UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM — MINORITY STAFF
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MEDICARE DRUG PLANS: RESTRICTIONS ON ACCESS TO FORMULARY DRUGS

PREPARED FOR

REP. HENRY A. WAXMAN

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EXECUTIVE SUMMARY

News accounts have reported that some Medicare beneficiaries have encountered hidden restrictions when they try to obtain prescription drugs through the new Medicare drug plans. Even when a drug is listed as available through a plan formulary, unexpected barriers — such as "prior authorization" requirements, "step therapy" requirements, and "volume limits" — have been used by the sponsors of drug plans to delay or deny access. The use of these restrictive tactics means that even if seniors have carefully researched a Medicare drug plan, they can still encounter obstacles in obtaining medications.

At the request of Rep. Henry A. Waxman, this report assesses the use and disclosure by Medicare drug plans of tactics that limit access to prescription drugs on plan formularies. It is based on three primary sources of information: (1) a Medicare database that provides information on prior authorization and step therapy requirements for over 1,000 Medicare drug plans; (2) a phone survey of the Medicare drug plans available to seniors in Rep. Waxman's district; and (3) information available online through the Medicare.gov website and the websites of individual Medicare drug plans. The report finds that the use of restrictive tactics by Medicare drug plans is widespread, but the disclosure of their terms is virtually nonexistent.

Specifically, the report finds:

- **The vast majority of Medicare drug plans restrict access to formulary drugs.** The Medicare data show that 97% of plans place either prior authorization or step therapy requirements on at least one of the 100 most popular drugs, with the average plan restricting access to over 10% of the popular drugs listed in its formulary. Some plans restrict access to over 40 of the 100 most popular drugs.

- **Medicare drug plans are unable to describe plan restrictions accurately.** Over two-thirds of the Medicare drug plans contacted in the phone survey were unable to describe accurately how the prior approval, step therapy, or volume limits worked with their particular plan. In a number of cases, plan representatives had no idea what these terms meant. In other cases, the representatives told callers that they could not obtain information on plan restrictions until after they signed up for the plan.

- **Medicare drug plans provide erroneous or conflicting information about restrictions.** A number of Medicare drug plans provided information that was erroneous or misleading or conflicted with other information provided by the plan in the phone survey. Several times, plans were called twice consecutively and gave completely different

answers to identical questions about whether plans restricted access to drugs and how these restrictions worked. In other cases, plans provided erroneous information about what drugs were and were not on their formularies.

- **The Medicare website and the websites of plan sponsors fail to provide adequate information about restrictions.** Seniors cannot rely on the Medicare.gov website or the websites of plan sponsors to inform themselves about the details of plan restrictions. Medicare.gov does present limited information about whether Medicare drug plans use restrictive tactics, but the information is buried within the website and provides no details of the terms of the restrictions. The websites of plan sponsors generally have the same limitations.

The findings in this report indicate that the complexity of Medicare Part D is putting many seniors in an unfortunate "Catch 22" predicament. Seniors cannot make a fully informed choice about a Medicare drug plan without knowing whether the plan will use prior authorization, step therapy, or volume limitations to discourage use of drugs listed on the plan formulary. Although the use of these restrictive tactics is common, it is nearly impossible for seniors to learn their terms until after they have subscribed and been denied drug access.

BACKGROUND

Seniors and people with disabilities are now presented with complicated and confusing choices for Medicare drug benefits. The full extent of this confusion became apparent when the program went into effect on January 1 and widespread problems appeared. The new Medicare Part D program has been described as a "fiasco,"[1] a "debacle,"[2] and a "disaster,"[3] as millions of seniors and disabled Medicare beneficiaries have been unable to obtain the drugs they need. Currently, less than one in four eligible seniors has voluntarily enrolled in the program.[4]

One critical factor for seniors considering participating in Medicare Part D is whether the Medicare drug plan they are considering will cover the drugs they

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1 *Medicare Fiasco Prompts Gov., Legislators to Team Up*, Los Angeles Times (Jan. 19, 2006).

2 *How to Bungle A Drug Plan*, San Francisco Chronicle (Jan. 25, 2006).

3 *Medicare Part D … For Disaster*, Washington Times (Feb. 11, 2006).

