THE HENRY J. KAISER FAMILY FOUNDATION

THE MEDICARE DRUG BENEFIT

Beneficiary Challenges in Using the Medicare Part D Appeals Process to Obtain Medically Necessary Drugs

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EXECUTIVE SUMMARY

In January 2006 Medicare began covering out-patient prescription drugs under the new Medicare Part D program. The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, states that everyone who enrolls in a prescription drug plan will have access to all medically necessary prescriptions. In order to have access, however, plan enrollees may have to enter the Part D appeals system in order to challenge a plan's decisions about the specific pharmaceuticals it includes on its formulary (the list of drugs the plan covers). Observers of the new Medicare drug program have raised questions whether this system is good public policy and whether it works to promote access to medically necessary drugs.

This brief describes the various steps of the Medicare Part D appeals process for obtaining necessary drugs not on a plan's formulary. Using case reports collected from a network of beneficiary advocates, it illustrates the challenges and problems encountered by some beneficiaries in navigating this aspect of the drug benefit. The paper concludes with a discussion of potential policy options including the implications of establishing an exceptions and appeals process that is uniform in paperwork and procedures.

This report was commissioned by the Kaiser Family Foundation to provide insights into Medicare beneficiaries' experiences with the Part D appeals system from the perspective of legal advocates who represent them. The problems described in this report are examples of problems encountered by a number of beneficiaries, but should not be construed to apply generally to the Medicare population.[1]

BACKGROUND

The coverage determination is the initial determination issued by the Part D plan. No appeal may be filed until a coverage determination is made. An exception request is a special subset of the coverage determination process and requires the participation of the prescribing physician. The exceptions process is used to request a change to the design of a plan's formulary or to request a reduction in the cost-sharing amount for a formulary drug. Once the plan issues an unfavorable coverage determination, including an unfavorable exception, the enrollee may proceed through five levels of appeal: redetermination by the drug plan; reconsideration by the independent review entity (IRE); hearing before an administrative law judge (ALJ); Medicare Appeals Council (MAC) review; and finally, appeal to federal court.

INFORMING ENROLLEES ABOUT THEIR DRUG PLAN'S APPEAL PROCESS

Detailed notice of the reasons for the denial of coverage for a requested drug under Medicare Part D is not required at the pharmacy counter, the place at which an enrollee first learns that his or her Part D plan will not pay for or otherwise provide a requested prescription drug. An enrollee who wants further information or wants to appeal must

first contact the plan to obtain a coverage determination. CMS requires each drug plan to arrange with its network pharmacies either to post a generic notice telling enrollees to contact the plan if they disagree with the information provided by the pharmacist or to distribute such a generic notice. Advocates report that the generic notices are not being posted or distributed in their area pharmacies, and if they are posted they tend to be difficult to read given the location where they are hung. As a result, advocates suggest that many beneficiaries are unaware of their appeal rights, and are at risk of switching to inappropriate medications or leaving the pharmacy counter without receiving any medication.

COMMUNICATION WITH DRUG PLANS

Communicating with drug plans through their call centers remains problematic for some beneficiaries. Call centers may not be available during normal business hours to answer inquiries. Even when available, some have been found to consistently provide incorrect information to enrollees and their advocates. In addition, there are instances where call centers have provided conflicting information to advocates and physicians who have called about the same case on the same day.

Advocates report that the process for filing a written request for a coverage determination has improved, however. Medical and consumer organizations worked with a health plan trade association to develop a model form for requesting coverage determinations and this standardized format is now being used by many drug plans.

TIMELY COVERAGE DETERMINATIONS AND REDETERMINATIONS

Despite clear statements in the implementing regulations and CMS guidelines concerning calculating time frames for acting on coverage determinations and redeterminations, some plans fail to comply with the standards, according to advocates. There have been cases in which plans report not having received the information needed to start the time calculation, calculate the time periods incorrectly, or disregard the time frames required for action. The failure to comply with time frames may delay beneficiary access to needed medication.

PRIOR AUTHORIZATION AS A TYPE OF COVERAGE DETERMINATION

Many part D plans impose prior authorization requirements on formulary-covered drugs and require the patient's physician to request approval from the plan before paying for the drug, much the same way that is required for exception requests that seek coverage for a non-formulary drug.[2] However, according to Medicare rules, prior authorizations are different from exceptions and do not require a supporting statement from the prescribing physician, even though a number of plans appear to be interpreting the requirements this way. Unlike exceptions, which are approved for the entire year, prior authorization requests may be approved by plans for limited time periods. Thus, beneficiaries may be required to repeat the prior authorization process several times during the course of a year.

EVIDENTIARY REQUIREMENTS

Each plan has its own criteria for evaluating prior authorization, exceptions and other requests. According to advocates, some plans impose substantial and burdensome requests on physicians for medical records and multiple journal articles to support prior authorization and exception requests. Even when doctors submit the requested supporting documentation, plans are not required to defer to the opinion of the treating physician. Overly burdensome evidentiary requirements may compromise beneficiary access to needed medications, particularly if physicians perceive them as onerous and time-consuming.

