



**U.S. Department of Health and Human Services
Office of Inspector General**

Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs

OEI-09-16-00411

September 2019

oig.hhs.gov

Suzanne Murrin

Deputy Inspector General
for Evaluation and Inspections





Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs

What **OIG** Found

Ideally, a Medicare beneficiary would be prescribed only medically necessary drugs, and would obtain any required preapprovals or exceptions before visiting a pharmacy so that prescriptions could be filled without extra steps. However, in 2017, Part D insurance companies (“sponsors”) rejected millions of prescriptions presented at pharmacies, and overturned a large number of drug-coverage denials when beneficiaries appealed. This pattern indicates that the ideal scenario does not always occur.

Key Takeaway

Some Medicare Part D beneficiaries faced extra steps to obtain drugs because their plans rejected prescriptions presented at pharmacies—or denied drug coverage requests—for avoidable or inappropriate reasons.

In 2017, sponsors’ automated systems rejected millions of prescriptions that beneficiaries tried to fill at pharmacies. Some of these rejections could have been avoided if the prescribed drugs were on the approved drug lists, met requirements, or received any required preapprovals. Although sponsors should reject prescriptions that do not meet requirements, the affected beneficiaries may still have needed medications and may have filed coverage requests, paid out of pocket, or contacted their providers to request different drugs. These extra steps can delay beneficiaries’ access to needed drugs, or deter them from getting them if they are unable or unwilling to navigate the process.

After receiving rejections at pharmacies, beneficiaries can file coverage requests, and if those are denied, they can appeal. Among coverage denials that beneficiaries appealed in 2017, sponsors fully overturned or partially overturned 73 percent. These overturned denials could have been avoided if sponsors had received, and correctly processed, all relevant information at the first request.

Through its oversight efforts, the Centers for Medicare & Medicaid Services (CMS) has determined that sponsors sometimes inappropriately rejected or denied pharmacy and drug coverage requests. These errors led to inappropriate denials or delays of beneficiary access to prescribed drugs.

What **OIG** Recommends and How the Agency Responded

We recommend that CMS (1) take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials; (2) take action to reduce inappropriate pharmacy rejections; (3) take action to reduce inappropriate coverage denials; and (4) provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials. CMS concurred with all four recommendations.

Why **OIG** Did This Review

This evaluation examines data and oversight related to Part D pharmacy rejections and coverage denials that, when issued for avoidable or inappropriate reasons, can lead to delays in beneficiary access to needed drugs. Part D is an optional benefit that helps beneficiaries pay for medically necessary prescription drugs. However, Part D’s shared-risk payment model can create an incentive for sponsors to deny requests for prescription drugs in an attempt to increase profits.

Because Part D covers more than 45 million beneficiaries, even low rates of denied or delayed medically necessary drugs or reimbursement could contribute to physical or financial harm for many Medicare beneficiaries.

How **OIG** Did This Review

For each Part D contract, we collected 2017 data on pharmacy rejections related to formulary and utilization management requirements and on coverage denials, appeals, and appeal outcomes. We calculated applicable volumes and rates. We also analyzed data from the independent entities that review the higher levels of Part D appeals.

To examine CMS audit findings, we analyzed the 2017 results for the Part D program audits and the related enforcement actions, and 2017 data from the formulary administration analysis. We also examined CMS websites to determine the location of information about sponsor performance.

TABLE OF CONTENTS

BACKGROUND	1
Methodology	7
<hr/>	
FINDINGS	
Many Part D beneficiaries experienced avoidable or inappropriate rejections of prescriptions at pharmacies	10
High overturn rates when beneficiaries appealed, and sponsor violations detected in audits, indicate that some Part D coverage denials were avoidable or inappropriate	13
Information about Part D sponsor performance problems related to pharmacy rejections and coverage denials is not easily accessible	16
<hr/>	
CONCLUSION AND RECOMMENDATIONS	
Take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials	18
Take action to reduce inappropriate pharmacy rejections	19
Take action to reduce inappropriate coverage denials	20
Provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials	20
<hr/>	
CMS COMMENTS AND OIG RESPONSE	22
<hr/>	
APPENDICES	
A: Medicare Part D Appeals Process	23
B: Detailed Methodology	24
C: Volumes and Rates of Part D Pharmacy Rejections, Coverage Determinations, and Appeal Outcomes, 2017	28
D: Volumes and Rates of Part D Denials Overturned by Independent Reviewers, 2017	29
E: CMS Comments	30
<hr/>	
ACKNOWLEDGMENTS	33

BACKGROUND

Objectives

1. To examine pharmacy rejections, and drug coverage denials, appeals, and overturns in Medicare Part D during 2017.
2. To examine CMS oversight findings related to pharmacy rejections and coverage denials during 2017.
3. To assess the public availability of information about Part D sponsor performance problems related to pharmacy rejections and coverage denials.

Structural factors in the Medicare Part D prescription drug program may in some cases lead to beneficiaries' being denied or delayed access to prescription drugs they need. In Part D, private insurers—called Part D sponsors—share insurance risk with the Medicare program for beneficiary drug spending.¹ Competition among sponsors encourages them to offer benefits that are attractive to beneficiaries, and to manage spending so that beneficiaries' premiums and cost-sharing remain affordable. However, because sponsors bear the risk for a portion of payments, they risk losing money if a beneficiary's drug spending is higher than they expect. This can create an incentive for sponsors to deny requests for prescription drug coverage in an attempt to increase their profits.

Complex Part D program rules, and short timeframes for processing requests, can also contribute to denial or delay of needed drugs. Sponsors are permitted to change the drugs that they cover every year, and the coverage rules for drugs are often complex. This can lead to confusion among prescribers and beneficiaries about which drugs are covered and how to meet coverage requirements, and may delay access while they navigate the process. When beneficiaries do file coverage requests, the short timeframes required for processing requests (intended to promote timely access to needed drugs) may lead to denials if sponsors are not able to obtain supporting information within the allotted timeframe. Sponsors receive millions of coverage requests each year and must issue a determination within 24-72 hours. Because Medicare Part D covers many beneficiaries (more than 45 million in 2019), even low rates of denied or delayed medically necessary drugs or reimbursement could contribute to physical or financial harm for many Medicare beneficiaries.

¹ Section 1860D-15(e) of the Social Security Act.

Medicare Part D

Medicare Part D is an optional prescription drug benefit available to Medicare beneficiaries. Beneficiaries can choose to enroll in Part D to supplement their traditional Medicare benefits or their Medicare Part C (Medicare Advantage) benefits. Of all Medicare beneficiaries, approximately three-quarters are enrolled in Part D.² In 2019, Medicare spending for Part D benefits is estimated to be \$99 billion.³

Sponsors administer the Part D benefit through one or more contracts with CMS to offer prescription drug plans.⁴ Part D sponsors can offer multiple plans that vary by prescription drugs covered, cost-sharing with beneficiaries, and in-network pharmacies. Each sponsor maintains a list of covered drugs, called a formulary, which is organized into tiers of cost-sharing between the plan and beneficiary. There are many Medicare requirements that govern how sponsors create and manage their formularies. At a minimum, sponsors must cover commonly needed drugs, and generally must offer at least two different drugs in each drug class and category.⁵

Part D sponsors contract with pharmacies to dispense prescription drugs to beneficiaries enrolled in their plans. When a beneficiary tries to fill a prescription at a pharmacy, the request is typically routed electronically from the pharmacy to the sponsor and any other applicable payers (such as secondary insurance). The sponsor's processing system then sends coverage and payment information back to the pharmacy. Point-of-sale processing occurs in real time and involves several steps to coordinate payment for a single claim.

Utilization Management and Pharmacy Rejections

Part D sponsors can omit certain drugs from prescription coverage and are allowed to impose utilization management requirements on drugs within certain parameters.⁶ Utilization management is an important tool to control costs and to ensure the safe use of drugs in Part D. Utilization management requirements include, for example, limiting the quantity that can be covered for certain drugs, or requiring that a beneficiary try a safer drug therapy before a more risky drug is covered. Sponsors are required to post their formularies and utilization management requirements on

² Kaiser Family Foundation, [Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing](#), May 17, 2018.

³ Congressional Budget Office, [Medicare—CBO's April 2018 Baseline](#), April 2018.

⁴ For the purpose of this report, we use the term "prescription drug plan" to refer to both "stand-alone" Medicare prescription drug plans and Medicare Advantage (Part C) prescription drug plans.

⁵ 42 CFR § 423.120(b)(2).