4 Kaiser Family Foundation, *Tracking Prescription Drug Coverage Under Medicare* (Feb. 2006).

use. To find this information, seniors must negotiate the Medicare website to learn whether the drugs they take are listed on the "formulary" of the plans they are considering. This can be a confusing process. The Medicare.gov website is not simple to navigate and requires viewing dozens of pages to identify and compare plans that list the desired drugs on their formularies.

Recently, several news articles have raised a new problem that many seniors are now encountering: even when drugs are listed on a plan's formulary, the drugs are "not readily available because of insurer's restrictions and requirements."[5] According to the director of health care systems at the American Psychiatric Association, who was interviewed in one account, "dosage and quantity limits are rampant ways of restricting access."[6] The president-elect of the American Medical Directors Association, which represents doctors who care for nursing home residents, warned: "We have seen signs that Medicare drug plans are using management controls to deter access to medically appropriate drugs, including drugs on their own formularies."[7]

These restrictive tactics are likely to create growing problems in coming weeks. In February 2006, in response to widespread reports of dual eligible beneficiaries who were unable to obtain medications after being switched to the Medicare benefit, CMS announced an extended transition period during which plans were required to provide dual eligible beneficiaries with medications regardless of whether they were covered under the plan's formulary, and regardless of prior authorization, step therapy, or volume limits.[8] This extended transition period expires on March 31, meaning that many dual eligible beneficiaries will once again become subject to these restrictions on necessary medications.

In addition, the May 15 deadline for enrollment is fast approaching, making the question of drug availability a prime concern for millions of seniors struggling to select a Medicare drug plan. When restrictive drug access provisions are employed by Medicare plans, even a careful review of plan formularies may not be sufficient to determine whether specific drugs will be available to a beneficiary.

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5 *Rules of Medicare Drug Plans Slow Access to Benefits*, New York Times (Feb. 14, 2006).

6 *Medicare Red Tape Snags Drugs*, USA Today (Feb. 28, 2006).

7 *Rules*, New York Times, supra note 5.

8 CMS, *Medicare Advantage Prescription Drug Plans and Medicare Prescription Drug Plans: Extension of Transition Period to March 31* (Feb. 2, 2006).

PURPOSE AND METHODOLOGY

At the request of Rep. Henry A. Waxman, this report investigates the provisions in Medicare drug plans that restrict drug access. It examines two questions: (1) How many Medicare drug plans use restrictive plan provisions? And (2) are the terms of these restrictive provisions disclosed to Medicare beneficiaries? The report is the first detailed analysis of the use of restrictive tactics by Medicare drug plans.

There are three principal provisions used by Medicare drug plans to restrict access to prescription drugs listed on plan formularies. They are:

- "Prior authorization" requirements. These provisions require the senior or his or her doctor to apply to the plan sponsor for approval before the plan will cover a specific drug. Often, prior authorization requirements can involve significant documentation burdens.

- "Step therapy" requirements. These provisions require the senior to use a variety of different drugs — and have these therapies fail — before the senior is allowed to obtain the drug of choice; and

- "Volume limits." Volume limits restrict the quantity or dosage of the drug that can be prescribed for a senior, regardless of whether the senior's doctor has determined greater quantities or dosages to be clinically necessary.

To determine the prevalence of these restrictive provisions among Medicare drug plans, the Special Investigations Division analyzed the Landscape of Local Plans Source File, which is a computerized database maintained by the Centers for Medicare and Medicaid Services.[9] This database contains detailed information on each Medicare-approved drug plan offered in each CMS region. There are 1,473 unique Medicare drug plans represented in the database. For each of these plans, the database indicates whether the plan imposes a prior authorization requirement or a step therapy requirement before a beneficiary can fill a prescription for one of the 100 most popular drugs.[10]

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[9] CMS, *Landscape of Local Plans Source File* (2006) (online at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/)

[10] The 100 most popular drugs are determined by the volume of prescriptions written for the drugs. The CMS database does not identify the specific drugs that are restricted by each plan. *Id.*