POLICY CONSIDERATIONS

Issues related to the appeals process can be addressed through enforcement of existing regulations, along with regulatory and statutory changes. The following list highlights potential changes to help improve the current appeals process:

- Require plans to provide the initial coverage determination, with information about the reasons for the denial and how to file an appeal, at the pharmacy counter (or via mail in the case of mail-order pharmacies) so the burden is not on the beneficiary to contact the drug plan for this information before an appeal may be filed.

- Limit the use of prior authorization to non-formulary drugs, rather than drugs that are listed as covered on plan formularies.

- Clarify that a prior authorization request is treated as an exception request, that a physician's statement is required, and that a request when granted remains in effect for the remainder of the plan year to standardize rules and procedures and minimize confusion.

- Establish unified criteria applicable to all plans for evaluating coverage determination requests, including exceptions and prior authorization, and require plans to defer to the opinions of the treating physician.

- Limit the number of journal articles and the extent of the clinical records required to support an exception or prior authorization request.

- Establish one standard process that all Part D plans must follow to simplify the appeals structure.

INTRODUCTION

In January 2006 Medicare began covering out-patient prescription drugs for those Medicare beneficiaries who enrolled in a drug plan under the new Medicare Part D program, established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, states that everyone who enrolls in a prescription drug plan will have access to all medically necessary prescriptions. In order to have such access, however, plan enrollees may have to avail themselves of various processes established by the MMA and its implementing regulations to challenge a plan's formulary decisions. Observers of the new Medicare drug program have raised questions whether this system is good public policy and whether it works to promote access to medically necessary drugs.

This brief describes the various steps of the Medicare Part D appeals process for obtaining necessary drugs not on a plan's formulary. Using case reports collected from networks of beneficiary advocates,[3] it illustrates the challenges and problems encountered by some beneficiaries in navigating this aspect of the drug benefit. The paper concludes with a discussion of potential policy options including the implications of establishing an exceptions and appeals process that is uniform in paperwork and procedures.

This report was commissioned by the Kaiser Family Foundation to provide insights into Medicare beneficiaries' experiences with the Part D appeals system from the perspective of legal advocates who represent them. The problems described in this report are examples of problems encountered by a number of beneficiaries, but should not be construed to apply generally to the Medicare population.[4]

BACKGROUND

Drug coverage under Part D is provided through private insurance companies that offer free-standing prescription drug plans (PDPs) and Medicare Advantage plans with prescription drug coverage (MA-PDs). The MMA and its implementing regulations give PDPs and MA-PDs broad discretion to decide which specific drugs to include in their formularies, the strengths and dosage forms of covered drugs to include, and the types of "utilization management processes" to use to control drug costs and usages.

As part of their utilization management processes, plans may establish different copayments for different drugs using "tiered pricing" which distinguishes among preferred drugs, non-preferred drugs, generic drugs, and specialty drugs. Plans may also limit the number of pills or dosage amounts, require that beneficiaries request prior authorization for covered prescription drugs, or require that they try particular medications included in the plan's formulary before paying for prescribed medications not on a plan's formulary ("step therapy").

Both the statute and the regulations require all Part D drug plans to have a process through which a plan enrollee may challenge the plan's decisions about drug coverage. A coverage determination is the initial determination issued by the Part D plan on a request to pay for or otherwise provide a prescribed medicine. No appeal may be filed until a coverage determination is made. An exception request, a special subset of the coverage determination, used to request an exception to the design of a plan's formulary, has its own process and procedure and requires participation by the prescribing physician. An exception is used to ask the plan to cover a drug that is not on its formulary or to reduce the cost-sharing amount for a formulary drug.

If a plan issues an unfavorable coverage determination, including an unfavorable exception, the enrollee may proceed through five levels of appeal: redetermination by the drug plan; reconsideration by the independent review entity (IRE); hearing before an administrative law judge (ALJ); Medicare Appeals Council (MAC) review; and finally, appeal to federal court.

The processes may be time-consuming and cumbersome. Enrollees must act affirmatively and provide substantial amounts of evidence through all levels of review. Some enrollees and those acting on their behalf have encountered a wide range of problems and challenges when attempting to request exceptions and other coverage determinations and appeals. Some problems occur as a result of the design of the appeals process, while others result from the failure of some Part D plans to implement the processes properly and to comply with statutory and regulatory requirements.

INFORMING ENROLLEES ABOUT THEIR DRUG PLAN'S APPEAL PROCESS

In order to appeal a decision by a drug plan not to pay for or provide a drug, plan enrollees must first know that they have a right to appeal. Information about the coverage determination, exceptions, and appeals processes is included in the welcome packet enrollees are supposed to receive when they first become members of their drug plan. Providing information at the time a denial occurs, however, may be another effective way to ensure access to the necessary information when a person is likely to need it most.