⁶ 42 CFR § 423.153(b).

their websites so that beneficiaries and prescribers can review them when deciding on the appropriate drug for the beneficiary's condition.⁷

To enforce utilization management requirements, sponsors can use automated rules that prevent a prescription from being billed to the sponsor when the beneficiary visits a pharmacy. When a beneficiary tries to fill a prescription for a drug that is not on the plan's formulary, or that does not meet a utilization management requirement (including any required preapprovals), the sponsor's processing system will automatically send a rejection notice back to the pharmacy. This type of automatic rejection at the pharmacy level is known as a "pharmacy rejection." CMS does not consider such rejections to be "official" Part D denials because the sponsor has not had the opportunity to review all relevant information. After an in-network pharmacy receives a rejection notification from the sponsor's system, the pharmacy must provide the beneficiary with a standardized notice that explains the beneficiary's right to request a coverage determination for the rejected prescription and how to contact the sponsor.

Part D Coverage Determination and Appeals Process

When needed, beneficiaries or their healthcare providers can request a coverage determination for approval to receive a drug and bill the sponsor for it, or for reimbursement for a drug already dispensed.^{8, 9} Coverage determinations include decisions about whether a beneficiary has fulfilled a utilization management requirement (e.g., whether a beneficiary needs a riskier drug after a safer drug therapy did not work), or whether to approve an exception to the sponsor's formulary or utilization management requirements (e.g., whether a beneficiary needs a dosage that is larger than the quantity limit for the drug). Beneficiaries can request coverage determinations before a drug is prescribed or after a prescription is rejected at the pharmacy. Sponsors review coverage requests, along with any supporting documentation, and approve,

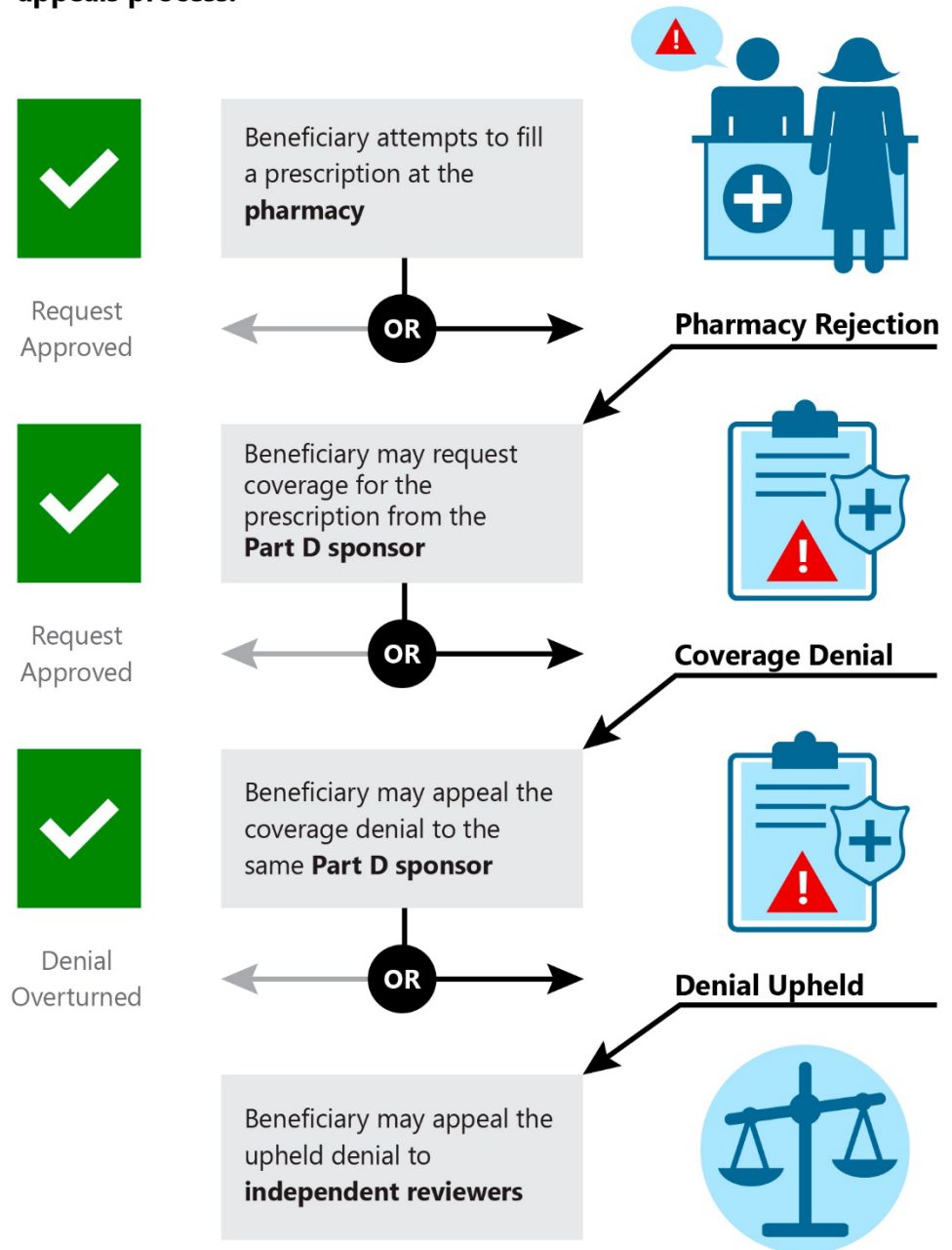
⁷ 42 CFR §§ 423.128(b)(4) and (d)(2).

⁸ Beneficiaries have the option to pay for a rejected drug at the pharmacy and then file a request for reimbursement. The *Medicare and You* handbook and plan coverage guidelines explain how to request reimbursement from plans. CMS, [Medicare & You](#), p. 91, 2019.

⁹ Some Part D sponsors delegate claims-processing responsibilities to other entities, such as pharmacy benefit managers. However, the sponsor is ultimately responsible for all coverage determinations, appeals, and grievances, even if the day-to-day responsibility is delegated to another entity.

partially approve, or deny the request.¹⁰ When beneficiaries receive a coverage denial, they have the right to file an appeal to try to get the denial overturned (see Exhibit 1).

Exhibit 1: When beneficiaries receive a rejection from their sponsor at a pharmacy, they can initiate the coverage determination and appeals process.



Source: OIG analysis of the Medicare Part D coverage determination and appeals process, 2019.

The Medicare Part D appeals process includes four levels of administrative review by several entities. At the first level, the Part D sponsor that issued the denial must revisit its original denial decision. When appeals continue to the higher levels, they are decided by independent reviewers within the

Department of Health and Human Services. At each level of review, the denial can be overturned, partially overturned, or upheld. If the denial is overturned, then the sponsor must authorize or pay for the prescription drug. If the denial is not fully overturned—if it is either upheld or partially overturned—the beneficiary can appeal the decision to the next higher level of review. See Appendix A for a detailed description of the Part D appeals process.

CMS Oversight of Medicare Part D

CMS uses several tools to oversee the provision of prescription drugs in Medicare Part D and to incentivize sponsors to improve their performance. These tools include formulary reviews; formulary administration analysis; program audits; and compliance and enforcement actions. CMS also provides guidance and model documents to clarify requirements for sponsors. For example, CMS provides model language for denial letters and requires sponsors to include clear instructions for beneficiaries on how to appeal denials.

Formulary reviews. CMS annually reviews Part D formularies to ensure that they include a range of drugs in a broad distribution of therapeutic categories or classes. As part of its formulary reviews, CMS assesses Part D sponsors' utilization management requirements to ensure consistency with current industry standards and with standards that are widely used with drugs for the elderly and people with disabilities.

Formulary administration analysis. Until 2019, each year, as part of the "formulary administration analysis" monitoring program, CMS reviewed a sample of pharmacy rejections to analyze how sponsors administer their formularies.¹¹ CMS selected a purposive sample of rejections for each contract that the sponsors administer. CMS then determined whether the rejections were consistent with program requirements, with the sponsor's approved formulary, and with the sponsor's approved utilization management requirements. CMS categorized rejections that do not meet these requirements as pharmacy rejection "failures" and calculates an overall failure rate for each contract. Pharmacy rejection failures included, for example, rejecting a prescription for a drug as being off-formulary

¹⁰ When a sponsor receives a request for benefits, it must notify the beneficiary of its determination within 72 hours or, for expedited requests, within 24 hours. Sponsors must notify beneficiaries of decisions related to reimbursement within 14 days. If a sponsor fails to make a decision within the required timeframe, it must forward the case to the Independent Review Entity for review, and notify the beneficiary that the case was forwarded. 42 CFR § 423 subpart M.