To determine whether plan representatives accurately describe the use of restrictive provisions when contacted by members of the public, the Special Investigations Division conducted a telephone survey of each of the 42 Medicare drug plans offered in Rep. Waxman's congressional district, the 30th Congressional District of California. This survey asked each plan for information about the use of prior authorization, step therapy, and volume limits for five sample drugs: Advair, an asthma medication; Norvasc, a blood pressure medication; Aciphex, a heartburn medication; Lexapro, an anti-depressant and anti-anxiety medication; and Ativan, an anti-anxiety medication. The five drugs were chosen because they include two drugs that are usually covered on plan formularies (Advair and Norvasc), two drugs that are less frequently covered on plan formularies (Aciphex and Lexapro), and one drug (Ativan) that is restricted by the Medicare law and cannot be covered by the plans. Multiple calls were made to each Medicare drug plan to check for consistency in the response.

To determine whether accurate information about the terms of restrictive provisions is disclosed online, the Special Investigation Division reviewed the Medicare.gov website and the websites of sponsors of popular Medicare drug plans.

The merits of restrictive plan provisions is a matter of dispute. Some doctors and health experts argue that these methods can "maximize savings and minimize harm."[11] At the same time, these experts have also indicated that their use could "reduce appropriate health care, adversely affect health status, and cause shifts to more costly types of care."[12] This report does not address these issues. Its focus is limited to assessing the prevalence of the plan restrictions and determining whether their terms are disclosed to beneficiaries.

FINDINGS

The report finds that the listing of drugs on the formularies of Medicare drug plans is not a reliable guide to the availability of the drugs to seniors. Virtually all Medicare drug plans use tactics that restrict access to at least some popular drugs listed on their formularies, with many plans restricting access to multiple drugs. The report also finds that the terms of these restrictions are virtually impossible for seniors to determine because plan representatives frequently provide confusing, conflicting, and erroneous information.

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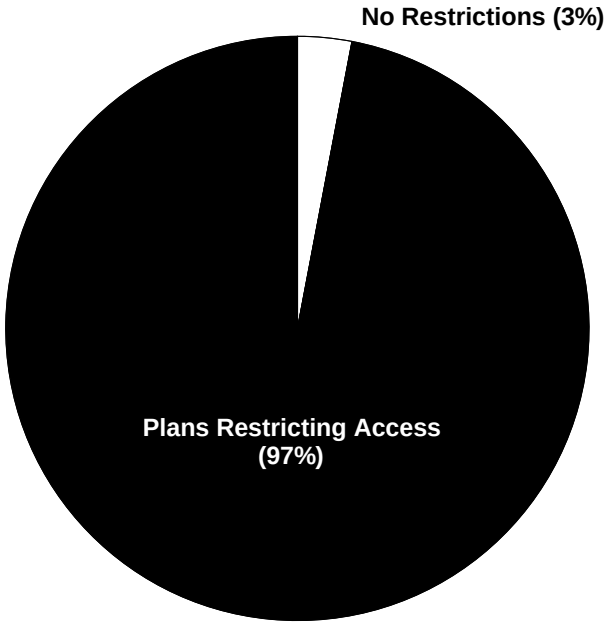
[11] Stephen B. Soumerai, *Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid*, Health Affairs (2004).

[12] *Id.*

The Vast Majority of Medicare Plans Restrict Access to Formulary Drugs

The CMS data reveal that vast majority of Medicare drug plans restrict access to popular prescription drugs listed on their formularies. There are a total of 1,473 unique drug plans that are approved by Medicare and represented in the CMS database. Of these plans, 1,434 (97%) place either prior authorization or step therapy requirements on at least one of the 100 most popular drugs. Figure 1.