Use of standard notice

A Part D enrollee generally first learns at the pharmacy that his or her plan will not pay for or otherwise provide a requested prescription. The Part D regulations do not require a detailed notice describing the denial and subsequent appeal rights to be provided at the pharmacy. Instead, the regulations require each drug plan to arrange with pharmacies within their network to either post a standard notice directing enrollees to contact the plan if they disagree with the information provided by the pharmacist or to distribute such a standard notice directly to plan enrollees. An enrollee who wants further information or wants to appeal must first contact the plan to get a coverage

determination that will inform him or her of any appeal rights that might ensue from the denial.

CMS developed the standard pharmacy notice, **"**Medicare Prescription Drug Coverage and Your Rights" for use by all plans and all pharmacies in each plan's network for denials that occur at the pharmacy counter.[5] Use of the standard pharmacy notice is mandatory; plans may not change the content. They may add the Medicare Rx mark if authorized to do so, and pharmacies may choose to add their logo.

Advocates report that the pharmacy notice is not always publicly displayed at the pharmacy. It is difficult to know whether a pharmacy has not posted the notice because notices are distributed directly to the enrollee when a prescription is not filled or because the pharmacy is has failed to comply with the notice requirement.

Consequences of lack of posted notice

When notices are not posted or distributed, enrollees often are unaware of their right to request a coverage determination, according to consumer advocates. For example, a Massachusetts beneficiary was told by a drug plan before he enrolled that the expensive medicine for his chronic condition would be covered. When he was denied coverage for the drug at the pharmacy counter, he was not told that he could request an exception to ask that the drug be covered. He instead changed to a formulary drug. The beneficiary is now experiencing adverse health consequences as a result of the drug change.[6]

As another example, a California elder law attorney complained to CMS after a beneficiary was turned away from a national chain drug store without a prescription and without any information about contacting the drug plan. When the attorney asked the pharmacy assistant why she did not provide the information to the beneficiary, the pharmacy assistant told the attorney that she was informed she could not provide any assistance when drug claims were rejected. CMS subsequently worked with the national drug store chain to make sure that that particular drug store understood and complied with the requirements. The elder law attorney later returned to the drug store and asked how enrollees were informed about their rights in the standard notice. At first the pharmacy assistant did not understand the attorney's question. Upon further explanation, she pointed to a notice, posted on the far wall behind the pharmacy counter, that was not only difficult to find but quite obviously difficult to read.

Advocates point out that notices, when posted, are not necessarily conspicuous. Because CMS only requires posted notices to be the size of a distributed notice, posted notices are generally on standard-sized 81/2 by 11 inch paper in 12-point font. Maryland advocates, for example, report notices being posted on the wall of the pharmacy work area far away from where pharmacy transactions occur and thus can not be read by pharmacy customers. In other circumstances, Maryland advocates report that often Medicare pharmacy notices are surrounded by other notices and informational items, making them difficult to find and/or read.

An alternative method of informing Part D plan enrollees of their rights would be to require denial notices to be distributed at the time of the transaction with the pharmacy. CMS, relying on a ruling from the Department of Labor regarding employer-sponsored plans, rejected this approach in favor of requiring enrollees to contact their plans for information about the coverage denial. Contacting the plan to get a coverage determination, which is a prerequisite to filing an appeal, adds another step to the appeals process. Thus, advocates argue that the already complicated process becomes more onerous for beneficiaries, who, because of low-incomes, chronic conditions, and/or diminished capacity may have difficulty requesting an appeal.

COMMUNICATION WITH DRUG PLANS

Plan call center responses

During the initial weeks of Part D implementation, advocates report that a number of beneficiaries and their physicians experienced difficulties when they attempted to contact drug plans concerning exception and other coverage determination requests. Communications have improved somewhat overtime. However, some physicians and advocates continue to experience problems such as long wait times on the phone and the inability to reach a plan representative, sometimes even during business hours. The following are a few examples of problems that have emerged:

Call center availability

An advocate in New York contacted CMS about the unavailability of a plan's call center. On June 13, 2006 she tried to call the plan at 4:45 PM Eastern Time. She received a message saying the phone lines were closed but also saying that the plan's phone lines are open from 7 AM - 11 PM Eastern Time.

- The daughter of a beneficiary in New York called her mother's plan to get information so that her mother's doctor could request an exception to a quantity limit requirement. The plan representative refused to give her a phone number to give to the doctor, but said that the plan would call the doctor directly with a fax number. No one called. When the daughter called the plan a second time, the representative gave her an 800 number for exceptions that was disconnected when dialed.

- In June 2006 a plan refused to discuss an exception request with a doctor in Iowa, citing privacy issues. The plan's record of the patient's address did not match the one the doctor gave. The patient called the plan the same day and got a recorded message informing him that the plan was in the middle of a system update and would not be open for calls until five days later.

