



Medicare Rights Center

**Statement for the Record of Robert M. Hayes
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**Hearing on “The Medicare Prescription Drug Benefit: Monitoring Early
Experiences”
Before the United States Senate Committee on Finance
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Thank you for the opportunity to submit this testimony on implementation of the Medicare prescription drug benefit.

The Medicare Rights Center (MRC) is a not-for-profit consumer service organization, with offices in New York, Washington and Baltimore. It is supported by foundation grants, individual donations and contracts with both the public and private sectors. We are consumer-driven and independent, relying on a small staff and hundreds of deeply committed volunteers to carry out our mission. Our non-partisan mission is to serve the 43 million men and women with Medicare.

Through national and state telephone hotlines, casework and professional and public education programs, MRC provides direct assistance to people with Medicare from coast to coast. Each year, the Medicare Rights Center receives over 80,000 calls for assistance from people with Medicare. We provide hotline services and technical assistance to professionals across the country who assist people with Medicare. We also offer Medicare Interactive, the nation's only independent, web-based Medicare counseling tool at www.medicarerights.org/help.html.

Last year, we launched a Part D appeals program, recruiting a battery of volunteer lawyers and physicians to assist people with Medicare to obtain medications denied by their Part D plans. Drug plans place the Medicare Rights Center's toll-free phone number on notices informing their enrollees that the Part D plan is denying coverage of a prescribed medication.

Our testimony today focuses on the Part D appeals system, the process people with Medicare must navigate when they discover that they can not get their prescription filled. We also bring to your attention the particular problems of our clients who are seeking coverage of drugs that have proven effective in treating their condition, even though they were originally approved by the Food and Drug Administration for different indications. Because of a misreading of the statute by the Centers for Medicare & Medicaid Services, our clients are told that their plan is legally barred from covering this "off-label" use of the drug under Part D, even though everyone, including their doctor and their Part D plan, agrees the drug is medically necessary.

The Part D Appeals System

Under the law, Part D plans are required to provide coverage for all medically necessary drugs, with the exception of those excluded by statute. They do not.

Plans are given wide discretion to decide what drugs will be listed on their formularies and what restrictions they will place on the drugs they cover. The appeals process exists to ensure that these formulary restrictions and exclusions do not undermine the fundamental requirement to cover any drug that is medically necessary. When this system fails, people are not just out of luck. They are out of needed medicine, and the promise Congress made to people with Medicare is broken.

To work, the Part D appeals system must meet the following tests:

- People with Medicare must be informed of their rights to appeal and given the information they need—forms, fax and telephone numbers and timelines—to launch an appeal;
- Part D plans must handle all appeals expeditiously, within mandatory timelines, and refrain from obstructing the process either through incompetence or neglect;
- Decisions on appeals must be made, both by Part D plans and in the independent review, on the basis of objective, clinical assessments and in conformity with the spirit and the letter of the law.

Sixteen months into the drug benefit, we report that the Part D appeals system fails all three tests. Common problems include misinformation, delays and plan denials that reflect ignorance of Medicare requirements and the urgent medical needs of our clients.

Many plan members do not know they can appeal the denial of drug coverage by their plan. This lack of information usually originates with plans' customer service representatives, who neglect to tell members that they have a right to appeal or else tell them they cannot appeal. When plan representatives do mention the appeals option, they do not provide appeals forms, fax numbers for requests or other information needed to begin the process.

If an individual is able to file an appeal, the process too often bogs down in delays and miscommunication. The problems begin with the first step in the appeals process, when the plan member tries to request a redetermination of the denial. At this stage, the member is only asking the plan to reconsider its decision. Plans block the process at the start by failing to respond to these requests. One plan, WellCare, failed to acknowledge four requests we faxed on behalf of a client; many plans never respond, even though the law requires a response within seven days. The following story illustrates how plans can obstruct the appeals process and turn it into a bureaucratic nightmare for people with Medicare in need of vital medicines:

In February 2007, we received a call from a Utah man whose son is a member of Sierra Health. Sierra Health denied the son's prescription for a pain medicine he used to control severe, debilitating migraines. Because of his illness, the son was unable to navigate the appeals system and his father, who didn't know what to do, sought our help. Our counselor faxed a request for a redetermination but could not reach anyone at Sierra who could answer questions about the status of the request. At one point, the counselor was disconnected. Another time, the customer representative could not obtain information because her "system was down."