¹¹ As part of this monitoring program, CMS reviews a sample of pharmacy rejections for every Part D sponsor that is not being audited that year. The samples include pharmacy rejections relating to nonformulary status, prior authorization, step therapy, and quantity limits.

when it is in fact on the plan's formulary, or rejecting a prescription because of a quantity limit restriction that CMS had not approved. Sponsors that had failure rates higher than 20 percent for one or more of their contracts received a notice of noncompliance, at a minimum, along with a report containing the details of each rejection failure. In 2019, CMS ended the formulary administration analysis program (see page 11 for more information).¹²

Program audits. Each year, CMS audits a limited number of Part D sponsors.¹³ During the audits, CMS evaluates sponsors' compliance with requirements related to formulary administration, coverage determinations, and other beneficiary protections that Medicare requires. CMS requires sponsors to develop and implement corrective action plans to address any violations detected in audits and to demonstrate that they have corrected deficiencies before CMS officially closes the audit.

Compliance and enforcement actions. When CMS identifies noncompliance related to a Part D sponsor's delivery of prescription drug benefits, it may take compliance or enforcement actions against the sponsor.¹⁴ Such actions include issuing notices of noncompliance, issuing warning letters, imposing civil money penalties, imposing intermediate sanctions (i.e., suspension of marketing, enrollment, or payment), or terminating a contract.

Related Work

In a companion study, OIG examined national trends and CMS oversight of denied services and payment in Medicare Advantage during 2014–2016.¹⁵ We found that beneficiaries and providers appealed only 1 percent of preauthorization and payment denials, but among the denials that were appealed, Medicare Advantage organizations overturned 75 percent of their own denials. We also examined CMS audit results, which highlighted widespread and persistent performance problems related to denials of care and payment in Medicare Advantage. We recommended that CMS enhance its oversight of Medicare Advantage contracts; address persistent problems identified in its audits; and provide beneficiaries with clear, easily accessible information about serious violations detected in audits. CMS concurred with all three

¹² CMS, [Announcement of Calendar Year \(CY\) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter](#), pp. 146-148, April 2019.

¹³ CMS selects the sponsors based on several factors, including the quality ratings, past performance data, significant changes in enrollment, and whether the sponsor has been audited recently.

¹⁴ 42 CFR § 423.752.

¹⁵ OIG, [Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials](#) (OEI-09-16-00410), September 2018.

recommendations. Many insurance companies administer contracts that offer both Medicare Advantage benefits and Part D benefits, and so are included in both that report and this one.

Methodology

To meet the objectives of this study, we analyzed data and documentation from CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board. To ensure our understanding of the submitted data and documentation, we followed up in writing with officials knowledgeable about the program. This section provides a brief overview of the methodology. See Appendix B for a detailed methodology.

Examining Pharmacy Rejections, Denials, Appeals, and Overturned Denials

We analyzed 2017 performance data for each Part D contract to determine the volumes and calculate the rates of pharmacy rejections, coverage denials, appeals, and denials overturned upon appeal at the sponsor level. We were unable to include in our analysis contracts that did not meet CMS's data validation standards in any one of the fields that we used in our calculations.¹⁶

We used the 2017 annual performance data for contracts with validated data to examine pharmacy claims that were rejected at the point of sale (pharmacy rejections). The reported data include five reasons a pharmacy transaction may be rejected: nonformulary status, prior authorization requirements, step therapy requirements, quantity limit requirements, or "high-cost edits" for noncompounded drugs.^{17, 18} However, we (and CMS) cannot determine exactly how many pharmacy rejections occurred because the pharmacy rejection data may in some cases contain duplicates—i.e., may have counted an individual prescription rejection more than once.¹⁹ Therefore, using the pharmacy rejection data, we calculated the maximum possible number of pharmacy rejections by summing the number of rejections reported in each rejection category for

¹⁶ Of the 535 contracts that reported performance data in 2017, 36 contracts could not be included in our analysis because they did not meet CMS's data validation standards.

¹⁷ An "edit" is an automated system process that—in some cases—rejects coverage at the point of sale.

¹⁸ Pharmacy rejections can occur for other reasons not included in our data, such as administrative errors, safety edits (i.e., automated system processes that reject approval for certain drugs or combinations of drugs for safety reasons), and early refill attempts (i.e., beneficiary attempts to refill a prescription earlier than the sponsor allows).

¹⁹ According to CMS, individual prescription rejections may be counted more than once for several reasons. For example, a prescriber may write more than one prescription to test a beneficiary's coverage limits, or a pharmacy may submit a prescription to the sponsor multiple times while waiting for coverage approval to be entered into the sponsor's system.

all contracts, which is likely an overestimation of the true number of rejected prescriptions and we note that throughout the report. We also divided the maximum number of pharmacy rejections by the total number of pharmacy transactions to calculate the rejection rate that corresponds to the maximum number of possible rejections.

We used the 2017 annual performance data for contracts with validated data to examine coverage denials and appeals. To determine the coverage denial rate, we divided the number of denied requests plus partially denied requests by the total number of requests (the sum of approved requests, denied requests, and partially denied requests). To calculate the appeal rate, we divided the number of appeal decisions issued by the number of denials issued.

From the same data, we determined the total number of appealed denials that Part D sponsors overturned. To calculate the overturn rate, we divided the total number of appealed denials that were fully overturned plus appealed denials that were partially overturned by the total number of appeal decisions that were issued (the sum of appealed denials that were overturned, appealed denials that were partially overturned, and appealed denials that were upheld). We also calculated the overturn rates for each Part D contract.

To determine the volumes and calculate the rates of denials that independent reviewers overturned on appeal during 2017, we analyzed appeals data from the Independent Review Entity, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board.

Examining CMS's Oversight Findings Related to Pharmacy Rejections and Coverage Denials

We analyzed the final audit reports that CMS issued to sponsors that were audited for the elements "Part D Coverage Determinations, Appeals, and Grievances" and "Formulary Administration" during 2017. We reviewed the reports for the 36 audited Part D sponsors—which collectively administered 135 contracts—and determined the number of contracts that CMS cited for each type of violation.

To assess CMS's 2017 formulary administration analysis, we reviewed the 2019 Part D Display Measure Data. These data reflect the results of CMS's formulary administration analysis for the 412 contracts that CMS reviewed in 2017. We reviewed the data and identified the number of contracts for which CMS identified at least one pharmacy rejection failure in their sample and calculated the range of failure rates.

To examine the availability of information about sponsor performance problems related to pharmacy rejections and coverage denials, we reviewed the Medicare Plan Finder Website and other CMS websites.

Limitations

For this study, we examined aggregate Part D contract data on pharmacy rejections and on coverage denials, appeals, and appealed denials that were overturned. We did not independently determine whether prescriptions were medically necessary for beneficiaries according to medical standards or Medicare coverage standards, nor did we independently determine whether sponsors correctly reported their data to CMS. The pharmacy rejection data that we used in this report may in some cases contain duplicate rejection numbers for a single prescription. Therefore, we were unable to identify the exact number of prescription rejections that beneficiaries experienced at pharmacies, and instead we report the maximum possible number and indicate it as such. Our analysis focused on pharmacy rejections for nonformulary status and for not meeting utilization management requirements. Rejections for other reasons, such as safety edits or early refill attempts,²⁰ are not included in this report.

Additionally, because not all Part D contracts' data met CMS's standards for data validation, we were unable to include some contracts in our analysis. Thus, the absolute numbers that this report provides, such as the number of coverage denials overturned upon appeal, likely underrepresent the actual number in the Medicare Part D program. The percentages that this report provides could overrepresent or underrepresent the actual percentages in the Medicare Part D program.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

²⁰ See footnote 18 for more information about safety edits and early refill attempts.

FINDINGS

Many Part D beneficiaries experienced avoidable or inappropriate rejections of prescriptions at pharmacies

Ideally, a Medicare beneficiary would be prescribed only medically necessary drugs, and would obtain any required preapprovals or exceptions before visiting a pharmacy so that prescriptions could be filled without further steps. However, the millions of pharmacy rejections that occurred in 2017 demonstrates that this does not always happen. To control costs and ensure the safe use of prescription drugs, Part D sponsors are expected to reject prescriptions for drugs that do not meet plan requirements. This includes rejecting prescriptions for drugs that are not on the plan formulary or that do not meet utilization management requirements (e.g., dosages that exceed quantity limits). However, pharmacy rejections can in some cases create extra burden on Medicare beneficiaries to obtain needed medications, or may deter them from obtaining treatment. Pharmacy rejections can be avoided before the beneficiary arrives at the pharmacy if (1) prescribers have information about the plan formularies and utilization management requirements that apply to their patients; (2) prescribers use that information to prescribe covered drugs or to obtain any needed preapprovals or exceptions; and (3) sponsors appropriately process the claim.



A **pharmacy rejection** means a beneficiary tried to fill a prescription at a pharmacy, but the sponsor's system automatically rejected it (e.g., because the drug is not on formulary, or the dosage exceeds a quantity limit).