Reaching appropriate call center staff

- An advocate in Massachusetts reported that enrollees are not able to call the appeals unit of one plan directly; they must call customer service, ask to be connected to the appeals unit, and then leave a voice mail message.

- Ms. S., a 79-year old Vermont beneficiary, was denied coverage on June 30, 2006 for a drug her plan had covered from January through May. An advocate called 6 different phone numbers, including the general customer service line and three contacts she had been given by the state, and was unable to reach anyone from the plan. The state of Vermont ended up covering an emergency one-month fill for Ms. S. so she would not have to go without her needed medication.

Conflicting information

- A Connecticut advocate, pharmacy, and doctor were given conflicting and changing information about prior authorization for a drug for a Medicaid recipient who became eligible for Medicare in July 2006. The pharmacy was informed by the plan that prior authorization was required and the doctor provided the necessary prior authorization information. After submitting the prior authorization response, the doctor was notified by the plan that prior authorization was not required. When the enrollee did not receive the drug by the end of July, her advocate checked the CMS website and discovered that prior authorization was indeed required. The prior authorization requirement was then confirmed by the plan. The plan also told the advocate that it did not have a prior authorization process for individuals who are temporarily enrolled at the pharmacy.[7] As a result the individual could not get her medication.

- A Massachusetts advocacy organization complained to CMS in July 2006 that the customer service representatives of a large plan, while uniformly courteous, supply incorrect information virtually every time the organization has contacted the plan. In one example, a physician and advocate each called customer service on the same day and were given inconsistent and conflicting information about the status of a case.

Using the correct terminology

- Failure to use the proper terminology may also create problems. A nurse in Virginia spent several weeks on the phone with a drug plan trying to get coverage of a drug for her husband. After receiving a consumer education piece that described the appeals process, she called the plan again and specifically asked for “a coverage determination.” The request was granted and her husband got his medicine the same day.

Coverage determination forms

Some enrollees and physicians seeking to file written coverage determination requests, and in particular written requests for exceptions and prior authorization, initially encountered other problems. Each plan had its own specific form, and in some cases multiple forms, to request an exception. Plans that required specific forms did not make them readily available on their web sites or through their call centers, according to advocates. The burden on many medical practices was enormous, especially considering the possibility of each medical practice having to be familiar with forms for over 40 different prescription drug plans in many parts of the country.[8]

To address this problem, a work group of medical, pharmacy, and consumer organizations, spearheaded by the American Medical Association, worked with America's Health Insurance Plans (AHIP), a trade association of health plans, to develop a standard Medicare Part D coverage determination request form. The form, which is also used for exceptions, is available on the CMS website as well as on the web sites of many of the largest Part D sponsoring organizations.[9] CMS informed drug plans in late spring 2006 that they must accept any form used to request a coverage determination, including the standard form. Advocates report that this has substantially helped minimize the burden on physicians and their medical practices.

TIMELY COVERAGE DETERMINATIONS AND REDETERMINATIONS

Part D plans are required to have a process for making timely coverage determinations, including decisions on formulary and cost-sharing tier exceptions.[10] The Part D regulations and guidance manual require all Part D plans to issue a written coverage determination, including a written decision on an exception, within 72 hours for a standard request and 24 hours for an expedited request. The time frame commences upon receipt of the coverage determination request or, in the case of an exception, receipt of the doctor's supporting statement, without which an exception cannot be granted.

The regulations and manual also establish set time frames for redeterminations by the plan (the first level of appeal) and reconsiderations by Maximus, the company with whom the agency contracts to serve as the Independent Review Entity (IRE). Plans must complete standard redeterminations within seven days and expedited redeterminations within 72 hours of receipt of a request. The redetermination time frames apply to reconsideration decisions issued by Maximus.

The time frames described above are the maximum allowed; plans are required to issue decisions more quickly if the health of the enrollee so requires. If plans cannot meet the time frames, they are required to send claims to Maximus, the IRE, for review within 24 hours of expiration of the regulatory time frame.

In an effort to obtain plan compliance with timeliness standards, CMS issued several reminders to drug plans about the regulatory and manual provisions concerning timely decisions. One letter issued in March 2006 also informed plans that CMS intends to monitor compliance closely and, if it finds that performance interferes with enrollee access to medication, CMS intends to take enforcement action.[11] Despite these reminders, some plans continue to take longer time periods to make a decision, often leaving beneficiaries without the medicine they require.

Plan call centers continue to give advocates and beneficiaries mis-information about time frames for all levels of the coverage determination and appeals process. Maine advocates, for example, continue to be told by a particular plan that coverage determinations will be issued within 24 business hours (3 days) or even 72 business hours (9 days). Since this plan use "business" hours, it may be giving itself even more time if it does not consider weekend days. Similarly, a Florida advocate was told by a plan that the IRE would issue a decision within 15 days to a month, even though the regulations require decisions be issued within 7 days.

