the sample of coverage determination case files we reviewed at the seven study sponsors, coverage of the requested drug was approved in approximately two-thirds of the cases.

Streamlined Processes Make Expeditious Coverage Determination Decisions Possible

The sponsors we studied developed coverage determination processes designed to produce decisions within the CMS-required time frames—72 hours for standard requests and 24 hours for expedited requests. To collect the patient information needed to make coverage determination decisions, study sponsors generally rely on drug-specific request forms. These forms typically ask a series of questions based on the sponsor's established coverage criteria for a given drug. Prescribing physicians are asked to use these forms to submit clinical information about a beneficiary that generally includes the diagnosis associated with the requested drug, and may include the beneficiary's other medical conditions and drug history. For instance, to process a coverage determination request for the osteoporosis drug Forteo, a sponsor may ask whether the beneficiary has a diagnosis of osteoporosis, has multiple risk factors for fractures, and has tried and failed other specific osteoporosis therapies. Some study sponsors had dozens of different forms for drugs in different classes, with a varying number of questions. For example, one sponsor asked 5 questions for the sleep medications Ambien and Lunesta and 23 questions for the injectable drug Pegasys, used to treat hepatitis. If a physician makes a coverage determination request over the phone, sponsor staff have on-line access to the drug-specific questions they need to ask.

With the information submitted by the prescribing physician, study sponsors used computer algorithms—a series of questions with yes/no answers—in order to make expeditious, consistent decisions. Technical staff, such as pharmacy technicians or call center representatives, enter the patient information into the computer system. The algorithms are used to assess the information to determine whether the beneficiary meets the sponsor's coverage criteria for the specific drug in question. This process

generates rapid, consistent decisions if sponsors receive sufficient information from prescribing physicians. When the technical staff cannot approve the drug, coverage determination requests are forwarded for a decision by clinical staff with more expertise, such as staff pharmacists. One sponsor reported that, on average, a standard coverage determination involving prior authorization takes about 40 minutes after the prescribing physician provides the needed information.

However, the pressure to make a coverage determination within the CMS-mandated time frames increased the likelihood that sponsors may deny requests when complete information is not at hand or can not be obtained quickly.²² Two study sponsors told us that if they were not successful in getting information they requested, they made decisions based on the information they had at the time. For example, if physicians are asked to provide a patient's medical records as part of their request but do not provide that information quickly, the sponsor may deny the request in order to meet the required time frame. Among the coverage determination case files we reviewed at the study sponsors, the sponsor requested additional information from the physician in about 13 percent of the cases and about 30 percent of the denials were for lack of requested medical information. One sponsor noted that there would probably be fewer denials at the coverage determination stage if sponsors had more time to acquire needed information.

Sponsors Apply a Range of Coverage Criteria in Making Coverage Decisions

Sponsors apply a range of coverage criteria to evaluate requests for drugs with restrictions. Their criteria are used, in part, to determine whether a requested drug can be covered under Part D program rules set by MMA or CMS. Sponsors consider a number of factors in reviewing a request, including the following:

- **Should the drug be covered under another part of the Medicare program?** There are an estimated 6,000 unique drug products²³ that

²²Sponsors must start the clock on the mandated processing times upon receipt of the coverage request, except for requests requiring a physician's supporting statement. In a 2007 CMS review of PDP sponsors, auditors found that one sponsor allowed itself additional time for coverage determinations. It categorized all requests so that the processing time began only after receiving a completed physician's supporting statement. As part of a corrective action plan, CMS required this sponsor to submit a monthly summary report of the volume and outcome of its coverage determination decisions.

²³Unique drug products include the multiple strengths and packages of a particular drug in which a product could be available.

potentially could be covered under either Part B or Part D of the Medicare program.²⁴ Which part of the Medicare program is the appropriate payer depends on factors such as the patient's diagnosis, when the beneficiary is taking the drug, or the setting in which the drug is being administered. For instance, immunosuppressive drugs suppress the body's immune response and are used to treat autoimmune diseases—diseases in which the body attacks its own tissues—and to prevent rejection of a transplanted organ. Immunosuppressives are covered by Part B when the physician prescribes them after a Medicare-covered organ transplant and by Part D for all other outpatient uses.

- **Is the requested drug in a Part D-excluded drug class?** Although sponsors generally can not cover drugs in 1 of 10 statutorily excluded drug categories, beneficiaries or prescribing physicians may request a coverage determination for a drug that is in an excluded drug category. For such coverage determinations, the physician must show that the drug is prescribed for a purpose that is not excluded under the law or that it has been mistakenly classified by the sponsor as excluded. For instance, medications for coughs and colds are generally excluded from Part D. However, CMS has issued guidance to plan sponsors that cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations. For example, if a physician prescribes a cough suppressant to a beneficiary because the beneficiary has osteoporosis and may break a bone if the cough is not controlled, then the cough suppressant would be considered a Part D-covered drug.
- **Is the requested drug medically necessary?** Part D sponsors must approve coverage when the requested drug at the requested dosage is medically necessary.²⁵ In order to show medical necessity, the prescribing physician must provide a statement that the requested drug is medically necessary because (1) all of the covered Part D drugs on the sponsor's formulary for treatment of the same condition would not be as effective for the beneficiary, would have adverse effects for the beneficiary, or both; (2) the prescription drug alternatives on the formulary have been ineffective in the past, are likely to be ineffective, or are likely to cause an adverse reaction for the beneficiary; or (3) the number of doses available

²⁴In general, Medicare Part B covers a range of medical services, including physician, laboratory, hospital outpatient services, and durable medical equipment. Medicare Part B covers selected outpatient drugs, typically those administered by physicians, drugs used with durable medical equipment, and other drugs specifically named in statute.

²⁵The drug must also be a Part D-covered drug.

under a quantity limit for a requested drug has been ineffective or is likely to be ineffective. In addition, sponsors are required to approve a tiering exception if they agree with the prescribing physician's statement that treatment of the beneficiary's condition using the preferred alternative drug would not be as effective for the beneficiary as the requested drug, would have adverse effects for the beneficiary, or both.

- **Is the requested drug being prescribed for a medically accepted indication?** Under Medicare Part D, a drug is considered to be prescribed for a medically accepted indication if the drug is FDA-approved for that use. Any off-label use²⁶—one not approved by FDA—is considered medically accepted only if it is supported by a citation in one of the three designated drug reference guides.²⁷ Beneficiary advocates have argued that the coverage restrictions on those off-label drug uses not listed in the designated drug reference guides cause beneficiaries to be denied coverage for needed drugs, some of which beneficiaries had been previously taking successfully. For instance, a beneficiary without cancer may have a condition which causes severe pain. After trying several medications, the beneficiary may have less pain with the use of Actiq, a medication approved only for breakthrough pain in cancer patients. Under Part D, the beneficiary would be denied coverage for the drug, even if the beneficiary's physician stated that the medication was medically necessary, because the drug was not prescribed for a medically accepted indication, and this use is not listed in one of the three drug reference guides.

Beyond ensuring compliance with MMA and CMS coverage rules, sponsors have discretion to develop their own drug-specific coverage criteria. Sponsors in our study also considered the following factors.

- **Has the beneficiary tried and failed on a generic or preferred alternative drug?** To reduce costs, sponsors may require beneficiaries to try and fail on generic or preferred alternative drugs before approving coverage for higher-cost drugs. Sponsors told us, and CMS has affirmed,

²⁶Evidence suggests that off-label drug use is frequent. One study estimated that 21 percent of drugs prescribed by office-based physicians were for off-label uses. See D. Radley, S. Finkelstein, and R. Stafford, "Off-Label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine*, vol. 166 (May 8, 2006).