Sponsors rejected millions of prescriptions that beneficiaries tried to fill at pharmacies, potentially creating extra steps for beneficiaries that could have been avoided

In 2017, Part D beneficiaries experienced up to 84 million rejections when they tried to fill prescriptions at pharmacies. The sponsors we included in our analysis collectively reported processing 2.4 billion pharmacy transactions in 2017, so 84 million rejections would represent a 3.5-percent rejection rate. However, we (and CMS) cannot determine exactly how many pharmacy rejections occurred, because the pharmacy rejection data may in some cases contain duplicate counts for individual

prescription rejections.²¹ See Exhibit 2 for the data on pharmacy rejections for not meeting formulary or utilization management requirements.^{22, 23}

Exhibit 2: In 2017, sponsors rejected millions of prescriptions for not meeting plan **formulary and/or **utilization management** requirements.**

	Requirements	Rejections*
	Formularies list the drugs that plans cover. Any exceptions must be approved by sponsors.	43.0M
	Prior authorization requires sponsor approval before drugs can be dispensed at the pharmacy.	23.8M
	Quantity limit restricts the amount of a drug that can be dispensed for a given period of time.	14.5M
	Step therapy requires starting with more cost-effective or safer drugs before trying more costly or risky drugs.	2.4M

*Note: The number of pharmacy rejections reported may contain duplicates within or across categories.

Sources: OIG analysis of 2017 Part D annual performance data for contracts that reported validated data, 2019. OIG analysis of Federal regulations and CMS guidance, 2019.

CMS does not collect data on what beneficiaries do when they receive a pharmacy rejection. In some cases, the beneficiary or pharmacist may be able to resolve the issue before the beneficiary leaves the pharmacy. In other cases, the beneficiary may take extra steps, such as contacting the prescriber to request a different drug, filing a coverage request with the sponsor, or paying for the drug out of pocket. These extra steps may delay beneficiary access to needed drugs, or deter them from getting the drugs if they are unable or unwilling to spend time navigating the approval process.

²¹ According to CMS, individual prescription rejections may be counted more than once for several reasons. For example, a prescriber may write more than one prescription to test a beneficiary’s coverage limits, or a pharmacy may submit a prescription to the sponsor multiple times while waiting for coverage approval to be entered into the sponsor’s system.

²² The data we analyzed does not include pharmacy rejections for reasons other than formulary or utilization management requirements, such as administrative errors, safety edits, or early refill attempts.

²³ The numbers in this paragraph and Exhibit 2 are rounded. See Appendix C for the exact number of pharmacy transactions and rejections reported by the sponsors included in our analysis.

Although mechanisms exist to help avoid Medicare beneficiaries' having prescriptions rejected at their pharmacies, the large number of pharmacy rejections suggests that the mechanisms were not always used or effective. Part D sponsors are required to post their formularies and utilization management requirements on their websites so that health care providers and beneficiaries can review them when deciding which treatment is right for the beneficiary. If the provider determines that an off-formulary drug is needed, the provider (or the beneficiary) can request an exception to the sponsor's formulary in advance. Similarly, if the provider determines that the appropriate drug for the beneficiary needs preapproval, the provider can file a coverage request with the sponsor. However, the large number of pharmacy rejections related to off-formulary and utilization management requirements may indicate that providers did not check plan formularies or requirements before prescribing drugs, or that they were unable to find, understand, or follow the requirements.



One sponsor was cited for calculating allowed quantities incorrectly, leading to inappropriate pharmacy rejections for 3,324 beneficiaries.

Sponsors sometimes inappropriately rejected prescriptions that beneficiaries tried to fill at pharmacies

Two CMS oversight efforts demonstrate that in some cases Part D sponsors inappropriately rejected prescriptions that should have been approved. In 2017, as part of its Part D program audits, CMS cited 119 of the 135 audited contracts (88 percent) for at least one violation that resulted in inappropriate pharmacy rejections. Although some of these violations affected only a few beneficiaries, others affected thousands. The most common violation that resulted in inappropriate rejections was plans' imposing utilization management requirements that CMS had not approved. For example, CMS cited Part D sponsors for imposing quantity limits on drugs without CMS's approval, or using more restrictive quantity limits than CMS had approved. Unapproved utilization management requirements were among the most frequent violations detected in audits of Part D sponsors in every year from 2011 through 2017, except for 2015.

Also in 2017, CMS determined through its formulary administration analysis that 72 of the 412 contracts (17 percent) it reviewed had issued inappropriate pharmacy rejections. Through this analysis, CMS reviewed a purposive sample of pharmacy rejections (up to 30 cases) for every contract that it did not audit that year. Among the 72 contracts, failure rates ranged from 3 to 67 percent of the rejections that CMS examined. For the four contracts that had failure rates greater than 20 percent, CMS issued notices of noncompliance to three of them, and issued a warning letter to the fourth.²⁴ CMS found similar causes of inappropriate pharmacy rejections in its formulary administration analysis as in its

²⁴ A notice of noncompliance is the first level of notice that CMS issues, most often in response to the first or minor instances of noncompliance. A warning letter is the next level of notice, issued to address either repeat instances or more substantial first instances.

program audits, such as unapproved or incorrectly applied utilization management requirements. For example, CMS found that one Part D plan rejected a prescription for being above the quantity limit for the medication, but no quantity limit existed for that drug.

In 2019, CMS ended two Part D oversight efforts related to pharmacy rejections.

Recent changes in CMS's oversight of Part D will eliminate two of the data sources that we used in this report to examine Part D pharmacy rejections. Beginning in 2019, CMS stopped requiring Part D sponsors to report annual data on pharmacy rejections, and CMS discontinued its formulary administration analysis program. As a result of this change, CMS no longer annually collects any pharmacy rejection data from sponsors, except when a sponsor is under audit.

CMS stated that it ended these oversight efforts because they were no longer needed and were burdensome for Part D sponsors. In explaining its decision, CMS stated that in 2013, 27 percent of contracts included in the formulary administration analysis exceeded CMS's failure rate threshold, but in 2017 only 1 percent of contracts did. However, OIG notes that CMS's failure rate threshold was 20 percent, meaning that more than one in five pharmacy rejections would need to be inappropriate for a contract to exceed the threshold. As our analysis found, 72 contracts (17 percent) had at least one inappropriate rejection in their formulary administration analysis results in 2017, although only 4 contracts (1 percent) exceeded the 20-percent threshold. Additionally, CMS audits continue to find problems related to inappropriate pharmacy rejections.

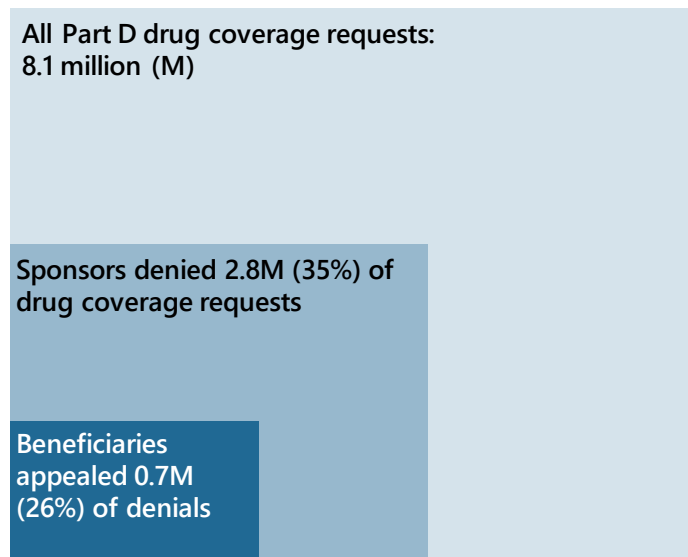
High overturn rates when beneficiaries appealed, and sponsor violations detected in audits, indicate that some Part D coverage denials were avoidable or inappropriate

Beneficiaries sometimes need drugs that require sponsor review and approval before the pharmacy can fill the prescription. In those cases, beneficiaries or their prescribers should request a coverage determination (i.e., a drug coverage request) from the Part D sponsor. As Exhibit 3 on page 14 shows, beneficiaries filed 8.1 million coverage requests with Part D sponsors in 2017. Of these coverage requests, sponsors fully denied or partially denied 2.8 million, about 35 percent. After receiving denials, beneficiaries took the extra step of appealing about one-quarter (744,987) of these denials. See Appendix C for the 2017 volumes and rates of Part D coverage determination and appeal outcomes.