Even when plan call centers do not give incorrect information about the time for issuing decisions, advocates report that some plans routinely ignore the statutory time frames for issuing coverage determinations, including exceptions, and redeterminations. Other timeliness issues include:

- Some plans deny having received the request for a coverage determination or redetermination and other supporting information, even when advocates have fax receipts that show the documents were transmitted. As a result, the coverage determination and appeals processes are delayed, extending the time in which some beneficiaries go without medicine.

- The Part D guidance manual requires plans to calculate the time frame for issuing a decision from the date and time the call or fax is received. Advocates report that a number of plans give themselves more time to respond by calculating time frames from a later date, sometimes when the request reaches the desk of the person who is handling it, rather than from the time it comes in to the plan.

- Advocates have notified CMS that some plans have ignored the regulatory time frames and issued untimely decisions. CMS responded to one such complaint, filed in August 2006, by asking a representative of the plan to contact the advocates who filed the complaint to discuss the problem.

The experience of Ms. S., the Vermont woman described above, whose advocate could not reach anyone at her drug plan to find out why coverage was denied, exemplifies a range of timeliness problems which impede her access to necessary medications:

> When the exception request filed by Ms. S's physician was denied, he immediately faxed a request for a redetermination. Several days later, on July

14, the plan informed the physician that he needed an 'appointment of representative' form[12] to appeal on behalf of Ms. S. The physician faxed the form on the same day and called to confirm its receipt. When he had not heard back by July 25, (well past the 7-day time limit) he called the plan, only to learn that the appeal was dismissed because the plan claimed it had not received the 'appointment of representative' form. The physician again faxed the appointment form on July 25 and asked that the redetermination be expedited. On July 27 the plan asked for more information, and the physician on the same day sent the plan all of Ms. S's medical records since 1982. On July 31, more than 72-hours after the medical records were faxed, the plan claimed that it did not start processing the redetermination until July 28, and so would not respond until the end of the workday on August 1, when Ms. S needed her next fill of medication. The decision would be issued 18 days after Ms. S' physician first faxed a request for redetermination.

PRIOR AUTHORIZATION AS A TYPE OF COVERAGE DETERMINATION

Many Part D drug plans impose prior authorization requirements for drugs that are listed as covered by their formularies. If a drug plan requires prior authorization for a particular drug, the plan will not pay for the drug unless the physician first seeks approval from the plan. Prior authorization is used differently in Medicare than in Medicaid. In Medicaid and other programs prior authorization is used to seek coverage for a non-formulary drug. Prior authorization may also be used as the generic tool through which a Medicaid recipient or other insured seeks to avoid step therapy or quantity limit requirements. Under Medicare, prior authorization applies to formulary, not non-formulary drugs, and may in some cases be separate from step therapy requirements.[13]

The Part D regulations do not mention prior authorization either as a coverage determination or as an exception. The guidance manual, however, confirms that an attempt to satisfy a prior authorization request constitutes a request for a general coverage determination and not a specialized request for an exception.[14] General coverage determination requests, unlike exception requests, do not need a supporting statement from the prescribing physician, though the guidance manual refers to physician involvement in the prior authorization request.

Drug plans generally treat prior authorizations the same way they treat exceptions, however. Plans may require a physician's statement and possibly additional medical evidence before a prior authorization request is granted, just as they are required for an exception. In a study of the nine drug plans in which people dually eligible for Medicare and Medicaid are automatically enrolled in California, the Center for Health Care Rights (CHCR) determined that all nine plans follow the same processes for prior authorization and exception requests. Three of the nine PDPs surveyed by CHCR use the term "prior authorization" to refer to both exception and prior authorization requests.

Despite following the same process for exceptions and prior authorizations, many drug plans do not treat a favorable prior authorization request in the same manner as a favorable exception request. The Part D regulations require that when an exception request is granted, it remains in effect for the remainder of the year in which it is granted, as long as the physician continues to prescribe the drug and the drug remains safe and effective for the person prescribed. Plans have discretion to continue an exception into the following year if the beneficiary remains enrolled in the plan. The regulations therefore protect plan enrollees from having to go through the often burdensome exception process each time a prescription must be refilled.

Because prior authorization requests are not technically exception requests, many plans place limits on the life of their prior authorization approvals. Some plans limit approval of prior authorization requests to 1, 3, or 6 months, even when the drug is for treatment of a chronic condition. In these circumstances, in order to continue receiving the drug, the enrollee and his or her physician are required to submit a new prior authorization request, or perhaps an exception to the prior authorization request, with a new physician's supporting statement. An office visit and additional testing may be required so that the physician can submit a new statement in support of the prior authorization request, thereby increasing both Medicare and enrollee expenditures, and placing unnecessary burdens on the physician and the enrollee. Indeed, a Massachusetts advocate reports that some plans refuse to explain why they authorize a drug for only one month, often citing privacy regulations as prohibiting them from divulging medical necessity criteria. A recent focus group discussion with State Health Insurance Counseling Program (SHIP) directors found similar reports of plans requiring enrollees to go through prior authorization on a monthly basis, placing a substantial administrative burden on physicians. As a result, directors explained that some physicians in their states were resistant to helping patients with prior authorization and were requiring patients to have a billable office visit before assisting with prior authorization requirements.[15]