Plan members have 60 days after receiving a redetermination in which to file an appeal to the next stage, to Maximus Federal Services, a federal contractor. When we filed an appeal with Maximus, as advised by a Sierra representative, Sierra's defense was that we filed too late—more than 60 days after the redetermination. Sierra said the redetermination was issued in January, though neither we nor our client received it.

After the Part D plan has issued a redetermination—routinely an affirmation of its original coverage denial, an appeal can be made for an independent review to Maximus, a contractor for Medicare.¹ With the exception of appeals for off-label uses of drugs, an area where a misreading of the statute by the Centers for Medicare & Medicaid Services (CMS) results in a ban on Part D coverage, the Medicare Rights Center generally wins its appeals to Maximus. This success should not be taken as a sign that the Part D appeals system is working. In fact, it shows the opposite: that Part D plans are failing to use the appeals process to objectively assess whether they are responsible for coverage. It illustrates how Part D plans use the appeals process to prevent, or at least delay, coverage for drugs that are medically necessary but whose expense diminishes their bottom line. The following case is illustrative:

Ms. R is a Medicare beneficiary and survivor of Hurricane Katrina who was diagnosed with acute myelogenous leukemia in March 2002. To treat this condition, she had a bone marrow transplant in March 2005. After her transplant, Ms. R's physicians prescribed Cellcept to treat the chronic graft host disease that resulted from the transplant. According to her physicians, this treatment has been instrumental in preventing rejection of the transplant. At the time of her transplant, Ms. R did not have Medicare coverage because she was in the twenty-four month period people with disabilities must wait for Medicare coverage.

Ms. R became eligible for Medicare in June 2005, and enrolled in Community Care Rx in January 2006 to access Medicare Part D prescription coverage. Until January 2007, Community Care Rx provided coverage for her Cellcept prescription. However, on January 5, 2007, she received a "Notice of Denial of Medicare Prescription Drug Coverage" stating that this medication was excluded from Part D coverage because coverage is available under Medicare Part B. Community Care Rx failed to recognize that Part B would only cover Ms. R's Cellcept prescription if her transplant was covered by Medicare. In both the determination and redetermination stage, Community Care Rx ignored evidence of the date of the transplant and the plain guidance from the Centers for Medicare & Medicaid Services mandating coverage under Part D.

Ms. R was forced to pay \$1,200 a month out-of-pocket for this prescription while in the appeals process. Ultimately, in March of 2007, over two months later, Maximus Federal Services issued a favorable decision granting coverage of her prescription. If Ms. R had not had access to help from an experienced advocate, she would likely still be without coverage.

A Part D appeals system that requires the help of an experienced advocate to navigate is a failure, especially where there is absolutely no federal support to provide advocacy services to people with

¹ Data provided by CMS shows 8,772 redeterminations issued by plans from January 1, 2006 to July 31, 2006 and 8,336 appeals decided by Maximus, the qualified independent contractor. Since every appeal for an independent review is of a negative redetermination by the plan, it follows that, during the period surveyed, plans denied coverage in 95 percent of cases. Decisions in the independent review stage overruled plans 42 percent of the time.

Medicare. Without a dogged advocate familiar with the rights afforded people with Medicare and the responsibilities of the Part D plans, there is little hope of success in this appeals system. Our advocates hound the plans to comply with deadlines, help doctors provide evidence that demonstrate the prescribed medicine is medically necessary and assemble a case to present to both the plan and Maximus. Under Part D, people with Medicare effectively need a lawyer to get the medicines they need.

Senators Baucus and Grassley, we urge this committee to use its jurisdiction to ensure CMS conducts vigorous oversight and enforcement of Part D plans' implementation of the Part D appeals process. We remain skeptical, however, that a system of private, for-profit Part D plans that have financial incentives to deny coverage of needed but expensive medicines will ever feature an appeals system that guarantees access to medically necessary drugs. Congress should give older adults and people with disabilities the option to obtain drug coverage directly through Medicare, the program they trust to provide coverage in their interest and on the basis of medical necessity instead of a responsibility to maximize profit for shareholders.

Medicare Part D Coverage of "Off-label" Prescriptions

The Medicare Rights Center is representing a number of clients in their appeals for Part D coverage of drugs used for off-label indications—to treat conditions other than those listed on the FDA label. These cases concern off-label uses of drugs that have proven effective for our clients and are backed by wider, published evidence of effectiveness. However, CMS' narrow reading of the statute holds that these off-label uses are excluded from Part D coverage, because the off-label uses are not listed in compendia cited by the statute. (Compendia list indications approved by the FDA as well as some off-label indications.) This interpretation precludes coverage of medically accepted indications for which there is evidence of effectiveness, such as in peer-reviewed literature, the standard that applies to coverage of Part B drugs. CMS should revise its statutory interpretation and require Part D plans to provide coverage for medically necessary off-label prescriptions.