Figure 1: Over 95% of Medicare Drug Plans Restrict Drug Access

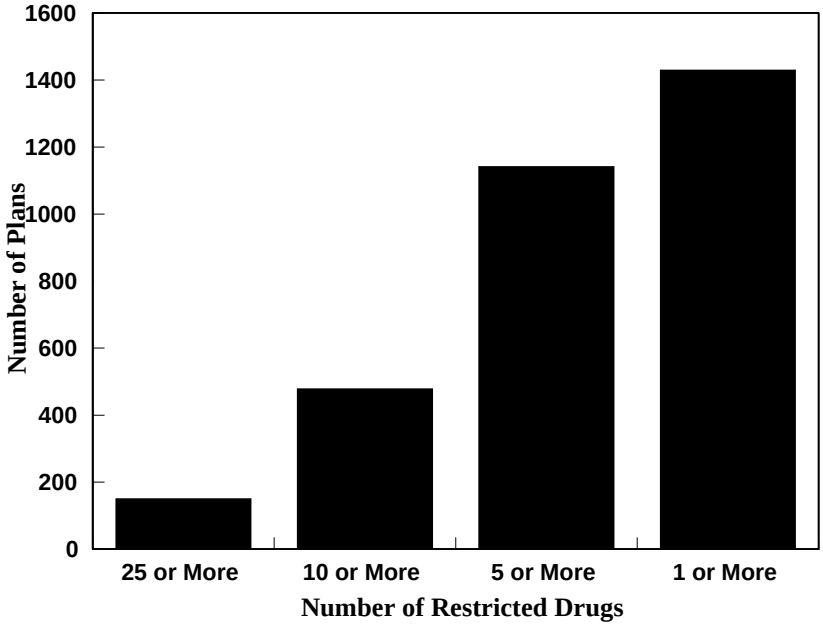


Most of these plans place restrictions on multiple drugs listed on their formularies. The average Medicare drug plan includes 93 of the top 100 drugs on its formulary. The average plan places either prior authorization or step therapy requirements on over 10% of these drugs, an average of 9.4 per plan.

Overall, 1,143 plans (77%) have prior authorization or step therapy requirements on five or more popular drugs; 480 plans (33%) have prior authorization or step therapy requirements on ten or more popular drugs; and 152 plans (10%) have

prior authorization or step therapy requirements on 25 or more of the top 100 drugs. Figure 2. Nine different plans have prior authorization or step therapy requirements on over 40 different popular drugs.

Figure 2: Many Medicare Drug Plans Restrict Access to Multiple Popular Drugs



Medicare Drug Plans Fail to Describe Plan Restrictions Accurately to Beneficiaries

A telephone survey was conducted of the Medicare drug plans in Rep. Waxman's district to assess how accurately the Medicare drug plans communicate the terms of the plan restrictions to seniors. In the telephone survey, 42 drug plans were called and asked about five drugs: Aciphex, Advair, Ativan, Lexapro, and Norvasc. Each plan was asked if the drug was on the formulary, and if so, if there were any additional prior authorization, step therapy, or volume limits on the drug. Forty-one plans included at least one of these drugs on their formulary. Of these 41 plans, 38 plans (93%) used at least one of the three forms of access restrictions.

In this survey, the drug plans were unable to provide basic information about the access restrictions they used. Seventeen of the 38 drug plans with access restrictions (45%) did not voluntarily provide any information about the restrictions. When the 38 plans were asked by the callers to describe the terms of

the access limitations, over two-thirds of the plans (26 plans) were unable to describe to beneficiaries how these limits worked with their particular plan.

Nine plans placed step therapy requirements on at least one of the five drugs in the survey. Two-thirds of these plans (6 plans) were unable to explain the nature of these requirements. Thirty-seven plans placed volume restrictions on at least one of the five drugs. Three-fifths of these plans (22 plans) were unable to provide descriptions of these limits. And 17 plans placed prior authorization requirements on at least one of the five drugs. Over one-quarter of these plans (5 plans) were unable to describe these requirements.

The plans offered a variety of reasons for failing to provide the information. In a number of cases, the plan representatives had no idea what prior approval, step therapy, or volume limits were. In other cases, the callers were told that only a beneficiary's doctor or pharmacist could provide specific information about plan restrictions. Numerous times, plan representatives told callers that they were not licensed to provide this information or that they simply did not have the information. In several cases, plan representatives told callers that they could not obtain information on plan restrictions until after they signed up for the plan or until after they provided detailed personal information such as their Social Security number.

Medicare Prescription Drug Plans Provide Conflicting or Erroneous Information to Beneficiaries

In several cases, the Medicare drug plans contacted in the survey provided information that was erroneous or misleading or that conflicted with information provided by the plan on other calls.

