Medicare Rights Center

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"Beneficiary Protections in Medicare Part D"
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Committee on Ways and Means
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Thank you Chairman Stark, Ranking Member Camp, distinguished members of the House Ways and Means Health Subcommittee, for holding this hearing on the consumer protections for people with Medicare under the Part D prescription drug benefit.

Unlike the hospital and outpatient medical benefits available under Medicare Parts A and B, prescription drug coverage is available only through private companies. There is no option to receive prescription drug coverage directly through Medicare. Instead of providing this option and using the purchasing power of 43 million people with Medicare to lower prescription drug prices, Congress established a system of private Part D plans which are at risk for the drug spending of their enrollees, a powerful incentive to hold down usage.

When enacting Part D in 2003, Congress recognized the financial incentives Part D plans have to restrict access to expensive medications and to discourage enrollment by people with Medicare who have high prescription drug costs. Congress therefore established a number of consumer protections under Part D that provide the right of appeal when Part D plan denies coverage for a prescription drug, that prohibit plans from designing formularies that discriminate against people who need high-cost drugs, and that ensure all people with Medicare, especially low-income older adults and people with disabilities, have access to coverage under a Part D plan. These and other statutory protections are vital to ensure Part D guarantees access to the prescription drugs people with Medicare need to stay alive and healthy. The experience over the first 18 months of the Part D benefit, however, shows that these consumer protections fall short. Legislation is needed to ensure both the Part D plans and the Centers for Medicare & Medicaid

Services (CMS) fulfill Congress' intent to provide meaningful consumer protections that guarantee access to quality, affordable drug coverage for people with Medicare.

Founded in 1989, the Medicare Rights Center is the largest independent source of information and assistance for people with Medicare. Since January 1, 2006, our case workers and volunteers have worked overtime helping people with Medicare deal with problems with the Part D prescription drug benefit. The problems fall into three broad categories:

- Problems securing and maintaining enrollment in the Part D plan that best suits their needs;
- Problems accessing affordable medicines under the low income subsidy, or Extra Help, program;
- Problems obtaining coverage for the medicines they need once they are enrolled in a Part D plan.

Enrollment

One of the most persistent and frustrating problems is the continuing inability of the computer systems used by CMS, the Social Security Administration (SSA) and the Part D plans to consistently and accurately transmit information on enrollment, premium and low-income status to each other. This information sharing is critical to ensure the correct premium for the right Part D plan is deducted from an individual's Social Security check and enrollment in the low income subsidy is reflected in the premium and cost sharing charged by the Part D plan.

Recently, we have been working to prevent people with Medicare from being dropped by their Part D plan for nonpayment of premiums. These individuals are having Part D premium deducted from their Social Security checks, but because of these systems problems, premiums are not finding their way to the Part D plans. We have been told repeatedly by CMS that these systems problems will be resolved "soon" but the resolution date has repeatedly slipped. Many of our clients are on low, fixed incomes. They cannot afford to have a premium deducted each month from their Social Security check, sometimes for a more expensive Part D plan that they quit last December, and also write a monthly check to their new Part D plan.

They should not have to. In fact, CMS told plans in March that they cannot disenroll individuals for nonpayment of premiums if the fault lies in these systems problems that fail to transmit funds deducted from Social Security checks to the correct plan. Despite this guidance from CMS, plans are still threatening to disenroll these individuals. This is one of the many areas where stronger oversight and enforcement by CMS of plan behavior is necessary.

Here is the story one person submitted to the Medicare Rights Center:

> I am writing on behalf of my 91-year-old mother, a California resident. Funds are being withdrawn in error out of her monthly social security check since January 2007. After 5 months of repeated phone calls, we still can't get anyone to accept responsibility and it still remains unresolved. Below is a brief summary of the steps we have taken.
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> In December, 2006, Medicare was notified that Mom dropped Humana Part D Drug Coverage and switched to SierraRx due to Humana raising their rates from $50.90 to $80.90.

> Since January 2007, $80.90 has been erroneously deducted each month from Mom's Social Security check through May 2007. In addition, Mom is paying her own SierraRx monthly fees by check.
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> I spoke to Social Security Security and they said there is nothing they can do. We were told by Humana in April that Social Security had updated its files, but $80.90 was again withdrawn for May's check. This has caused much emotional and financial stress.