Illustrative Case:

Mr. H, a Medicare beneficiary and veteran of the U.S. Navy, was severely injured in a tornado on March 29, 1997. He suffered severe craniofacial trauma for which he underwent removal of his left eye, removal of portions of the left frontal lobe of his brain, and extensive cranial facial reconstruction. At the time of the injury, he was diagnosed with organic brain disease that causes him to suffer from severe migraines. Shortly thereafter, he became eligible for Medicare on account of his disability.

Since the tornado, Mr. H has required pain medication to manage the incapacitating headaches that cause seizures when left untreated. As a result, he has developed a tolerance to pain medications, causing most pain killers to be ineffective in managing his acute migraines.

For six years, Mr. H was using Actiq, which is indicated by the FDA to treat breakthrough pain in cancer patients, to manage his migraines and reduce the risk of seizing. Before the enactment of Medicare Part D, Mr. H received coverage of his Actiq prescription under the state Medicaid program, TennCare. Initially, when Medicare Part D was enacted and Mr. H was forced to enroll in a Medicare prescription drug plan, Humana covered his Actiq prescription. In October 2006, however, Mr. H was suddenly told by his pharmacist that Humana was denying coverage. Mr. H did not receive notice that his coverage would change nor did he receive a transitional supply.

Because he could not afford to pay for his Actiq prescription out-of-pocket, Mr. H's prescribing physician, Dr. B, prescribed Fentora, which is also indicated by the FDA to treat breakthrough pain in cancer patients, as a replacement for the Actiq. Fentora has also proven to successfully ease Mr. H's pain. Initially, Humana provided coverage of Mr. H's Fentora prescription, but in January 2007, ended this coverage without prior notification or transition fill.

Because his Fentora prescription costs approximately \$1,500 a month, Mr. H cannot afford to pay for it out-of-pocket. As a result, he visits the emergency room on a biweekly basis so that he can receive the medication at the hospital and avoid suffering from a seizure caused by his extremely severe pain. Maximus Federal Services has denied his appeal for Part D coverage and MRC is representing him in his appeal for review by an Administrative Law Judge.

Legal background:

The Medicare Part D statute creates a benefit that requires drug plans to cover drugs that are reasonable and necessary for the treatment of an illness, excepting explicitly listed exclusions. Nevertheless, Medicare regulations, specifically 42 C.F.R. § 423.100, exclude coverage of drugs that are not prescribed for a “medically accepted indication” as defined by the Medicaid statute in 42 U.S.C. § 1396r-8(k)(6). This regulation violates the purpose of the statute.

“Medically accepted indication” is defined in the Medicaid statute as,

any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act of the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).” 42 U.S.C. § 1396r-8(k)(6).

The language of the Medicare Part D statute does not exclude coverage of off-label prescriptions. “Covered Part D drug” is defined in relevant part as,

a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2)...and such term **includes** a vaccine licensed under section 351 of the Public Health Service Act and

any use of a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6)). 42 U.S.C. § 1395w-102(e).

Although this definition includes drugs that are prescribed for medically accepted indications, it **does not exclude** coverage for those that are prescribed for other indications, such as off-label prescriptions. Likewise, the reference to subparagraph (A) of section 1927(k)(2) specifically incorporates only subparagraph (A) and does not explicitly incorporate other paragraphs in section 1927 that limit coverage to medically accepted indications. Congress could have created a bar against coverage of off-label prescriptions, as it did by referencing the list of specific exclusions, but explicitly did not do so. *See* 42 U.S.C. § 1395w-102(e)(2).

Similarly, the structure of the Medicare Part D statutes demonstrates an intention to provide coverage for prescriptions that are medically necessary unless explicitly excluded. In developing their formularies, Part D plans are required by statute to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. 42 U.S.C. § 1395w-104(b)(3)(B)(i). Part D plans are also required to implement an appeals process that will allow enrollees to secure coverage of drugs that are not included in the plans formulary but are medically necessary. 42 U.S.C. § 1395w-104(h)(2). Under the statute, enrollees have the right to coverage if their prescribing physician indicates that none of the drugs on the formulary would be as effective. *Id.* Looking more broadly, Medicare Part B provides coverage of medically necessary off-label prescriptions. 42 U.S.C. § 1395x(t).

For these reasons, the purpose of the Medicare Part D statute should be honored by requiring plans to provide coverage for medically necessary off-label prescriptions.