²⁷Drug reference guides include information on drugs, such as dosage, safety, and FDA-approved and investigational uses. The three MMA-approved reference guides, or drug compendia, are the American Hospital Formulary Service Drug Information, US Pharmacopeia-Drug Information, and DRUGDEX Information System.

that beneficiaries generally can switch to a therapeutically equivalent drug without disruption to their care.²⁸ Therefore, although a beneficiary has been stable on a particular drug for a period of time, sponsors may require the beneficiary to switch to a generic or preferred alternative drug.

- **Has the physician conducted specific tests to confirm the beneficiary's diagnosis or condition?** Study sponsors sometimes also ask for information from specified tests or studies that document a patient's diagnosis or condition. For instance, one sponsor told us that it requires genotype tests for hepatitis drugs because the length of time a patient should be on the drug is determined by the genotype.²⁹
- **Is the beneficiary already stable on the requested drug?** Sponsors may consider whether the beneficiary is stable on the requested drug when deciding whether to approve or reapprove coverage.
- **Does the beneficiary have other medical conditions or take other medications that may contraindicate the use of the requested drug?** For instance, one sponsor's criteria for the drug Actiq—used to treat breakthrough cancer pain—stipulated that the enrollee must not have severe asthma or chronic obstructive pulmonary disease, which are contraindications to Actiq. This same sponsor's criteria for the antidepressant Ensam noted that the medication should not be approved if the enrollee is taking other types of antidepressants, such as monoamine oxidase inhibitors or tricyclic antidepressants.

Duration of the approval period depends upon the drug requested and on plan policies. In general, sponsors told us they approve coverage of a requested drug for either the duration of the year or a 12-month period. Some sponsors also approve requests for as long as the beneficiary remains enrolled in the plan in cases where the drug treats an illness that can last for the duration of a person's life (such as multiple sclerosis). All sponsors said that certain drugs, such as those with a specified length of treatment for safety reasons, may be approved for shorter time periods. For example, some injectable drugs are approved for 24 weeks. If coverage criteria are not met, study sponsors' denial letters generally included the reason for the decision. For instance, denial notices may state that the

²⁸Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drugs.

²⁹A genotype test shows the genetic makeup of the hepatitis virus.

requested drug was not covered because the preferred alternative drug must be tried first. Some, but not all, sponsors that we visited sent notification letters to prescribing physicians that identified which preferred drug should be tried. The IRE told us that some sponsor denials are vague. For instance, sponsors may not do a good job of explaining which specific requirements have not been met.

Study Sponsors Approved Two-Thirds of Coverage Determination Requests in Sample Month

Study sponsors approved about 67 percent of the coverage determination requests among the October 2006 requests that we reviewed. Approval rates varied among sponsors, ranging from 57 percent to 76 percent. We also found that coverage determinations in MA-PD plans were more likely to be approved than coverage determinations in PDPs; the approval rate for MA-PD plans was 72 percent, compared to 63 percent for PDPs. Sponsors in our study approved standard requests more often than expedited requests. The approval rates for standard and expedited requests were 67 percent and 53 percent, respectively.

We found that nearly all requests for coverage determinations were made by physicians on behalf of their patients. Approximately 94 percent of the coverage determinations in our case file review were requested by a physician or a physician's office staff. At the coverage determination stage, we also found that only a small proportion of requests were expedited. Of the coverage determination case files we reviewed, just 4 percent of the requests were expedited.

We found that the most commonly requested drug class and category combinations were, in order of decreasing frequency, (1) blood modifier agent/hematopoietic, (2) endocrine-metabolic agent/antidiabetic, (3) central nervous system agent/analgesic, (4) dermatological agent/antifungal, (5) gastrointestinal agent/antiulcer, (6) anti-infective agent/antifungal, and (7) musculoskeletal agent/antirheumatic. These seven drug class and category combinations accounted for about half of the requested drugs in the 421 cases we reviewed. At the individual drug level, the five most requested drugs—collectively accounting for about one-quarter of our sampled coverage determination requests—were Procrit, Lamisil, Byetta, Celebrex, and Omeprazole.

Appeals Processes Allow for Better Informed Decisions, Have Often Resulted in Coverage Approvals, and Are Impeded by AOR Requirement

The appeals process allows for individuals not involved in the previous case review to make better-informed decisions by considering additional supporting evidence. In making redeterminations—the first level of appeal—sponsor staff evaluate any corrected or augmented evidence to see if coverage criteria have been met. In conducting reconsiderations—the second level of appeal—IRE officials 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. We found that, for some standard appeals, missing AOR documentation contributed to delays in study sponsor redetermination decisions and dismissals of IRE reconsideration cases. Some study sponsors have developed “workarounds” to eliminate the need for a completed AOR form.

Appeals Processes Involve Clinical Evidence and Patient Information Not Previously Available

Appeals processes at both the study sponsors’ level and the IRE typically involve (1) reviewing more information than was available for the previous decision level and (2) different decision makers.

First-Level Appeals to Sponsors

In conducting redeterminations—the first level of appeal—sponsors typically receive corrected or augmented patient information that was not submitted within the allotted time frame for the coverage determination. For example, prescribing physicians may not have identified the beneficiary’s conditions with sufficient specificity or included a complete drug use history when making the coverage determination request; for redeterminations, physicians often provide new information on the reason for the requested drug and a list of drugs the beneficiary had previously tried but were found to be ineffective or not well tolerated. Physicians may forward laboratory test results or chart notes that sponsors had requested previously. In addition, our reviews of sponsors’ redetermination case files showed that physicians revise the statements they had provided originally to address issues raised in the sponsors’ coverage denial letters.

To determine whether the sponsor’s drug-specific coverage criteria have been met, study sponsor staff reassess the submitted information, along with any additional support not previously considered. For redeterminations that involve requests for off-label uses of drugs, study sponsors said they make an effort to look for citations in one of the three Part D-designated drug reference guides to see if one of them supports use

of the drug for the indication for which it was prescribed.³⁰ In reviewing requests for dosage limit exceptions, in addition to considering a beneficiary's medical record, study sponsors may also examine medical research literature for evidence not included in the reference guides. In addition, sponsors may discuss a case directly with the prescribing physician. We found that study sponsors contacted prescribing physicians to obtain additional information in 31 percent of the redetermination case files we reviewed.

CMS requires that redetermination decisions be made by individuals not previously involved in reviewing the drug request. Study sponsors' redetermination decision staff making clinical decisions consist largely of pharmacists or staff medical directors. If the staff pharmacist does not approve a decision, a medical director makes the final decision. CMS additionally requires that decisions concerning the medical necessity of the requested drug be made by a physician with expertise in the field of medicine appropriate to the condition being treated. Some of the study sponsors contract with external physicians or utilization review companies for this function.³¹

Second-Level Appeals to the IRE

Along with the information in the sponsor case file, IRE staff review any new supporting information they receive or solicit from the prescribing physician as well as relevant medical literature.³² In making a reconsideration decision—the second level of appeal—the IRE is likely to have more information than did the sponsor at the first level of appeal. It not only has information from the sponsor's case file, but also information in the physician's letter or beneficiary correspondence that may be submitted with the reconsideration request. In addition, IRE staff told us

³⁰One sponsor told us that about 75 to 80 percent of clinical redetermination requests reviewed by medical staff involved off-label uses of drugs. Some study sponsors noted that, in determining whether a particular drug use is medically indicated, they have less flexibility in accepting evidence from peer-reviewed literature for drug coverage decisions under Part D than under commercial plans.

³¹All but one of our study sponsors used clinical staff not involved in the decisions at the previous level to make redeterminations, as required. One sponsor told us that it used the same staff for both decision levels in 2006 and had now corrected its procedures.