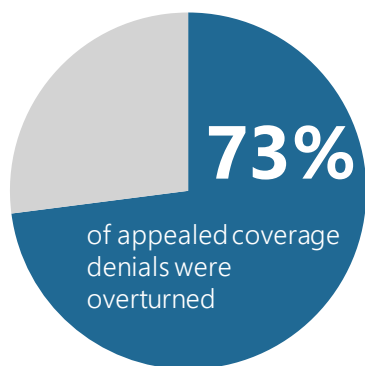


A **coverage denial** means the sponsor denied a request to fulfill, or be exempted from, plan requirements (e.g., utilization management restrictions or the plan's formulary).

Exhibit 3: In 2017, sponsors denied more than one-third of drug coverage requests.



Source: OIG analysis of 2017 Part D annual performance data, 2019.
Note: The numbers in this exhibit are rounded.



Sponsors overturned 73 percent of drug coverage denials that were appealed, indicating that some denials could have been avoided

When beneficiaries appealed coverage denials to their sponsors at the first level of appeal, they were usually successful in getting the denials overturned. Of the 744,987 appeals that beneficiaries filed in 2017, they were fully or partially successful in getting 543,590 denials overturned (73 percent). When sponsors upheld denials and beneficiaries chose to continue their appeals, independent reviewers at the higher levels of appeal fully or partially overturned an additional 6,902 Part D denials in favor of beneficiaries.²⁵ See Appendix D for the volumes and rates of denials that were overturned by each of the independent review entities.

A sponsor may overturn its initial denial upon appeal for several reasons. In some cases, the sponsor may determine that its original decision was incorrect, and therefore overturn the denial. In other cases, the sponsor may determine that the initial decision to deny coverage was correct based on the information available at the time, but find that the provider or beneficiary added new information in an appeal that demonstrates the denial should be overturned.

Although overturned denials do not necessarily mean that sponsors' initial denials were inappropriate, each overturned denial represents a case in which a beneficiary had to file an appeal to receive a medication that ideally would have been covered when initially requested. The extra step

²⁵ Independent reviewers overturned between approximately 19 and 31 percent of the appealed denials that they reviewed.

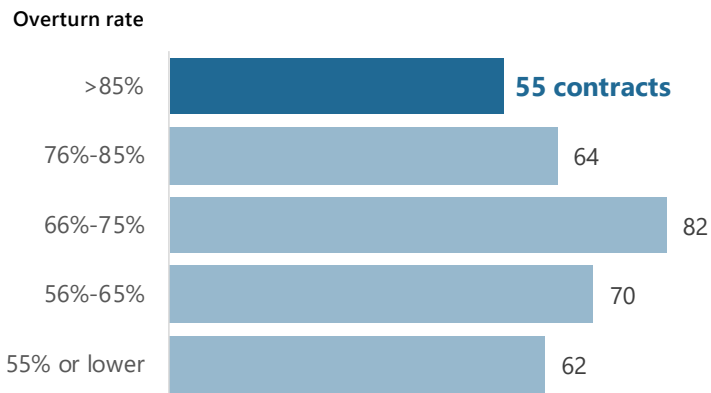
of appeal represents friction in the program, and may create an administrative burden for beneficiaries, prescribers, and Part D sponsors.

One contributing factor to the high number of denials in Part D may be the timeline requirements for processing coverage requests. In an effort to ensure the beneficiaries can get needed medications in a timely manner, Federal regulations require Part D sponsors to issue a determination within 24-72 hours of receiving a drug coverage request.²⁶ Therefore, when a sponsor is not able to obtain supporting information from the prescriber within the allotted timeframe, the sponsor may issue a denial and then process any subsequent information that it receives as part of an appeal of that denial. Thus, when coverage denials are overturned upon appeal, it suggests that at least some of the original denials could have been avoided if all of the information included in the appeal had been provided at the time of the first request.

Variations in rates at which Part D contracts overturned denials may indicate differences in sponsor behavior or performance. In 2017, overturn rates by contract ranged from approximately 21 to 98 percent, with a median of 69 percent.²⁷ On the high end, 55 Part D contracts overturned more than 85 percent of their own denials upon appeal (see Exhibit 4).

Exhibit 4: Part D contracts' overturn rates varied widely in 2017.

Fifty-five contracts overturned more than 85% of denials upon appeal.



Source: OIG analysis of 2017 Part D annual performance data for contracts that received at least 50 appeals, 2019.

²⁶ Sponsors must notify the beneficiary of drug coverage determinations within 24 hours for expedited requests and within 72 hours for standard requests. They must notify beneficiaries of reimbursement determinations within 14 days. 42 CFR §§ 423.568 and 423.572.

²⁷ We calculated the range and median of contract-specific denial overturn rates for the 333 Part D contracts that received at least 50 appeals and reported validated data in 2017.



Several sponsors were cited for inappropriately instructing beneficiaries to go back to their prescribers to request drug coverage—misclassifying hundreds of beneficiary coverage requests as “inquiries.”

Sponsors sometimes processed drug coverage requests incorrectly, leading to inappropriate denials or delays

In 2017, CMS cited 76 of the 135 Part D contracts that it audited (56 percent) for at least one coverage determination process violation that led to beneficiaries’ not receiving drugs, or led to delays in beneficiary access to drugs or reimbursement. Although some of these violations affected only a few beneficiaries, others affected thousands.

The most common violation that led to inappropriate denials or delays was misclassifying beneficiary coverage requests as grievances or customer service inquiries. Such misclassification denies the beneficiary an opportunity to appeal because the plan does not formally deny the coverage request. Further, the beneficiary either may not get the medication or may have to pay for it out-of-pocket. CMS has identified this “misclassification” violation as a persistent problem; it was one of the most common violations detected in audits of Part D sponsors each year during 2011-2017. CMS attributed these violations to Part D sponsors’ having inappropriate procedures, insufficiently training their staff, or lacking adequate oversight of this aspect of operations.

Information about Part D sponsor performance problems related to pharmacy rejections and coverage denials is not easily accessible

Information about problems that CMS identifies with Part D sponsor performance (e.g., violations detected in audits) or corrective actions that CMS imposes (e.g., civil money penalties) can be difficult to locate because some information is not publicly available, and other information is spread across multiple CMS websites. As a result, beneficiaries may not be aware of some sponsor performance problems when making decisions about which Part D plan to enroll in. The Medicare Plan Finder is a Federal government website managed by CMS that beneficiaries can use to compare and select a Part D plan. Although the website provides a composite quality rating (known as a Star Rating) for each Part D contract, and signals if a sponsor is under sanction, it does not provide detailed information about the results of CMS audits, violations cited by CMS, or civil money penalties that CMS imposes on sponsors. Rather, beneficiaries would need to navigate to other CMS websites that were not designed to be as user-friendly as Medicare’s Plan Finder (see steps in Exhibit 5 on page 17).

Exhibit 5: Medicare beneficiaries would have to take several steps to find certain performance data for Part D sponsors.

Steps to find a sponsor's complete **audit results** (including violations and corrective actions):

- X** Not publicly available.

Steps to find a sponsor's **pharmacy rejection failure rate**:

1. Navigate to the "[Part C and D Performance Data](#)" page on CMS's website.
2. Download the compressed folder with the Star Ratings and Display Measures data for the desired year.
3. Find the data file in the compressed folder that contains the display measures.
4. Identify column "DMD15" for the formulary administration analysis measure.
5. Find the cell that contains the failure rate for the desired Part D contract.

Steps to find a sponsor's **civil money penalties**:

1. Navigate to the "[Part C and D Enforcement Actions](#)" page on CMS's website.
2. Search by sponsor name to find any Civil Money Penalty Notices.
3. Download the notice, review to identify the sponsor performance problems that led to the penalty.

Source: OIG analysis of CMS websites, 2019.

The results of CMS's oversight provide valuable information about sponsor performance that can be useful to Medicare beneficiaries and their health care providers and advocates. For example, ready access to information about civil money penalties that CMS imposes on a sponsor, and the violations that led to the penalties, might help beneficiaries avoid plans that have serious and repeated performance problems.²⁸ However, as recently as April 2018, CMS expressed its concern that "beneficiaries typically do not go to [the enforcement actions website] when evaluating plans for enrollment."²⁹

CMS's approach in Part D differs from its approach in other arenas. For example, on the Nursing Home Compare website, CMS publishes the full results from surveys of nursing homes, including any cited violations, penalties, or other enforcement actions. The Nursing Home Compare website encourages beneficiaries to use these results as one source of information when choosing a nursing home.

²⁸ As a result of the 2017 audits, CMS issued a total of \$2.4 million in civil money penalties to 16 sponsors for Part D violations detected in audits. This total does not include penalties issued to these sponsors related to the administration of Medicare Part C benefits.

²⁹ CMS, [Announcement of Calendar Year \(CY\) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter](#), April 2018.