The extent to which plans impose prior authorization requirements varies, according to advocates. Some plans impose prior authorization requirements on a substantial number of drugs, while others use prior authorization sparingly. Early analysis by the Alzheimer's Association found that the formularies of three large Part D sponsoring organizations imposed prior authorization requirements for all drugs used to treat Alzheimer's disease. Through advocacy with CMS, two large sponsoring organizations agreed in July and August 2006 to remove the prior authorization requirements for beneficiaries over age 65. Medicare beneficiaries who are under age 65 may still need to request prior authorization. The third organization has yet to resolve the issue and enrollees with Alzheimer's disease in this plan must request prior authorization for any drug approved to treat the disease, effectively denying them easy access to all necessary medicines.

EVIDENTIARY REQUIREMENTS

Part D plans have flexibility in designing their benefit structures and formularies, including the utilization management tools they use to control plan costs. CMS also gave plans flexibility to develop their coverage determination and exception processes within the parameters of the statute and regulations. Each plan establishes its own criteria for determining whether and when to grant such a request. Physician statements in support of an exception are not binding on plans.

Burdensome evidentiary requirements are yet another problem encountered by some enrollees and their physicians. Advocates report the following examples of problems that have emerged related to the submission of supporting evidence in the appeals process:

- The redetermination request filed on behalf of Ms. S. in Vermont by her physician was denied because of insufficient supporting data, despite the over 20-years of medical records submitted by the physician.[16]

- In a Florida case that began in April and was yet to be resolved at the beginning of August, the physician was required to submit two journal articles to support the exception request. Although four such articles were submitted, the plan continues to deny coverage. The case has been appealed to the IRE for the second time.

- A physician in Massachusetts sought an exception in May for coverage of a brand name, long-acting narcotic pain medication that had initially been paid for by the plan. In 2005, the beneficiary failed two state Medicaid-program requested trials with generic versions of the drug. Six pages of clinical notes documenting the adverse effects of the alternative medicines were submitted with the exception request, which was denied on the grounds that the formulary covers other short-acting drugs. The physician appealed and received a "request for additional medical information" asking for "medical documentation indicating trial/failure of any previous medications prior to this one." The physician had already submitted this information with the initial exception request.[17]

NOTICE OF UNFAVORABLE COVERAGE DETERMINATIONS AND REDETERMINATIONS

Plans must provide written notification of an adverse coverage determination or redetermination to the enrollee or the enrollee's appointed representative. If a physician requested the coverage determination, including an exception, notice must be provided to both the enrollee and the physician. A plan that notifies the enrollee and/or physician orally must also follow-up with a written notice.

While some initial problems, such as the failure to use the standard coverage determination notice form developed by CMS, have been resolved,[18] some enrollees continue to encounter problems with their plans, such as:

- Plans failing to provide written notice when a coverage determination or redetermination request is denied.

- Plans providing explanations of reasons for denial that do not state the reasons why coverage was denied or indicate what additional evidence may be required for coverage to be granted are not easily understood by beneficiaries, their physicians, or advocates.

- Plans offering misinformation about alternative formulary drugs.[19]

- Plans failing to provide specific information about where and by when to file an appeal.

- Plans not supplying both physicians and enrollee with notice of an unfavorable coverage determination as required under the regulations.

Advocates report that the complexity of the notices and the processes themselves create confusion for beneficiaries. For example, a couple from Chicago who wanted to request a reconsideration of an unfavorable redetermination decision by their drug plan did not fully understand the redetermination notice they received. Because the redetermination notice came from their drug plan, and because the earlier decisions had been made by their drug plan, the couple filed their reconsideration request with the drug plan rather than with the IRE. By the time they were informed by an advocate of the proper procedure, the time frame for requesting reconsideration from the IRE had expired.

POLICY CONSIDERATIONS

While some enrollee difficulties with the Part D coverage and appeals processes resulted from start-up problems and have since been resolved, many on-going problems persist due to the structure and design of the appeals processes or the failure to enforce plan compliance with Part D statutory and regulatory requirements.

There continue to be reports of plans' non- compliance, such as not abiding by regulatory time frames or requirements to provide notices of coverage denials. These issues are, in some ways, easiest to address. CMS could exercise its enforcement authority to ensure that plans implement the appeals processes correctly, fairly, and completely. Plans that do not do so could be sanctioned or given monetary penalties and, if necessary, excluded from participation in Part D in future years.

Questions remain whether and to what extent CMS will take enforcement actions against plans.[20] While CMS has assisted individual beneficiaries in egregious circumstances, it is unclear what sanctions it will take against plans for misconduct, particularly in cases where certain plans consistently fail to follow Part D rules.