³²Under Part D, cases reach the IRE because they are either requested by the beneficiary (or on behalf of the beneficiary) or forwarded by sponsors because required time frames were not met. This differs from appeals procedures under Medicare Advantage, where all adverse appeals decisions by health plans are automatically forwarded to the IRE, regardless of whether the time frame was met.

that they contact the physician or beneficiary to obtain specific details about the beneficiary's health or to clarify the information submitted, such as adverse effects the beneficiary has experienced or contraindications to the preferred formulary drugs. During its review, the IRE may also perform additional research in the drug reference guides on the reason the physician is prescribing a particular drug or dosage. For instance, IRE staff may be successful in researching the Part D-designated drug reference guides for a specific off-label drug use that a sponsor had not identified.

As Medicare's independent external appeals contractor, the IRE employs medical professionals subject to conflict-of-interest prohibitions, which bar them from having certain relationships with any health insurance utilization review company, provider network, or drug supply company. The IRE staff conducting most reconsiderations are predominantly physicians credentialed in various medical specialties. For example, according to IRE officials, appeals cases involving opioids are handled by pain management specialists because these cases need a specialty review. IRE officials also said that, when necessary, the IRE contracts with external specialists to review cases.

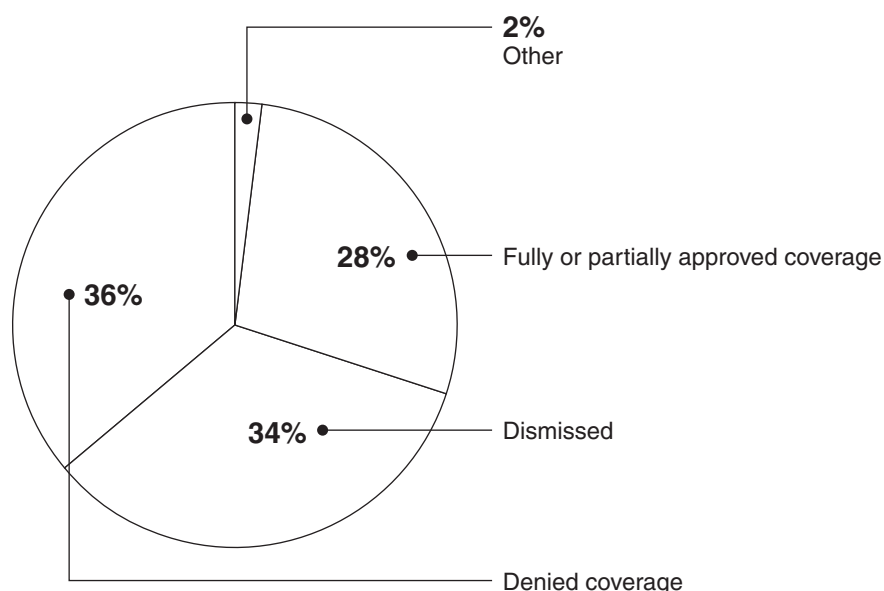
First-Level and Second-Level Appeals Approved Drug Coverage in 40 Percent and 28 Percent of Cases, Respectively

Consideration of new evidence during the appeals process often leads to decisions that reverse the sponsors' decisions. At the first level of appeal, CMS appeals data show that, from July 2006 through December 2006, the median approval rate across all Part D sponsors was 40 percent. Across Part D sponsors, approval rates ranged from 0 percent to 100 percent for all appeals during that period. PDP sponsors were somewhat more likely to approve coverage; the median rate of approvals for PDPs was about 45 percent, compared to about 38 percent for MA-PDs.

At the second level of appeal, IRE appeals data show full or partial coverage approvals of the requested drug in about a quarter of the 11,679 reconsideration cases decided from July 2006 through June 2007. IRE data for this period show that the IRE either fully or partially approved³³ coverage in 28 percent of appeals and denied coverage in 36 percent of appeals. A significant proportion of IRE cases, 34 percent, were dismissed for various reasons, such as the lack of AOR documentation. (See fig. 1.)

³³In a partial approval, the IRE may, for example, approve coverage of the requested drug for the appealing party but not in the quantity prescribed.

Figure 1: IRE Disposition of Part D Appeals, July 2006 through June 2007



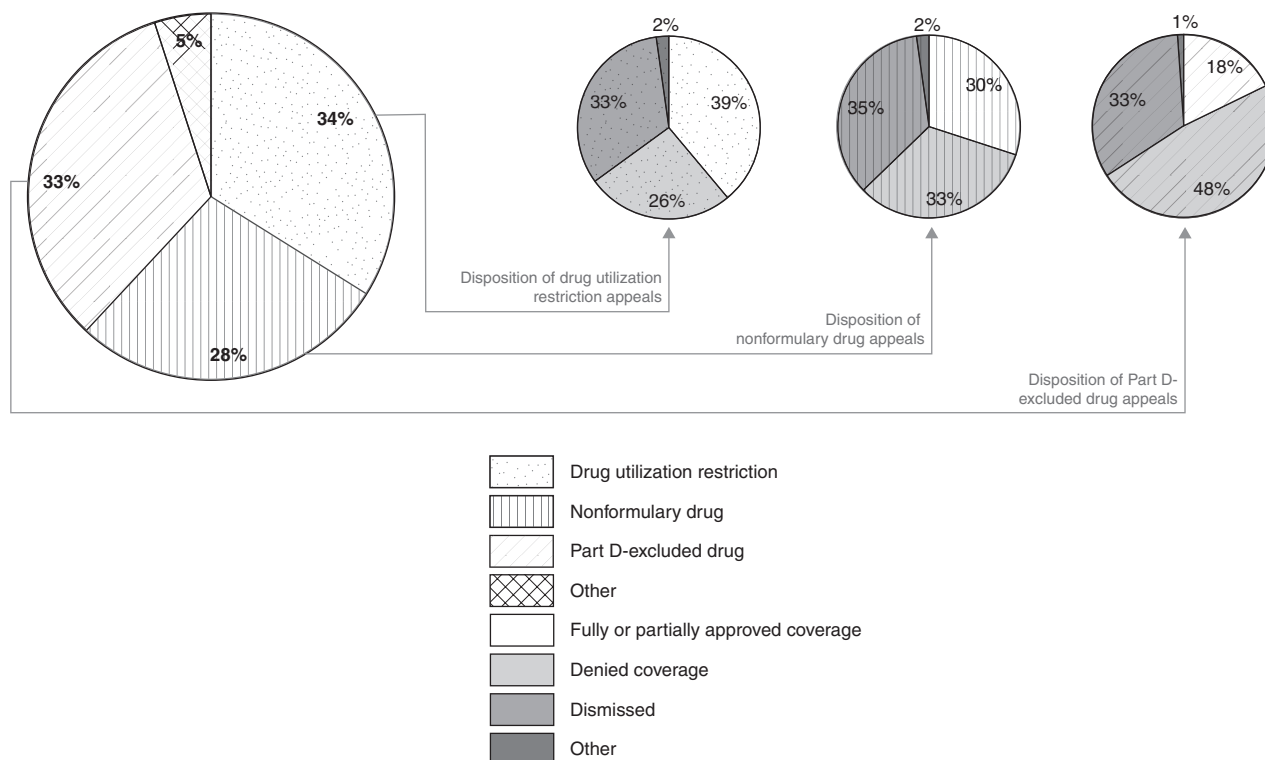
Source: GAO analysis of IRE data.