CONCLUSION AND RECOMMENDATIONS

In 2017, Medicare Part D beneficiaries faced millions of pharmacy rejections and drug coverage denials when their sponsors did not initially approve the drugs that their health care providers prescribed. Although sponsors are expected to reject any prescriptions that do not meet program requirements in order to control costs and ensure the safe use of drugs, our analysis raises concerns that in many cases these pharmacy rejections or drug coverage denials were avoidable, and were in some cases issued inappropriately. Some of these beneficiaries may have gone without treatment, paid for the drug out of pocket, or had to take extra steps to receive approval for the prescribed drug or an alternative. Any avoidable or inappropriate extra steps to receive treatment can cause unnecessary delays and administrative burdens for beneficiaries, prescribers, and sponsors. Although CMS uses several compliance and enforcement tools to address sponsor performance problems related to pharmacy rejections and drug coverage denials, in 2019 it ended two of its oversight efforts related to pharmacy rejections. More action is needed to reduce inappropriate and avoidable coverage denials and pharmacy rejections.

Therefore, we recommend that CMS:

Take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials

To reduce avoidable pharmacy rejections and coverage denials, CMS should take additional steps to work with sponsors to make beneficiary-specific drug coverage and cost information visible to prescribers who want to consider that information when prescribing. CMS has already taken some important steps toward this goal. For example, its May 2019 final rule requires Part D sponsors to implement an electronic real-time benefit tool capable of integrating with prescribers' e-prescribing and electronic health record systems by January 2021.³⁰ CMS has also proposed requiring sponsors to support a standard for electronic prior authorization.³¹ Effective use of a real-time benefit tool and electronic prior authorization could decrease pharmacy rejections and unnecessary use of the coverage determination and appeals process.

However, the final rule requires sponsors' real-time benefit tools to be able to integrate with only one e-prescribing or electronic health record system (at a minimum). Although this is a good first step, further

³⁰ 84 Fed. Reg. 23832, 23847-51 (May 23, 2019).

³¹ 84 Fed. Reg. 28450, 28450-28458 (June 19, 2019).

expansion of this effort will likely be needed to ensure that sponsors' systems can communicate with as many prescribers' systems as possible. In addition, CMS acknowledged that without an industry standard for real-time benefit tools, prescribers may be offered multiple options. This may create a burden for vendors of electronic health record systems, and may have limited utility for prescribers if the tools do not integrate with their systems.

Therefore, after January 2021, CMS should examine sponsors' implementation of the requirement for an electronic real-time benefit tool. CMS's examination should include not only whether sponsors implemented such a tool, but whether the tools are being used. OIG recognizes that a full-scale evaluation of the effectiveness of every real-time benefit tool is not feasible or cost-effective. Rather, CMS could have discussions with sponsors about the extent to which their chosen tools are able to integrate with prescribers' systems, for example, and could consult with provider groups about the extent to which the sponsors' tools provide reliable, useful, and beneficiary-specific information to prescribers. CMS should then use the results of its efforts to expand, modify, or replace its requirements, as appropriate, to continue to improve communication between sponsors and prescribers and to reduce avoidable pharmacy rejections and coverage denials throughout the Part D program.

We also encourage CMS to reach out to stakeholders—such as the National Council for Prescription Drug Programs and the Office of the National Coordinator for Health Information Technology—to explore developing a national standard for real-time benefit tools and to explore incentives for integration of these tools into e-prescribing and electronic health record systems.

Take action to reduce inappropriate pharmacy rejections

In addition to the audits that it already conducts, CMS should conduct targeted oversight of pharmacy rejections each year to ensure that sponsors are not inappropriately rejecting beneficiary prescriptions at pharmacies. In 2017, CMS cited 88 percent of audited contracts with at least one violation that resulted in inappropriate pharmacy rejections. Although CMS oversight efforts such as the formulary administration analysis indicate that Part D sponsors have made progress in improving compliance, the large number of pharmacy rejections issued each year underscores the need for ongoing oversight to protect beneficiary access to needed drugs. However, during the course of this evaluation, CMS ended two oversight efforts related to pharmacy rejections: it stopped collecting annual pharmacy rejection data from sponsors, and stopped the formulary administration analysis program. Given the persistent audit findings related to inappropriate pharmacy rejections, and that

beneficiaries experience tens of millions of pharmacy rejections every year, OIG finds the cessation of these oversight efforts concerning.

To implement this recommendation, CMS should develop a risk-based approach to identify which sponsors warrant targeted oversight related to pharmacy rejections each year. To achieve this, CMS could develop and implement a new oversight mechanism, or could reconsider ending one of the oversight efforts that it had in place. Using the results of its targeted oversight, CMS should provide technical assistance, and issue compliance or enforcement actions as needed.

Take action to reduce inappropriate coverage denials

To reduce inappropriate coverage denials, CMS should analyze the annual performance data that it already collects from sponsors and identify those that warrant targeted oversight. CMS should conduct contract-specific or sponsor-specific analysis and identify sponsors with extreme rates, such as extremely high denial and denial overturn rates. CMS should engage with these sponsors to determine whether they are meeting program requirements and take corrective action as appropriate. Engagement could include having account managers meet with sponsors to determine why they had extreme rates, conducting a small probe review of denial or appeal cases, or other steps to determine the root causes of the rates. If through these efforts CMS determines that a sponsor is not meeting program requirements, it should take appropriate corrective or enforcement action to improve compliance. These actions could include providing technical assistance, ongoing monitoring, conducting additional audits, or issuing civil money penalties.

Provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials

Details about sponsor violations detected in audits, including those that lead to civil money penalties and other enforcement actions, are a valuable source of information for beneficiaries to consider when choosing a Part D plan. CMS should develop a method for informing beneficiaries about these serious performance problems. The information should be clear, meaningful, and easily accessible to beneficiaries in places where beneficiaries typically access information, such as on the Medicare Plan Finder website. CMS already includes information about the most serious performance problems (those that led to sanctions) on the Plan Finder website, and it could expand this effort to include information about all audit-detected violations and civil money penalties, similar to what it does on its Nursing Home Compare website.

CMS could also revisit policy options for adjusting plans' quality ratings (called Star Ratings) in response to audits and enforcement actions, such

as adding a new performance measure that takes enforcement actions into account, or by directly adjusting a sponsor's overall and summary ratings in response to enforcement actions. This would help to ensure that quality ratings serve as a "one-stop shop" on the Medicare Plan Finder website for beneficiaries to evaluate differences in performance among sponsors.

CMS COMMENTS AND OIG RESPONSE

In response to the draft report, CMS stated that it is committed to ensuring that Medicare Part D beneficiaries have access to the drugs they need, and it concurred with all four of our recommendations.

CMS concurred with our first recommendation, for it to take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials. CMS stated that after the requirement for real-time benefit tools goes into effect in January 2021, it will examine sponsors' implementation of the tools.

CMS concurred with our second recommendation, for it to reduce inappropriate pharmacy rejections through targeted oversight. CMS stated that to address this recommendation, it will continue monitoring pharmacy rejections to ensure that sponsors maintain the current level of performance and will examine ways to reduce inappropriate rejections if performance decreases. However, CMS did not indicate how it would identify which sponsors warrant targeted oversight of pharmacy rejections each year, or what that oversight may consist of, particularly in light of CMS's recently ending two oversight efforts related to pharmacy rejections.

CMS concurred with our third recommendation, for it to take action to reduce inappropriate denials through targeted oversight. CMS stated that it will analyze annual performance data from sponsors and determine how to provide additional oversight to prevent unnecessary coverage denials.

CMS concurred with our fourth recommendation, for it to provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials. CMS noted that it is currently gathering feedback from beneficiaries and stakeholders about what information consumers would like to see on the Medicare Plan Finder website, and said that it will consider changes after reviewing the feedback. However, CMS did not indicate whether it is soliciting feedback specifically related to sponsor performance problems.

For the full text of CMS's comments, see Appendix E.

APPENDIX A: Medicare Part D Appeals Process

The Medicare Part D appeals process includes four levels of administrative review by several entities. At each level of review, the denial can be overturned, partially overturned, or upheld. If the denial is overturned, then the sponsor must authorize or pay for the prescription drug. If the denial is not fully overturned—either upheld or partially overturned—the beneficiary can appeal the decision to the next higher level of review.

First-level appeals: Part D sponsor. At the first level of appeal, the Part D sponsor must redetermine its decision to deny coverage or reimbursement for the drug. The sponsor must review the evidence that led to the original decision and any additional evidence that the beneficiary or prescriber submits as part of the appeal. If the sponsor does not process the appeal within required timeframes, it must forward the appeal to the Independent Review Entity for review.³² If the sponsor upholds its original denial, the beneficiary can appeal to the next level.