Statements issued by CMS in June and July 2006 indicate a focus on customer service call center wait times, not content of information provided or processing of coverage determination and appeal requests.[21] Both, however, are important. Nonetheless, the overwhelming response by CMS to complaints has been to issue warning letters, not to impose fines or other sanctions.

Since there is a pattern of some plans failing to comply with coverage determination and appeals time frames even after CMS issued reminder letters in March, advocates question whether warning letters are necessarily the most effective way to address non-compliance problems. Consistent non-compliance with rules and time frames by certain plans demonstrates the importance in CMS continuing to make public its enforcement activities, including sanctions that it imposes on plans that fail to comply with its coverage determination requirements and appeals regulations and guidance.

Potential regulatory or legislative changes

Other, more structural difficulties may need to be addressed administratively through revisions to the Part D regulations or through legislation.

Notice of coverage denial

The current regulatory system requires Medicare beneficiaries who, by definition, are elderly and/or disabled, to take affirmative steps to obtain a basic explanation of why a drug is not covered and of the actions that may be available to get the drug covered. This burden may be too great for some beneficiaries, who therefore will not ask for a coverage determination and will not be able to access the appeals process. Like the beneficiary in Massachusetts described above, a beneficiary may think their only recourse is to change to a potentially less effective formulary drug and may risk adverse health consequences as a result. Or, as in the California example, the beneficiary may walk away from the pharmacy counter without the drug and without knowing to contact the plan to begin the appeal process.

A regulatory change requiring plans to provide the initial coverage determination, with information about the reasons for the denial and how to file an appeal, at the pharmacy counter (or via mail in the case of mail-order pharmacies) would help by eliminating the burden on the beneficiary to contact the drug plan for this information before an appeal may be filed.

Prior authorization and exceptions

The Part D regulations do not clearly define how to request prior authorization for a formulary drug. The Part D guidance manual calls prior authorization requests "coverage determinations," which do not require a doctor's supporting statement as do exceptions requests to cover non-formulary drugs. Yet the manual refers to the physician's prior authorization request, implying that physician involvement is required.

The distinctions between requesting prior authorization for a formulary drug and an exception for a non-formulary drug are nonexistent for all practical purposes. Drug plans appear to treat prior authorization requests the same way that they treat exceptions.

Ironically, beneficiaries who are granted an exception for a *non-formulary* drug have greater protection under the regulations than those who receive prior authorization for a *formulary* drug. A granted exception request remains in effect for the remainder of the year and can extend into future years if the beneficiary remains in the plan, while some plans grant prior authorization for as little as 30 days, requiring the enrollee to repeat the process each month.

An alternative would be to limit the use of prior authorization to non-formulary drugs. For those beneficiaries enrolled in one of the three drug plans that require prior authorization for all Alzheimer's drugs, for example, needing to get prior authorization is virtually equivalent to these plans not covering any drugs for this condition. If prior authorization were limited to non-formulary drugs, beneficiaries could then use the exceptions process to get coverage for those drugs and, if successful, they would be granted coverage for the plan year. Such a change would require stricter formulary review by CMS to ensure that each plan meets the requirement of including two drugs in each category and class of drugs, and may require a legislative change to limit the use of prior authorization.

A simpler approach may be for CMS to modify its regulations to include prior authorization as an exception. The regulations would also assure that granted prior authorization requests extend through the plan year. At a minimum, CMS could include clarifications in its policy manual. A regulatory or statutory change could limit the use of prior authorization to non-formulary drugs. Alternatively, CMS could modify the Part D regulations and manual to clarify that a prior authorization request be treated as an exception request, that a physician's statement is required, and that a request when granted remains in effect for the remainder of the plan year.

Evidentiary requirements

The system burdens physicians by requiring their participation in the exceptions and prior authorization processes, but then does not necessarily accord their statements significant weight in the decision-making process. Physicians are being asked to submit substantial clinical and scientific evidence, sometimes multiple times, without assurance that the request will be granted even when plan demands are fully met.

CMS could modify its regulations to establish unified criteria for evaluating coverage determination requests, including exceptions and prior authorization, and require plans to defer to the judgment of the treating physician. CMS could also impose limits in its regulations on the number of journal articles and the extent of the clinical records required to support an exception or prior authorization request. To simplify the appeals structure, CMS could establish one standard, simplified process that all Part D plans must follow.

CONCLUSION

Overall, the Part D processes for requesting an exception or other coverage determination and for then appealing from an unfavorable decision are complex and varied. Rather than facilitating access to prescribed medications, some aspects of the appeal system's design may inadvertently create barriers for patients to access needed medications.