Note: Fully approved cases: the IRE totally disagrees with the sponsor's redetermination and decides in favor of the appealing party. Partially approved cases: the IRE disagrees with one part of the sponsor's decision but agrees with another part. Denied cases: the IRE agrees with the sponsor's decision against the appealing party. Dismissed cases: those with missing AOR documentation or other deficiencies. "Other" refers to the remaining cases, such as those that were withdrawn.

The 11,679 cases reviewed by the IRE addressed a variety of issues. From July 2006 through June 2007, about one-third of IRE cases concerned a drug utilization restriction, such as a prior authorization requirement or quantity limit. Another 33 percent of IRE cases were requests for a drug not covered under Part D, such as a drug in one of the 10 Part D-excluded categories. Twenty-eight percent of cases were requests for Part D drugs not on the sponsor's formulary. The remaining 5 percent of IRE cases involved issues such as requests to pay a lower cost-sharing level and reimbursement for drugs provided outside of the sponsor's pharmacy network.

IRE approval rates for Part D appeals were highest for disputes involving drug utilization restrictions and lowest for cases involving Part D-excluded drugs. The IRE fully or partially approved coverage in 39 percent of the appeals concerning a drug utilization restriction, 30 percent of appeals involving nonformulary drugs, and 18 percent of appeals for coverage of a drug that sponsors denied as an excluded drug under Part D. (See fig. 2.)

Figure 2: IRE Decisions by Issue Addressed in the Request, July 2006 through June 2007



Source: GAO analysis of IRE data.

Note: Fully approved cases: the IRE totally disagrees with the sponsor's redetermination and decides in favor of the appealing party. Partially approved cases: the IRE disagrees with one part of the sponsor's decision but agrees with another part. Denied cases: the IRE agrees with the sponsor's decision against the appealing party. Dismissed cases: those with missing AOR documentation or other deficiencies. "Other" refers to the remaining cases, such as those that were withdrawn.

As part of the decision process, the IRE determines whether the sponsor has met its obligation for coverage under the Part D rules.³⁴ IRE staff told us that during the first year of the program, some sponsors denied requests because they did not fully consider the beneficiary's overriding medical need for the requested drug, as CMS requires. In contrast, at the IRE, the beneficiary's medical condition is the determining factor when

³⁴The IRE compares all of the beneficiary information against the sponsor's coverage criteria to see whether the sponsor properly applied the appropriate coverage criteria when making its denial. The IRE lacks authority to change a sponsor's coverage criteria because these have already been approved by CMS.

the sponsor's coverage criteria cannot be met. For example, in one case, a sponsor denied a physician's request for the drug Celebrex—a drug used to treat arthritis and other conditions—because the physician did not provide documentation of the beneficiary's trial and failure of the sponsor's formulary medications—Naproxen, Ibuprofen, or Ketoprofen. In this case, the sponsor did not cover the requested drug because its step therapy requirement had not been met. However, in reviewing the case, the IRE applied medical necessity criteria because the prescribing physician stated that use of the sponsor's preferred formulary alternatives were contraindicated for treatment of his patient's condition. As a result, the IRE overturned the sponsor's decision, stating that an exception to the sponsor's step therapy requirement was warranted and that the sponsor should provide coverage of the drug until the end of the plan year.

Missing AOR Forms at Study Sponsors and the IRE Cause Appeals to Be Delayed or Dismissed

At our study sponsors and at the IRE, we found evidence that decisions on standard appeals submitted by prescribing physicians—redeterminations and reconsiderations—had been delayed and sometimes dismissed due to missing AOR forms. Without written authorization from the beneficiary, sponsors and the IRE may begin collecting relevant documentation to support a physician-submitted standard request, but they cannot complete their review. Also, the time frame for making the decision does not begin until the completed AOR form is received. According to most study sponsors and the IRE, if they do not receive the signed AOR form within a reasonable amount of time—which ranges from about a week to about a month after receiving the request—they deny or dismiss the request. Of the cases we reviewed at the study sponsors, missing AOR forms generated processing delays in 7 percent of cases. These delays were typically about 14 days, but could stretch to 67 days. At the IRE, missing AOR forms caused dismissals of about 9 percent of appeals, which is about one in every five reconsideration cases that were dismissed.³⁵

Data on the prevalence of delays in processing redetermination requests attributable to missing AOR forms mask the fact that some sponsors in our study have developed “workarounds” to eliminate the need for a completed AOR form. For example, one sponsor told us it treats all physician appeals as expedited, regardless of the priority level indicated by the physician. Our review of a sample of sponsors' case files showed

³⁵In one of the cases we reviewed, the IRE returned the case to the sponsor for proper processing.

that 26 percent of redetermination requests were classified as expedited compared to 4 percent of the coverage determination case files we reviewed. Although expediting requests precludes the need for an AOR form, one sponsor stated that because these requests may not be truly urgent, it may not be in the beneficiary's best interest for the appeal to be rushed. Expedited appeals allow less time—72 hours versus 7 days—for reviewers to consider the evidence at hand or to request additional information, which might affect the outcome of the appeal. For the case files we reviewed, the denial rate for expedited redeterminations was 73 percent compared with a denial rate of 67 percent for standard redeterminations.

In another workaround, sponsors obviate the need to obtain two signatures—the beneficiary's to appoint the physician to act as a representative and the physician's to accept the appointment—by arranging for the redetermination request to be made by the beneficiary. For example, one sponsor reported contacting beneficiaries to ask whether they want to initiate the redetermination instead of their physicians, who had contacted the sponsor first. Our case file reviews showed that beneficiaries made requests in about 36 percent of redetermination cases compared to 2 percent of coverage determination cases. This approach was designed to identify those beneficiaries who wish to initiate an appeal rather than having their physician appeal on their behalf, thus reducing the need for the AOR paperwork.

Most sponsors in our study and IRE officials reported that the requirement that prescribing physicians be formally appointed beneficiary representatives with a signed AOR form in order to initiate standard appeals is an administrative impediment. The only actions prescribing physicians without explicit authorization cannot take are initiating the appeal, opening discussions with a sponsor or the IRE about an ongoing appeal requested by the beneficiary, or receiving notices of adverse standard redeterminations or reconsiderations. In practical terms, prescribing physicians' involvement in a standard appeal does not differ significantly whether they are appointed representatives or not.

CMS Efforts to Inform Beneficiaries about Sponsors' Performance Have Improved; Oversight Hindered by Poorly Defined Reporting Requirements

CMS has improved its efforts to inform beneficiaries about sponsors' performance, but its oversight of sponsors is hindered by poorly defined reporting requirements. CMS publicly reports information on two performance metrics: the rate at which sponsors met required time frames for decision making and the rate at which the IRE concurs with sponsors' redetermination decisions. In November 2007, for one of these metrics, CMS modified the way it informs beneficiaries by grading sponsors' performance against absolute benchmarks, rather than relative rankings as it had done previously. To oversee sponsors' processes, CMS requires that sponsors report data on several coverage determinations and appeals measures; however, the agency provided minimal guidance on the information to be included in each coverage determination measure. As a result, our study sponsors have reported data differently to CMS, hindering the agency's ability to monitor sponsors' activities adequately. In its audits of PDP sponsors, CMS found that most of the sponsors it audited were noncompliant with many of the coverage determination and appeals requirements.