Second-level appeals: Independent Review Entity. The Independent Review Entity reviews appealed denials that sponsors upheld to determine whether the sponsor made the correct decision.³³ The Independent Review Entity is a CMS contractor that employs physicians and other consultants to review the denials and determine whether sponsors complied with relevant Medicare requirements. If the Independent Review Entity upholds a denial or partially overturns it, the beneficiary can appeal to the next level.

Third-level appeals: Office of Medicare Hearings and Appeals.

Administrative law judges or attorney adjudicators within the Office of Medicare Hearings and Appeals review appeals of Independent Review Entity decisions. If the beneficiary is dissatisfied with the decision of the Office of Medicare Hearings and Appeals, he or she can appeal to the next level.

Fourth-level appeals: Departmental Appeals Board. The Departmental Appeals Board's Medicare Appeals Council reviews appeals of decisions made by the Office of Medicare Hearings and Appeals. The Council provides the last level of review within the Department of Health and Human Services' process for appealing decisions in Medicare Part D. If a beneficiary is dissatisfied with the decision of the Council, he or she can appeal to Federal district court by filing a civil action.

³² 42 CFR § 423.590(c).

³³ In Part D, some Independent Review Entities are referred to as Part D Qualified Independent Contractors.

APPENDIX B: Detailed Methodology

For this study, we analyzed Medicare Part D data and documentation to examine, for 2017: (1) pharmacy rejections, and coverage denials, appeals, and overturns; (2) CMS oversight findings related to pharmacy rejections and coverage denials; and (3) beneficiary access to information about performance problems related to pharmacy rejections and coverage denials. To ensure our understanding of the submitted data and documentation, we followed up in writing with officials knowledgeable about the program.

Examining Pharmacy Rejections, Denials, Appeals, and Overturned Denials

We collected and analyzed annual performance data from CMS for each Part D contract for 2017. CMS requires sponsors to report annual performance-related data for each contract that they administer.³⁴ Among other data, sponsors must report the number of transactions at the pharmacy counter and the number of pharmacy rejections. Sponsors must also report the total number of coverage determinations and their outcomes (i.e., the number of requests for coverage of prescription drugs that the sponsor approved and denied), and the number of appeals and their outcomes. These data go through two external reviews to verify the validity of the reported data.³⁵

The datasets that CMS provided to OIG did not include contract-specific data for fields that did not meet CMS's validation standards. For example, some contract data passed validation standards for the number of denials overturned upon appeal, but not for the number of denials upheld. This prevented us from calculating an overturn rate for those contracts. Therefore, we could not include in our analyses any contracts that had missing values in any fields that we used in our calculations. Exhibit 6 on page 25 shows the number of contracts that were and were not included in our analysis, and the number of beneficiaries associated with those contracts. The contracts that we included in our analysis covered 98 percent of Part D beneficiaries.

³⁴ 42 CFR § 423.514(a)

³⁵ For more information on CMS's data validation process, see CMS's [Part C and Part D data validation](#) website.

Exhibit 6: OIG could not analyze annual performance data for 36 contracts because some of the contracts’ 2017 data did not meet CMS’s validation standards.

Contracts included in OIG analysis	Beneficiaries enrolled in contracts included in analysis	Contracts not included because of data validation issues	Beneficiaries enrolled in contracts not included in analysis
499	39,841,464	36	1,020,002

Source: OIG analysis of 2017 Part D annual performance data, 2019.

Pharmacy rejections. To calculate the volume and rate of pharmacy rejections, we analyzed the 2017 annual performance data for contracts with validated data. CMS requires sponsors to report data on certain pharmacy claims that are rejected at the point of sale (i.e., “pharmacy rejections”), including rejections for nonformulary status, prior authorization requirements, step therapy requirements, quantity limit requirements, and “high-cost edits” for noncompounded drugs.³⁶ Pharmacy rejections for other reasons, such as administrative errors, safety edits, or early refill attempts, are not included in the data. CMS notes that in some cases prescriptions may be counted twice in the pharmacy rejection data. Because of this, we were unable to calculate the exact number of pharmacy rejections issued in 2017. Instead, we calculated the maximum possible number of rejections and note that it is likely an overestimation of the true number of rejections that beneficiaries experienced.

To determine the maximum number of rejections, we summed the number of pharmacy rejections that sponsors reported for each rejection category for all of their contracts with validated data. To determine the maximum rejection rate, we summed all pharmacy rejections across all contracts and divided by the total number of pharmacy transactions for all contracts. This analysis is consistent with analyses published by CMS.³⁷ See Appendix C for the maximum number and rate of pharmacy rejections across all contracts.

Sponsor coverage denials, appeals, and overturns. To examine coverage denials, appeals, and overturned denials at the sponsor level, we analyzed the 2017 annual performance data for contracts with validated data. We calculated the total number of full and partial denials that sponsors issued in 2017. To calculate the denial rate, we divided the total number of full and partial denials by the total number of coverage determinations.

³⁶ CMS, *Analysis of CY2016 Medicare Part D Reporting Requirements Data* p. 13, May 2018.

³⁷ Ibid, pp. 14 and 30. CMS reported the number and percentage of pharmacy transactions rejected in 2016 by rejection reason, but did not add them up to calculate an overall number of rejections or rejection rate. As of July 2019, CMS had not released its analysis of the 2017 data.

To calculate the appeal rate, we divided the number of appeal decisions issued by the total number of full plus partial denials.

We calculated the total number of appealed denials that Part D sponsors fully and partially overturned in 2017. To calculate the overturn rate, we divided the total number of fully plus partially overturned appealed denials by the total number of overturned, partially overturned, and upheld appealed denials. See Appendix C for the volumes and rates of Part D appeal outcomes.

In the annual performance data, Part D sponsors report the number of appeal decisions that they issued in each year, but not the dates that the appeals were filed, or the original denials were issued. Therefore, some of the appeal decisions made early in 2017 were likely for denials issued in 2016, which were not captured in our data. Similarly, some of the denials issued at the end of 2017 were likely not appealed until 2018, and so those appeal decisions were also not captured in our data. We could not adjust the appeal rate based on when denials were issued and appeals were filed, so we calculated the first-level appeal rate by dividing the total number of appeal decisions issued by the number of denials issued during the same period (calendar year 2017).

To examine the contract-specific denial overturn rates, we analyzed the 2017 annual performance data for the contracts that reported validated data. Because contract-specific rates can be skewed by low volumes, we did not include low-volume contracts in this analysis. Therefore, we analyzed data only for the 333 contracts that received at least 50 appeals.

Independent Reviewer appeals and appeal outcomes. To calculate the volumes and rates of overturned denials for the independent reviewers, we collected data on appeal decisions issued by each entity during 2017 from CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board. Because independent reviewers reported their own appeals data, we were able to examine higher level appeals for all Part D contracts, including contracts that we could not examine at the sponsor level because of data validation issues.

To calculate the volume of denials overturned by each reviewer during 2017, we added the number of overturned denials to the number of partially overturned denials. To calculate the denial overturn rates, we divided the number of overturned plus partially overturned denials by the number of denials that were overturned, partially overturned, or upheld by the reviewer. We did not examine appeals for which the entity did not affirm or reverse the previous decision, such as appeals that were dismissed, withdrawn, or that resulted in an administrative action (e.g. remanding back to a lower appeal level). See Appendix D for the volume and rate of overturned denials for each independent reviewer.

Examining CMS's Oversight Findings Related to Pharmacy Rejections and Coverage Denials

To assess CMS's 2017 program audit findings and enforcement actions related to Part D pharmacy rejections and coverage determinations, we reviewed documentation from CMS. To determine the number of contracts that CMS cited for each type of audit-detected violation, we analyzed the final audit reports that CMS issued to Part D sponsors that were audited for "Coverage Determinations, Appeals, and Grievances" and "Formulary Administration" during 2017. We reviewed the 39 reports for the 36 audited Part D sponsors that collectively administered 135 contracts.³⁸

To assess CMS's 2017 formulary administration analysis, we reviewed the 2019 Part D Display Measure Data. This data reflects the results of CMS's formulary administration analysis for the 412 contracts that CMS reviewed in 2017. We reviewed the data and identified the number of contracts for which CMS identified at least one failure in their sample, and calculated the range of failure rates. We also reviewed internal CMS documentation about the pharmacy rejection failures.

To determine the amount of civil money penalties that CMS issued in response to the 2017 Part D program audit findings we reviewed internal CMS documentation for the 18 Part D sponsors that received a penalty. To examine the availability of information about audit-detected violations and pharmacy rejections, we reviewed the Medicare Plan Finder Website and CMS's website.

³⁸ The number of audit reports was more than the number of unique sponsors because one sponsor was audited twice, and another sponsor had three separate audits that covered different contracts.