CMS, health plans, provider groups, and beneficiary advocates have worked together to identify and resolve a number of issues with the coverage determination and appeals systems. Nonetheless problems in these areas continue to emerge. Therefore, continued monitoring of beneficiary reports of problems with the Part D appeals process is necessary so that CMS administrators and other policy makers can take appropriate action to ensure that the coverage determination, exception, and appeals processes work as anticipated in protecting plan enrollees' rights to receive coverage for medically necessary Part D drugs.

RESOURCES

42 U.S.C. §§1395w-104(g), (h).

42 C.F.R. §423, Subpart M.

CMS, Prescription Drug Benefit Manual Chapter 18 – Part D Enrollee Grievances, Coverage Determinations and Appeals.
http://www.cms.hhs.gov/PrescriptionDrugCovContra.

NOTES

[1] Part D plans are required to report quarterly the number of prior authorizations requested and the number approved, the number of exceptions requested and the number approved, and the number of appeals requested and the number approved.
[2] Hoadley J., et al., "An In-Depth Examination of Formularies and Other Features of Medicare Drug Plans," prepared for the Kaiser Family Foundation, April 2006.
[3] The networks of advocates include attorneys, paralegals, case workers, volunteers, pharmacists, doctors and other health care providers who assist older people and people with disabilities with their Medicare Part D problems.
[4] A recent survey found that 80% of beneficiaries are satisfied with Part D, however, those in poor health, taking more drugs, or with incomes below $20000 were more likely to experience problems.
http://www.kff.org./kaiserpolls/7547.cfm
[5] The notice may be found on the CMS web page at
http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp#TopOfPage.
[6] The beneficiary could seek an exception to have the plan cover his previous drug. The drug is expensive, however, and because he is now in the coverage gap or "donut hole" he cannot afford to pay the full cost of the drug.
[7] CMS created the point of service (POS) process to provide temporary enrollment in a Part D plan, and therefore temporary drug coverage, for those dually eligible for Medicare and Medicaid whose Medicaid drug coverage ends before they are enrolled in a Part D plan. The POS process begins at the pharmacy when the pharmacy sends an electronic "E-1" transaction to the Medicare contractor in charge of this process.
http://www.cms.hhs.gov/States/Downloads/Wellpoint4Steps.pdf
[8] The American Medical Directors Association (AMDA) issued a press release on June 1, 2006, describing results of a survey of their members. They reported, "52% of respondents are spending more than 4 hours per week working with drug plans and pharmacies to obtain medically necessary medications for their patients. Of those, 13% reported spending 8 hours or more per week."
[9] http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.
[10] A tiering exception is used to request that an enrollee be charged a lower cost-sharing amount for a particular drug. A formulary exception is used to request coverage for a drug not on a plan's list of covered drugs or to request that a utilization management requirement such as step therapy be waived.
[11] Gary Bailey, Letter to Part D plans, "Critical Steps as Transition Period Ends" (March 31, 2006).
[12] Only a plan enrollee or someone appointed by the enrollee may request an appeal. An enrollee may use CMS Form 1696 or another writing that contains the same information as Form 1696 to appoint a representative to pursue the appeal. The appointment of representative must be signed by the enrollee.
[13] As evidenced by the new Medicare beneficiary in Connecticut whose plan gave different information to her pharmacy, her doctor, and her advocate, prior authorization may completely preclude access to a prescribed medication.
[14] Prescription Drug Manual, Chapter 18, Part D Enrollees Grievances, Coverage Determinations and Appeals, Section 30.1, http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDManualChapter18.pdf. Note that a physician or enrollee may request an exception to a prior authorization requirement on the grounds that the drug is medically necessary. Such a request is different from an effort to satisfy the prior authorization requirement.
[15] Julie James, Tricia Neuman, and Michelle Kitchman Strollo. "Early Experiences of Medicare Beneficiaries in Prescription Drug Plans," for the Kaiser Family Foundation, August 2006.
[16] Note that the physician, despite being the appointed representative, received no notice of the denial. The information was provided by the state of Vermont when asked by her advocate to provide a second emergency file of her prescription.
[17] After Maximus, the independent review entity, issued a favorable reconsideration decision granting coverage, the drug plan still failed to cover the drug. Coverage was finally granted after CMS intervened.

[18] The standard coverage determination notice is available on the CMS web site at http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp#TopOfPage. Advocates raise concerns that the language in the notice may confuse some beneficiaries as to whether their next step is to request an exception, which is a type of coverage determination, or a redetermination, which is the first level of appeal.

[19] For example, in the Massachusetts case cited above, the plan listed three short-acting narcotic drugs as formulary alternatives to the long-acting narcotic, and not other long-acting drugs.

[20] See, T. Edelman, *Enforcement of Part d Requirements: Federal Role and Responsibility (Kaiser 2006)* for a discussion of CMS enforcement authority under Part D.

[21] See, "Medicare Details Steps Taken to Improve Customer Service By Drug Plans," June 29, 2006, "Medicare Issues Information on Complaints About Prescription Drug Plans," July 19, 2006, .http://www.cms.hhs.gov.

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