CMS Improved Its Use of Performance Metrics to Inform Beneficiaries

Using quarterly IRE data, CMS has developed two performance metrics to gauge how well sponsors' coverage determination and appeals processes are operating. CMS calculates metrics on (1) the rate at which sponsors met required time frames for coverage determinations and redeterminations, as measured by the number of cases, per 10,000 beneficiaries, automatically forwarded to the IRE because of delays in sponsors' decision making; and (2) the rate at which the IRE concurs with sponsors' redetermination decisions, as measured by the percentage of cases in which the IRE upheld, or agreed with, sponsors' coverage denials.³⁶ CMS officials told us that the agency selected these two performance metrics, in part, because beneficiaries could interpret their meaning easily. CMS includes the two metrics in information made

³⁶This metric, measured by the percentage of cases where the IRE agrees with sponsors' coverage denials, excludes cases that are dismissed, remanded, or withdrawn. In addition, the metric excludes any cases that are not related to Part D.

available to the public on the Medicare Prescription Drug Plan Finder—a Web site designed to help beneficiaries compare drug plans.³⁷

CMS account managers—staff responsible for overseeing sponsors’ performance—review sponsors’ scores on these performance metrics to monitor how well their coverage determination and appeals processes are operating.³⁸ Sponsors with the highest rates of cases forwarded automatically to the IRE and the lowest percentages of cases in which the IRE agreed with their decisions are viewed as problematic. When a sponsor is identified as an outlier, the assigned account manager contacts the sponsor to discuss its coverage determination and appeal procedures and works with the sponsor to identify ways to improve its performance, such as conducting additional training sessions.

Both the IRE and the sponsors in our study noted certain limitations in the data underlying each of these metrics. The number of automatically forwarded cases used for the timeliness metric may understate sponsors’ timeliness.³⁹ According to IRE officials, some sponsors have forwarded cases to the IRE believing they had exceeded the required decision time frames when they had not. According to the officials, these sponsors automatically forwarded cases when they had not yet received a signed AOR form or a physician statement to support a coverage request. In such cases, the required time frames have not yet expired and the IRE returns the case to the sponsor for processing. Because these sponsors automatically forwarded cases to the IRE inappropriately, their rates of missed time frames are higher than they should be.

Another limitation is that the performance metric on the IRE’s concurrence with sponsors’ decisions can be misleading. In discussing this

³⁷ CMS uses its Web site to publicly report sponsor performance information in key domains. For beneficiaries enrolling in Part D plans effective January 1, 2007, CMS used five key domains—customer service, complaints, appeals, data systems, and drug pricing. For beneficiaries enrolling in Part D plans effective January 1, 2008, CMS is combining the five key domains into three—customer service, access to prescription drugs, and drug pricing and utilization. The appeals performance metrics are two of seven metrics in the access to prescription drugs domain.

³⁸ The account managers also act as liaisons between sponsors and CMS to help ensure that sponsors understand CMS regulations and guidance regarding Part D.

³⁹ According to CMS, sponsors may not always automatically forward late cases to the IRE. The agency has instructed sponsors not to automatically forward cases where sponsors are a few hours late and are issuing fully favorable decisions for beneficiaries.

measure with the sponsors in our study, one sponsor commented that a low rate of IRE agreement with their decisions implies, unfairly, that the sponsor's decisions were flawed. They contend that the IRE often receives additional supporting evidence that results in an overturn, as we found by interviewing IRE officials. They state that had they received the same information within their time frame for processing the case, they may have approved the request. In their view, a low percentage of cases in which the IRE agrees with the sponsor's decisions does not necessarily mean that the sponsor was not performing well. However, a CMS official asserted that sponsors are responsible for collecting all the information needed to adjudicate a request in the time allotted and are accountable if they do not obtain the same information available to the IRE.

CMS uses these performance metrics to inform beneficiaries of sponsors' performance and to encourage poor performing sponsors to do better. In an effort to improve the information shared with beneficiaries for the 2008 open enrollment period, the agency changed the manner in which it calculates and displays these metrics—using a star designation system.⁴⁰ For the 2007 open enrollment period, CMS used 2006 data from the IRE to rank order sponsors' rates, classify sponsors into groups based on sponsors' relative performance, and assign a star designation to each group.⁴¹ For example, CMS chose to assign three stars, indicating very good performance, to 90 percent of sponsors for each metric. The next 5 percent of sponsors were assigned two stars, indicating acceptable performance, while the remaining sponsors were given one star, indicating poor performance.

By setting the star designations using relative comparisons rather than defined benchmarks for different levels of performance, CMS implied that those sponsors receiving the most stars had superior performance while those with fewer stars were not meeting a CMS-set standard. The clustering of 90 percent of sponsors in the three-star designation could have been misinterpreted by beneficiaries as identifying those sponsors with superior performance when, in fact, by definition, 90 percent of

⁴⁰Each year, beneficiaries have an opportunity to change prescription drug plans during the annual coordinated election period (open enrollment). The 2008 annual coordinated election period runs from November 15 through December 31, 2007, with enrollment changes effective as of January 1, 2008.

⁴¹CMS updated its Medicare Prescription Drug Plan Finder in April 2007 using data for all of 2006. For the 2008 annual coordinated election period, CMS used data from January 1 through June 30, 2007.

sponsors received three stars. Moreover, the performance of sponsors in the top category varied significantly. For example, among the 26 PDP sponsors receiving three stars, the percentage of cases where the IRE concurred with sponsors' redetermination decisions ranged from 39 to 75 percent. At the same time, the remaining categories were quite compressed. A relatively small difference in rates could have placed a sponsor in the lowest category rather than the highest category. CMS designated an IRE concurrence rate of 39 percent to be very good performance, but a 36 percent rate as acceptable performance, and 34 percent as poor performance.

Recognizing the value of comparing sponsor performance against absolute standards (benchmarks), CMS changed its star designation system in time for the 2008 open enrollment period. For the performance metric on IRE concurrence, the agency now assigns sponsors to one of five star categories using fixed benchmarks rather than a percentile ranking. Table 2 shows how sponsors are assigned to different performance categories for the metric on IRE concurrence. For example, under the new designation system, only those sponsors with IRE concurrence rates better than 95 percent receive five stars, indicating excellent performance. Also, stars are only displayed for sponsors that have at least five appeals cases reviewed by the IRE.

Table 2: CMS’s Revised Metric on IRE Appeals Decisions, as of November 2007	
CMS star designation	IRE appeals uphold rate
5 stars (Excellent)	> 95 percent
4 stars (Very good)	> 90 percent and ≤ 95 percent
3 stars (Good)	> 75 percent and ≤ 90 percent
2 stars (Fair)	> 50 percent and ≤ 75 percent
1 star (Poor)	≤ 50 percent
Insufficient data	1 to 4 cases reviewed by the IRE
No appeals required review	0 cases reviewed by the IRE

Source: CMS.

For the 2008 open enrollment period, CMS expanded its star designation system for the timeliness metric from three stars to five stars. Although it retained the relative ranking approach, CMS more evenly distributed the sponsors across the star categories. For example, whereas previously CMS assigned the top 90 percent of sponsors—those with the lowest rates of cases forwarded to the IRE because of missed time frames—the highest

rating, the agency now assigns the highest rating to the top 15 percent of sponsors. Previously, CMS assigned 5 percent of sponsors the lowest rating, but now it assigns the lowest rating to 15 percent of the sponsors. The remaining sponsors are distributed more evenly across the two-, three-, and four-star designations. CMS continues to include among the top performing sponsors those with no cases forwarded to the IRE due to missed time frames. In our examination of 2006 publicly reported performance data, we found that, among the 60 PDP sponsors receiving three stars for making timely decisions, 21 did not forward any cases to the IRE because of missed time frames.

**CMS Monitoring
Hampered by Lack of
Specificity in Reporting
Requirements; Audits
Identified Sponsors
Needing Improvement**

CMS's oversight of sponsors' coverage determination and appeals processes include both monitoring and auditing.