APPENDIX C: Volumes and Rates of Part D Pharmacy Rejections, Coverage Determinations, and Appeal Outcomes, 2017

Part D contracts included in this analysis **499**

Pharmacy Outcomes (may contain duplicates)

Total number of pharmacy transactions	2,426,377,880
Maximum number of rejections	83,771,736
<i>Not on formulary</i>	43,048,107
<i>Prior authorization not obtained</i>	23,793,071
<i>Exceeds quantity limit</i>	14,505,344
<i>Step therapy requirement not fulfilled</i>	2,377,130
<i>Rejection due to high-cost edits for noncompounded drugs</i>	48,084
Maximum rejection rate	3.45%

Coverage Determination Outcomes

Total number of coverage determinations*	8,119,779
<i>Number of fully adverse determinations</i>	2,800,004
<i>Number of partially adverse determinations</i>	27,644
<i>Number of fully favorable determinations</i>	5,292,131
Denial rate	34.82%

First-Level Appeal Outcomes

Total number of appeals*	744,987
<i>Number of denials overturned</i>	538,969
<i>Number of denials partially overturned</i>	4,621
<i>Number of denials upheld</i>	201,397
Rate of appeal to Part D sponsor	26.35%
Rate of successful appeal (denials overturned or partially overturned)	72.97%

* The number of coverage determinations and appeals presented in this report do not include requests that were dismissed or withdrawn.

Source: OIG analysis of 2017 Part D annual performance data for contracts that reported validated data, 2019.

APPENDIX D: Volumes and Rates of Part D Denials Overturned by Independent Reviewers, 2017

Independent Review Entity

Number of appeal decisions issued	34,687
<i>Number of denials overturned or partially overturned</i>	6,516
Rate of denials overturned	18.79%

Office of Medicare Hearings and Appeals

Number of appeal decisions issued	1,244
<i>Number of denials overturned or partially overturned</i>	335
Rate of denials overturned	26.93%

Departmental Appeals Board

Number of appeal decisions issued	167
<i>Number of denials overturned or partially overturned</i>	51
Rate of denials overturned	30.54%

Source: OIG analysis of 2017 Part D data from CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board, 2019.

APPENDIX E: CMS Comments




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP - 3 2019

TO: Suzanne Murrin
Deputy Inspector General, Office of Evaluation and Inspections

FROM: Seema Verma
Administrator 

SUBJECT: Office of Inspector General (OIG) Draft Report: Some Medicare Part D Beneficiaries Face Avoidable Extra Steps that Can Delay or Prevent Access to Prescribed Drugs (OEI-09-16-00411)

The Center for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on this draft report. CMS is committed to ensuring Medicare Part D beneficiaries have access to the drugs they need.

Many Medicare beneficiaries opt into Medicare prescription drug coverage by enrolling in prescription drug plans that provide the Medicare Part D benefit. Coverage varies from plan to plan, but each prescription drug plan must provide at least a standard level of coverage set by Medicare.

Timely access to necessary drugs is a top priority for CMS, and it is important to note that, often times, the initial reason a beneficiary's drug is not available can be resolved before the beneficiary leaves the pharmacy. A beneficiary could initially be told their Part D drug could be unavailable because it is not on the plan formulary, prior authorization was not obtained, its quantity limits would be exceeded, or step therapy requirements were not met. In these cases, the pharmacist can, for example, contact the beneficiary's Part D sponsor to check step therapy requirements or contact the prescriber to change the medication to an alternative on the formulary. Because many of these issues are resolved through additional coordination among the beneficiary's prescriber, plan, and pharmacy, appeals of denied drug coverage requests in the Part D program are low compared to appeals in other Medicare programs, as OIG noted.

CMS regularly conducts activities to ensure plans are not inappropriately rejecting prescriptions that beneficiaries try to fill at pharmacies. For example, CMS reviewed 30 pharmacy rejections that were at high risk for being inappropriate from every Part D contract. The analysis showed that, in 2017 (the year of the OIG's review), less than one percent of the contracts had an inappropriate rejection rate greater than 20 percent, and the median plan in 2017 had zero inappropriate pharmacy rejections. Because CMS was reviewing a purposive sample of pharmacy rejections that were at high risk for being inappropriate, the inappropriate pharmacy rejection rates in our analysis are likely much higher than the plans' actual inappropriate pharmacy rejection rates.

CMS also conducts oversight of plan sponsors and has programs in place to help plan sponsors meet program requirements and help beneficiaries select prescription drug plans. For example,

CMS conducts program audits that measure a sponsoring organization's compliance with Medicare program requirements, including the requirements related to a beneficiary's access to covered medical services and prescription drugs. Through these audits, CMS ensures plan sponsors are not inappropriately rejecting prescription drugs at the pharmacy. Sponsors also receive regular assistance from CMS account managers, including when sponsors have issues program requirements.

CMS has encouraged sponsor support of real-time benefit tools (RTBT), and in a recent final rule, required sponsors to implement one or more RTBTs that are capable of integrating with at least one prescriber's e-prescribing or electronic health record by January 1, 2021.¹ RTBTs currently used in the industry make beneficiary-specific drug coverage information visible to prescribers at the point of prescribing, which allows them to prescribe covered medications and avoid pharmacy rejections. However, CMS recognizes that without an industry standard for RTBT, prescribers may be offered tools that are not integrated with their own e-prescribing or electronic health record systems, thus limiting its utility. As we stated in the final rule adopting the RTBT requirement, CMS would have preferred to consider and name a single industry standard for use in Part D, had it been available. The National Council for Prescription Drug Programs (NCPDP) is currently developing an industry-wide standard for RTBT and once a suitable RTBT standard emerges, CMS can consider it for future rulemaking. Should a suitable RTBT standard emerge, CMS can consider it for future rulemaking. The Department of Health and Human Services will continue to engage with standards development organizations, such as NCPDP, to encourage the development of standards.

OIG's recommendations and CMS's responses are below.

OIG Recommendation

Take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials.

CMS Response

CMS concurs with this recommendation. CMS is engaging in efforts to improve electronic communication through the implementation of electronic standards, such as electronic prior authorization, and by improving the formulary and benefit standard, which could help reduce avoidable pharmacy rejections and denials by providing a faster and more precise way to transfer information.

As noted above, CMS has required sponsors to implement an RTBT capable of integrating with at least one prescriber's e-prescribing or electronic health record by January 1, 2021. Once this requirement goes into effect, and to the extent it is not replaced by a subsequent requirement, CMS will examine plan sponsors' implementation of electronic RTBT.

OIG Recommendation

Take action to reduce inappropriate pharmacy rejections.

¹ 84 Fed. Reg. 23848, <https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf>

CMS Response

CMS concurs with this recommendation. CMS has already taken significant and successful steps to reduce inappropriate pharmacy rejections. As stated above, CMS regularly conducts activities, including focused audits, to ensure plans are not inappropriately rejecting prescriptions that beneficiaries try to fill at pharmacies. Our formulary administration analysis has shown that, in 2017, less than one percent of Part D contracts had an inappropriate rejection rate greater than 20 percent (a significant reduction from 27 percent in 2013) and the median plan in 2017 had zero inappropriate pharmacy rejections. In addition, the inappropriate pharmacy rejection rates in our analysis are likely much higher than plans' actual inappropriate pharmacy rejection rates for the reasons previously mentioned. However, CMS will continue monitoring pharmacy rejections to ensure sponsors maintain the current level of performance in this area and will examine additional ways to take action to reduce inappropriate pharmacy rejections if sponsors' performance decreases.

OIG Recommendation

Take action to reduce inappropriate coverage denials.

CMS Response

CMS concurs with this recommendation. CMS has already taken several steps to ensure sponsors receive assistance on this issue. CMS also conducts program audits that measure a sponsoring organization's compliance with Medicare program requirements, including the requirements related to a beneficiary's access to covered medical services and prescription drugs. Going forward, CMS will analyze annual performance data from plan sponsors and determine how to best provide additional oversight to prevent unnecessary coverage denials.

OIG Recommendation

Provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials

CMS Response

CMS concurs with this recommendation. CMS is currently gathering feedback from beneficiaries and plan quality improvement staff that will help CMS understand what information consumers expect and/or would like to see on Medicare Plan Finder (MPF) to help them make informed choices. After reviewing the feedback, CMS will consider how best to include it on MPF.

ACKNOWLEDGMENTS

Rosemary Rawlins served as the team leader for this study, and Ivy Ngo served as the lead analyst. Office of Evaluation and Inspections staff who provided support include Clarence Arnold, Joe Chiarenzelli, Christine Moritz, and Paula Satariano.

This report was prepared under the direction of Blaine Collins, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Abby Amoroso and Michael Henry, Deputy Regional Inspectors General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the healthcare industry concerning the anti-kickback statute and other OIG enforcement authorities.