For example, three calls were made to Humana plans (the Humana PDP Basic, Humana PDP Enhanced, and Humana PDP Complete plans) to ask about limits on the drug Aciphex. On the first call, the plan representative informed the caller that none of the three plans had any limits. On the second call, a second representative informed the caller that the opposite was true: that all three Humana plans had step therapy and quantity limits on this drug. And on the third call, the representative had no idea what prior approval, step therapy, or volume limits were and referred the caller to a different customer service phone number. When called, the plan representative at the phone number provided inaccurate information. He informed the caller that there was a quantity limit of 30 on the drug and told the caller that this meant a senior could refill a prescription for Aciphex 30 times in a year. In fact, the quantity limit of 30 applies to the number of pills per month, meaning that a prescription could only be filled once a month.

In another case, three calls were made to Pacificare plans (the Pacificare Select, Pacificare Comprehensive, and Pacificare Saver plans) to ask about quantity limits on the drug Norvasc. Each time, the plan representative told the caller that there were no limits on this drug. Upon further questioning, the representative indicated that there were in fact limits of 30 pills per month, but then stated that the representative "did not consider that to be a quantity limit."

Two calls were made to Silverscript plans (the Silverscript Basic and Silverscript Plus plans) to ask about quantity limits on the drug Lexapro. On the first call, the plan representative told the caller that both plans had quantity limits. On the second call, the representative told the caller that the opposite was true: that neither of the plans had quantity limits.

In other cases, plans provided inaccurate information about the reasons why drugs were or were not on their formulary. A representative with the Prescription Pathway Silver plan was asked about formulary coverage of the drug Aciphex. The representative told the caller that it was not covered and that the drug was excluded by law from all Medicare plans. This is untrue.

Other calls were made about Ativan, a drug that actually has been excluded by law from coverage by Medicare plans. This time, representatives with three Cignature plans (the Cignature Rx Complete, Cignature Rx Plus, and Cignature Rx Value plans) told the caller that their plan did cover this drug.

Information about the Terms of Plan Restrictions Is Inaccessible Online

Another avenue that is potentially available to seniors to learn about plan restrictions is online research through the Medicare.gov website or the websites of plan sponsors. But these resources also fail to provide seniors with the terms of the access restrictions they will encounter if they subscribe to a specific plan.

The "Medicare Plan Finder" on the Medicare.gov website provides some information about plan restrictions, but the information is limited and buried far within the website. In order for a senior to evaluate Medicare drug plans, the website requires the senior to input the list of the drugs he or she takes. The plan finder then lists all the plans available to the senior, with the least expensive plan first. At no point in this process does the website indicate whether there are restrictions on access to the drugs.

When the beneficiary chooses a menu item titled "Cost Details," the website provides additional information on the cost of each individual drug. This

webpage has a small asterisk next to the drug name that informs the senior that "this drug may be subject to prior authorization, step therapy or quantity limits."

In order to obtain additional information on drug restrictions, the senior must then use a further menu, titled "Drug Details." At this point, the website provides only a simple yes/no description of whether there are prior authorization, step therapy, or volume limits on the drug. The website provides no additional detail about the nature of these restrictions. And it provides no detail about the terms of the restrictions for specific drugs.

The Special Investigations Division also examined the websites of five leading sponsors of Medicare drug plans.[13] The content was similar to the Medicare.gov website. In general, the existence of plan restrictions was available on the websites, but difficult to find. In no instances did the websites provide basic details about the plan restrictions, such as the terms of the restrictions.

CONCLUSION

This report evaluates the use and disclosure of restrictions in Medicare drug plans that limit the access of seniors to drugs on plan formularies. It finds that plan restrictions are widespread but their terms are not disclosed. Seniors thus face a "Catch 22" predicament. They cannot make fully informed decisions about Medicare drug plans without knowing how the restrictions will affect the drugs they use, yet they have no practical way of determining what these restrictions are until after they subscribe to a plan and are denied access to drugs.

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[13] These plans were the AARP Medicare Rx Plan, the Blue Cross Medicare Rx Plan, the Humana PDP Standard Plan, the Well Care Signature Plan, and the Medco YourRx plan.