CMS's Monitoring Efforts

In monitoring the coverage determination processes, CMS reviews quarterly data reported by sponsors. The coverage determination measures selected for reporting capture information about the extent to which beneficiaries use the coverage determination process and the outcomes of that process. An agency official involved in selecting the measures to be reported noted that CMS sought to minimize the administrative burden on sponsors by selecting measures for which data were likely to be readily available. For 2006, the first year of the Part D program, CMS required sponsors to submit data on the following types of coverage determination cases:

- the number of requests and the number of approvals for formulary drugs requiring prior authorizations;
- the number of requests and the number of approvals for formulary exceptions, such as for nonformulary drugs; and

-
- the number of requests and the number of approvals for tiering exceptions.⁴²

CMS used the submitted coverage determination data to calculate an overall request rate and an overall approval rate. In its analysis of the 2006 sponsor-reported data, CMS identified sponsors with relatively high overall rates of coverage requests and low overall rates of approvals. The agency wrote to these sponsors requesting that they confirm whether their submitted data were accurate and not the result of clerical errors.

We found that our study sponsors submitted information differently to CMS because the agency provided limited guidance on the information to be included in each coverage determination measure.⁴³ CMS defined the coverage determination measures sponsors are required to report too broadly, thus allowing each sponsor to use its existing data categorizations for each of the measures. After examining data reported for the third and fourth quarters of 2006, and following up with our study sponsors, we found substantial discrepancies in how sponsors reported these overall data for requests and approvals, as the following illustrate.

- While four of our seven sponsors said their measure of formulary drug requests requiring prior authorizations included requests for quantity limit exceptions, three sponsors included only a portion or none of these types of cases. For example, one sponsor told us that it omitted 6,032 requests for quantity limit exceptions in reporting the formulary drug request measure in the fourth quarter of 2006. These cases accounted for about 22 percent of the sponsor's total coverage determination requests during

⁴²In addition, sponsors submit data for several appeals-related measures, including the number of standard and expedited redeterminations requested, the number of redeterminations resulting in a reversal of the original decision, the number of coverage determinations and redeterminations submitted to the IRE due to inability to meet time frames, the number of standard and expedited reconsiderations resulting in a reversal of sponsors' decisions, and the number of standard and expedited reconsiderations resulting in an approval of sponsors' decisions. See CMS, *Medicare Part D Reporting Requirements*, (Baltimore, Md.: updated Jan. 25, 2006).

⁴³In 2006, CMS provided limited guidance in reporting instructions. It required that sponsors exclude from the formulary drugs with prior authorization and tiering exception measures "first pass step therapy edits"—referring to requests to approve higher cost drugs when there are previous claims in their systems showing that the available lower cost alternatives have been tried. CMS also instructed sponsors to exclude "early refills"—that is, requests for a refill of a drug before the minimum time allowed, given the quantity dispensed—from the count of formulary drugs with prior authorization, formulary exception, and tiering exception measures.

that period. Another sponsor did not include 4,608 requests involving quantity limit exceptions in reporting the formulary drug request measure. These cases accounted for about 25 percent of all its coverage determination requests in the fourth quarter of 2006.

- Some, but not all, study sponsors included other types of cases in the requests and approvals for formulary drug measures. For example, three of our seven study sponsors included cases disputing coverage under Part B or Part D in their formulary drug measures, and four study sponsors included requests for drugs excluded from coverage under Part D.
- One of our seven study sponsors stated that, while it included all prior authorization requests in the formulary drug request measure, it included all requests for step therapy and quantity limits in the nonformulary drug request measure, based on a definition for nonformulary drugs in the Medicare Part D manual.⁴⁴ In contrast, another sponsor in our study reported in the nonformulary drug category requests for drugs that it inadvertently did not include when designing its open formulary.
- We identified two sponsors that double counted the number of requested and approved tiering exceptions by reporting them in two different measures. For example, one of our study sponsors included 13,986 requests for tiering exceptions in its count of prior authorization requests for formulary drugs reported to CMS. The inclusion of these tiering exceptions in the number of requests for formulary drugs increased the requests for formulary drugs reported by about 43 percent.

For the 2007 contract year, CMS made a number of modifications to its reporting requirements. CMS instructed sponsors to begin reporting data on the number of requests and approvals for quantity limit exceptions measures and renamed the other measures to better convey the types of coverage determinations to include in their reporting.⁴⁵ CMS also instructed sponsors to exclude cases related to Part B versus Part D coverage from their data submissions.⁴⁶ However, because CMS has yet to address categorization issues, such as whether the measures should be

⁴⁴CMS, *Medicare Part D Manual “Chapter 6—Part D Drugs and Formulary Requirements,”* Section 30.40.1, (Baltimore, Md.: Mar. 9, 2007), 24.

⁴⁵CMS, *Medicare Part D Reporting Requirements: Contract Year 2007*, (Baltimore, Md.: updated Mar. 21, 2007).

⁴⁶CMS, *CY2007 Part D Reporting Requirements: Frequently Asked Questions*, (Baltimore, Md.: revised Apr. 26, 2007).

mutually exclusive, sponsors' data reporting may remain inconsistent. Until data reliability issues are addressed, CMS may not be in a position to use these measures to oversee sponsors' coverage determination process effectively.

CMS's Auditing Efforts

In its 2007 compliance audits of five PDP sponsors, CMS found numerous violations of Part D standards.⁴⁷ The agency used an audit protocol that examined 13 elements related to the coverage determination process and 13 elements of the appeals processes. CMS auditors reported that the number of violations across sponsors ranged from 15 to 26 specific coverage determination and appeals process requirements. CMS has required sponsors to fix the violations by adopting corrective action plans.

Areas of sponsor noncompliance ranged from incomplete written policies and procedures to delays in authorizing drug coverage after the IRE approved an expedited request. Auditors found that some sponsors did not notify beneficiaries of coverage decisions within the required time frames. Several sponsors were cited for not using CMS-approved decision notices; such notices must explain the reasons for denying requests or inform beneficiaries of their appeal rights. Other sponsors did not have policies to use physicians to review appeals of coverage requests denied for a lack of medical necessity. Table 3 shows those audit elements for which CMS found at least four of the five sponsors noncompliant. As of October 2, 2007, each of the five sponsors had submitted to CMS corrective action plans to remediate the identified deficiencies, which CMS was in the process of reviewing.

⁴⁷CMS selected sponsors for audit based on enrollment and issues identified through monitoring. As of September 24, 2007, CMS had completed five PDP sponsor audits, representing seven contracts.

Table 3: Audit Elements Found Deficient at Four or More Sponsors in CMS's Audits of Five PDP Sponsors, as Reported in October 2007

Audit elements found deficient: coverage determinations^a	Audit elements found deficient: appeals^a
Notices instructing enrollees to contact their plan to obtain a coverage determination must be posted or arranged with network pharmacies.	Use of a reviewer not involved in the initial coverage decision, or use of physicians to review denials based on lack of medical necessity.
Maintain policies and procedures for tracking and addressing the timely resolution of requests, as well as for accepting or denying requests for expedited decisions.	Maintain policies and procedures for addressing requests for standard and expedited redeterminations.
Timely notification of decisions for requests for drug coverage or reimbursement.	Timely notification of decisions, and, if applicable, authorization for • standard redeterminations involving drugs, • redeterminations involving reimbursement, and • expedited redeterminations involving drugs.
Use of CMS-approved decision notices.	Provide for the timely transfer of cases to IRE.
Establish and maintain procedures for processing and approving requests for tiering and nonformulary exceptions.	Provide for the timely authorization of drug coverage (for standard and expedited requests), or timely reimbursements, when coverage was approved by the IRE.

Source: GAO analysis of CMS data.

Note: CMS produced seven audit reports for the five audited PDP sponsors. For this analysis, we analyzed combined audit findings for the two sponsors with multiple contracts.

^aA deficiency on an audit element could mean the following: (1) actual failure of the sponsor to take the desired action, such as transferring cases to the IRE within required time frames; (2) failure to address the audit element sufficiently in policies and procedures; or (3) failure to provide sufficient information or data to enable CMS auditors to make an assessment of compliance.

A number of the audit findings indicate that the publicly reported performance metric on sponsor timeliness may not accurately reflect sponsors' adherence to the requirement to automatically forward cases to the IRE. In reviewing case files, for example, CMS found that sponsors inconsistently forwarded standard coverage determination cases to the IRE when they did not meet the required CMS time frame, with one of the sponsors providing CMS with a written statement acknowledging that it had not forwarded any cases to the IRE for review during the audit period. Another two sponsors inappropriately allowed themselves more time to process certain coverage determination requests by starting their coverage determination review only after they received a supporting statement from the physician.

In a separate initiative, CMS has worked with a selected group of sponsors to improve their performance on coverage determinations and appeals. Using a collaborative approach to performance improvement, CMS has conducted evaluations of two sponsors with comparatively high reversal rates at the IRE level of appeal to identify reasons why the IRE often did not agree with these sponsors' prior coverage decisions.⁴⁸ After examining a random sample of IRE case files for each sponsor in 2006, CMS identified several process-related issues that each sponsor could improve and provided feedback in the form of recommendations to each sponsor. For example, at one sponsor, CMS found that in about two-thirds of the reviewed cases, the sponsor should have done a better job of obtaining and assessing documentation of the evidence to support the request. The agency recommended that the sponsor revise certain forms in order to obtain all the information needed to make appropriate coverage determination decisions. CMS officials told us that both sponsors improved their performance by increasing the number of cases in which the IRE agreed with their decisions. As of September 2007, CMS was completing its evaluation of a third sponsor that did not receive a three-star designation for the performance metric based on the 2006 data.

Conclusions

In the Part D program, beneficiaries' access to prescription drugs is a function not only of whether a particular drug is on a plan's formulary and whether it is subject to utilization management tools, but also how plan sponsors make individualized coverage decisions when requested. The Medicare drug benefit allows sponsors to operate in a regulated but flexible environment. Thus, sponsors in our study follow similar procedural steps but apply discretion in making coverage determinations and appeal decisions.

Administrative barriers in the appeals process can have implications for beneficiaries' drug coverage. Efforts to implement the requirement that prescribing physicians be formally appointed beneficiary representatives with a signed AOR form in order to initiate standard appeals have been cited as an impediment to the appeals process. We found evidence that missing AOR forms have caused delays and some dismissals in cases being

⁴⁸ A collaborative partnership with sponsors is one of five objectives CMS established in its 2006–2009 Strategic Action Plan. See CMS, *Achieving a Transformed and Modernized Health Care System for the 21st Century, CMS Strategic Action Plan 2006-2009*, (Baltimore, Md.: Oct. 16, 2006) www.cms.hhs.gov/MissionVisionGoals (accessed July 12, 2007).

considered. A more streamlined approach that reduces AOR paperwork by quickly identifying those beneficiaries who wish to initiate an appeal could improve the process while maintaining physician involvement.

While CMS has improved its efforts to inform beneficiaries about sponsors' performance, its oversight efforts remain mixed. The agency has begun to hold sponsors accountable for maintaining compliance with coverage determination and appeals requirements. Agency auditors cited sponsors for widespread deficiencies and have required them to revise procedures to better serve beneficiaries. However, CMS lacks the data it needs to routinely monitor coverage determination and appeals requests and approvals across all sponsors. The agency has not taken steps necessary to ensure that sponsors report data consistently.

Recommendations for Executive Action

To improve the Medicare Part D coverage determination and appeals processes, we recommend that the Administrator of CMS:

- reduce the need for completed AOR forms by requiring sponsors and the IRE, upon receipt of standard appeal requests submitted by prescribing physicians without completed AOR forms, to telephone beneficiaries to determine whether they wish to initiate the appeal, and
- ensure that sponsor-reported data used for monitoring coverage determination and appeals activities are accurate and consistent by providing specific data definitions for each measure.

Agency Comments and Our Evaluation

In written comments on a draft of this report, CMS remarked that our review presents a balanced evaluation of Part D coverage determination and appeals procedures and the associated data reporting procedures, and does an excellent job of highlighting various challenges in the Part D appeals process. (See app. II.) The agency reported that it is exploring the adoption of one of the report's recommendations and is in the process of implementing the other. In addition to comments on each of our recommendations, CMS provided detailed, technical comments that we incorporated where appropriate.

CMS stated that it intends to consider our recommendation that the need for a signed AOR form be reduced through a process where sponsors call beneficiaries when physicians request appeals on their patients' behalf. However, it noted that it was not certain whether any change to the current policy could be implemented without modifying the statutory and

regulatory provisions associated with the AOR requirement. The agency pointed out that physician representation of beneficiaries is limited by law because only a Medicare Part D eligible individual can bring an appeal at the IRE level. Therefore, CMS said that it is reviewing the current legal requirements about making appeal requests to determine whether changes are appropriate and necessary. CMS added that it intends to work with physician groups to ensure that physicians promptly submit any needed AOR forms.

We are pleased that CMS is considering how it can implement our recommendation to address the difficulties regarding the AOR requirement. In making this recommendation, we considered relevant statutory and regulatory provisions and found no limitations that would preclude its adoption by CMS. Our recommendation would reduce the need for AOR forms by requiring that sponsors and the IRE determine at the outset whether beneficiaries want to initiate their appeals or have physicians do so on their behalf. If it is determined that the beneficiary is requesting the appeal, an AOR form would not be needed and the sponsor or IRE could immediately process the request. However, if sponsors or IRE find that beneficiaries want their physicians to initiate the appeal for them, then completed AOR forms would still be required. We have slightly reworded our recommendation, to clarify our intent and eliminate any ambiguity, and included the revised language in the final report.

CMS agreed with our recommendation to ensure that sponsor-reported data are accurate and consistent by providing specific data definitions for the coverage determination and appeals measures. The agency noted that it has taken steps to modify the Part D Plan Reporting Requirements guidance on data element definitions. It plans to reinforce this guidance during upcoming calls with Part D sponsors, as well as in memoranda to sponsors, Frequently Asked Questions documents, and conference presentations. In addition, to minimize data entry errors, CMS has implemented data edit rules that will, among other things, reject a value that exceeds an expected range. It also developed procedures for sponsors to correct previously submitted information.

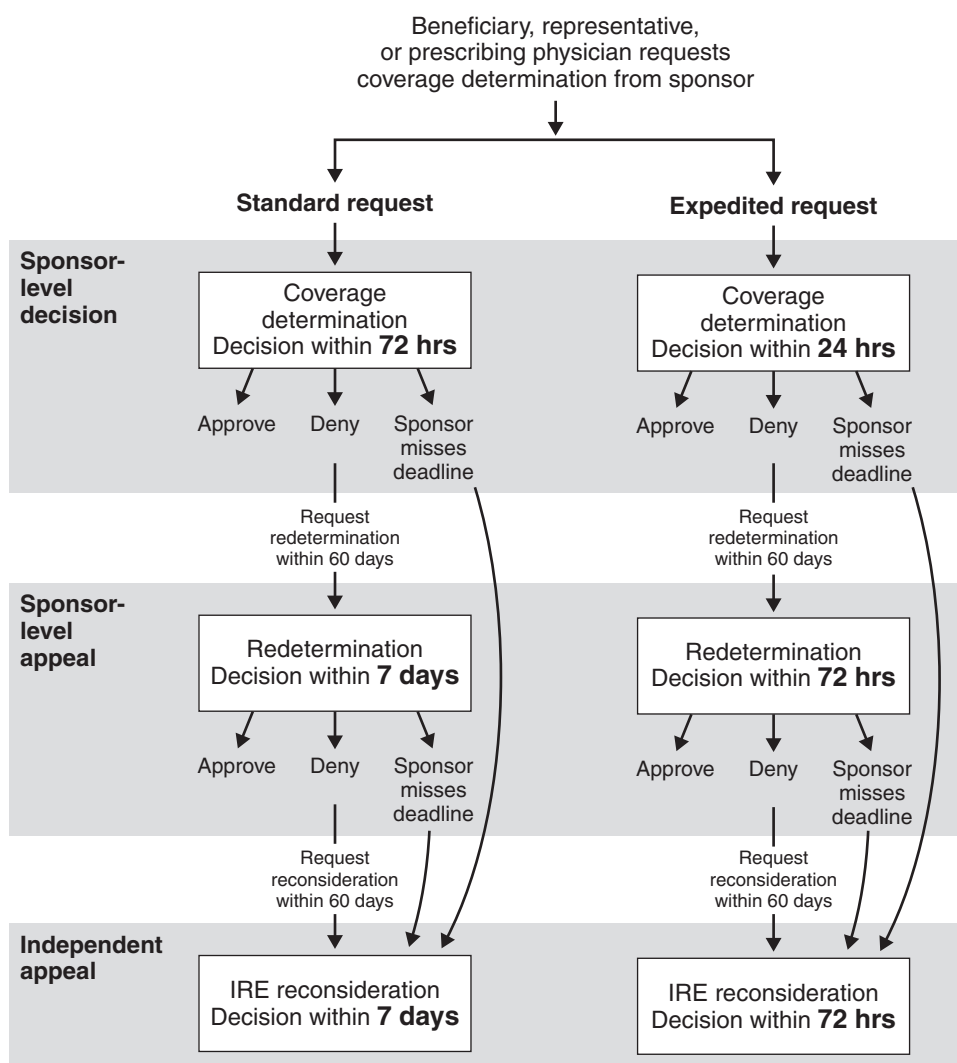
As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this report. We will then send copies to the Administrator of CMS, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request. This report is also available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact Kathleen King at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Kathleen M. King". The signature is written in a cursive, flowing style.

Kathleen M. King
Director, Health Care

Appendix I: Steps and Time Frames for Part D Coverage Determination and Appeals



Source: GAO analysis based on CMS information.

Notes: For coverage determinations, time frames generally begin when the sponsor receives a request; in some cases it begins when the sponsor receives the physician's supporting statement. In addition to the appeals levels shown, there are three other levels of appeal: administrative law judge hearing, a Medicare Appeals Council review, and federal district court review. This chart reflects situations in which expedited reviews have been granted.

Appendix II: Comments from the Centers for Medicare & Medicaid Services



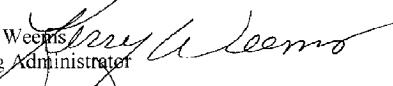
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: DEC 20 2007

TO: Kathleen M. King
Director, Health Care
Government Accountability Office

FROM: Kerry Weems 
Acting Administrator

SUBJECT: Government Accountability Office (GAO) Draft Report: "MEDICARE PART D: Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could Be Improved" (GAO-08-47)

Thank you for the opportunity to review and comment on the above GAO Draft Report. This study focused on the Part D Sponsors' process for drug coverage appeal determinations and CMS monitoring of such information via plan reported data.

We appreciate the GAO's thorough review of the issues involved, as well as the recommendations for enhancing CMS' current procedures. Overall, the report presents a balanced evaluation of the Medicare Part D coverage determination and appeals procedures and the associated data reporting procedures, and does an excellent job of highlighting various challenges of the Part D appeals process. As the GAO report cites, CMS developed two new measures related to the sponsors' timeliness and determination outcome of coverage decisions in the Medicare Plan Ratings available on www.Medicare.gov. These two measures, in combination with the other Medicare plan ratings, provide beneficiaries with valuable information to make informed decisions regarding plan selection. CMS is committed to providing clear differentiation of the various plans to beneficiaries, as well as utilizing effective data for operations and plan evaluation purposes.

CMS welcomes constructive suggestions on improving both the sponsors' adherence to Part D drug coverage processes, and CMS' oversight, and we are in the process of implementing some of the report's recommendations. For example, we have taken immediate steps to modify our Part D Plan Reporting Requirements guidance around data element definitions and plan to review this information during upcoming user calls.

We address each of the report's recommendations below, followed by detailed additional comments.

Page 2 – Kathleen M. King

GAO Recommendation

Reduce the need for completed appointment of representative (AOR) forms by requiring sponsors and the independent review entity (IRE), upon receipt of standard appeal requests by prescribing physicians, to telephone beneficiaries to determine their intention to initiate the appeal.

CMS Response

We support steps aimed at decreasing barriers to appeals and intend to consider carefully GAO's recommendation that the need for a signed AOR form can be reduced through a process where plans call beneficiaries when their physicians requests appeals on the members' behalf. However, we are concerned that GAO's recommendation does not fully consider the statutory and regulatory provisions associated with this requirement. The current Medicare Part D regulations place a limitation on physician representation of enrollees because section 1860D-4 of the Social Security Act provides that with respect to appeals at the IRE level and above, "...only a Medicare Part D eligible individual shall be entitled to bring such an appeal". We are not certain that any change to the current policy could be implemented without either a statutory change or, at a minimum, changes to the Medicare Advantage and Part D regulations.

Thus, we are carefully reviewing the current regulatory requirements about making appeal requests in light of the GAO recommendation. Based on this review, we intend to determine whether associated regulatory changes are appropriate and necessary. As CMS conducts this review and decides how best to proceed, CMS intends to continue working with physicians, through groups such as the American Medical Association and the American College of Physicians, to ensure that physicians promptly submit any needed AOR forms and medical documentation.

GAO Recommendation

Ensure that sponsor reported data used for monitoring coverage determination and appeals activities is accurate and consistent by providing specific data definitions for each measure.

CMS Response

CMS has extended many educational opportunities to sponsors and other stakeholders to reinforce the importance of providing accurate and consistent reporting requirements data. CMS has offered guidance via Medicare Part C and D User Calls, Health Plan Management System (HPMS) memos, Part D Plan Reporting Requirements Frequently Asked Questions documents, and presentations at numerous industry conferences. In addition, both the Part D Reporting Requirements email mailbox and the HPMS Help Desk provide sponsors with the opportunity to obtain assistance regarding technical and other policy related questions.

Page 3 – Kathleen M. King

The draft report lists several examples of sponsors' inconsistencies in reporting. CMS expects to continue providing clarification in the Part D Plan Reporting Requirements data elements and the Part D Plan Reporting Requirements Frequently Asked Questions documents to help increase consistency in reporting. Specific enhancements to the existing data descriptions are under discussion and review, and will be released once finalized.

Accuracy in plan-reported data is a priority for CMS. In an effort to minimize data entry errors, HPMS data edit rules have been implemented. An example of these data edit rules include HPMS rejection of a value that exceeds an expected range. CMS has also developed procedures for plans to correct previously submitted data.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen King, (202) 512-7114 or kingk@gao.gov

Acknowledgments

In addition to the contact named above, Rosamond Katz, Assistant Director; Lori Achman; Todd Anderson; Hazel Bailey; Krister Friday; Lisa Rogers; and Jennifer Whitworth made major contributions to this report.

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