Our caseworkers also handle a number of enrollment cases that are the fallout of aggressive and deceptive marketing, generally of Medicare Advantage plans that include the prescription drug benefit. The victims of such marketing abuses often need to retroactively disenroll from their MA plan in order to get Original Medicare to pay for medical care that the plan refuses to cover. They also have to return to the Part D plan they had previously through a Special Enrollment Period that is allowed for victims of marketing abuse. Even our experienced caseworkers can experience difficulty getting CMS regional offices to process these enrollment transactions. Although some CMS staff members are responsive, in other instances, MRC caseworkers must hound the regional office to process the enrollment and disenrollment while our clients wait months to get their Part D and Medicare coverage rectified.

The situation is even worse for the vast majority of people with Medicare that do not receive assistance from an MRC caseworker, a counselor with a State Health Information and Assistance Program or from the constituent services staff of their congressional representative. Our clients report being told by operators at 1-800-Medicare to “call your plan” when they seek to disenroll after being duped into a Medicare Advantage plan. When they call the plan, however, they are told that they

cannot disenroll, that they are locked in, even though individuals who are the victims of marketing abuse are entitled to a special enrollment period.

There is a common thread underlying all these enrollment problems. There are no due process protections for enrollment decisions under Part D or under the Medicare Advantage program. An individual dropped from their Part D plan for nonpayment of premiums who can show the premiums were deducted from her Social Security check has no guarantee of an independent review that could reinstate coverage. Someone seeking reinstatement in a Part D plan and disenrollment from a Medicare Advantage plan has no recourse if CMS officials do not believe she was victimized by fraudulent or deceptive marketing. Congress should enact due process protections that govern enrollment decisions made by CMS and Part D plans. It's common sense, basic fairness and a requirement of constitutional law.

We also recommend that Congress lift lock-in for the Part D and the Medicare Advantage programs, a broader solution that would help resolve these and other Part D consumer problems. Last winter, a number of clients reported that they had not received notice from their Part D plans about premium increases, formulary changes or curtailments to the coverage in the doughnut hole. These complaints focused on a far wider array of plans than the single company CMS identified publicly as failing to send out its annual notice of change in time. By the time consumers discovered the changes to their coverage, it was too late. They were barred by the statutory lock-in provision from changing their Part D plan.

Because of the way enrollment periods are structured, however, these clients did have the ability to change their Part D coverage, but only if they traded a stand-alone

drug plan for a drug plan that came with a Medicare Advantage plan, a so-called MA-PD. Congress should align the enrollment periods, extending the ability to change Part D plans into the first three months of the calendar year. This will provide people an opportunity to change plans once they have become aware, at the pharmacy counter and through the bills they receive, of how coverage in their Part D plan has changed. There is no reason why someone can change Part D coverage only when one of the parties to the transaction is a Medicare Advantage plan, but not when the change is between stand-alone Part D plans. This extended enrollment period will also provide make it easier for the data exchange systems to accommodate enrollment decisions made just days before the December 31 deadline.

Any steps Congress takes to add flexibility to the Part D enrollment process will help people with Medicare who find it difficult to select among multiple plans, each with different formularies, cost sharing, premiums and drug prices. Both drug prices and formularies can change at any time during the year, as of course can the medical condition and the need for specific medicines, of a Part D enrollee. Lock-in removes the ability of most consumers to respond to those changes after January 1.

Many people with Medicare, especially, but not exclusively, individuals with cognitive impairment or low levels of literacy, are unable to conduct the formulary review and on-line price comparison necessary to make an informed selection of a Part D plan. Congress recognized this reality when it provided for automatic Part D enrollment for individuals transitioning from Medicaid to Part D drug coverage. CMS extended that process by "facilitating" enrollment of all individuals receiving the low income subsidy who have not made an independent plan selection.

Assignment of plans under automatic enrollment, however, is completely random, with no regard given to whether the assigned Part D plan covers the drugs of its new enrollee. Many of the coverage problems that people experienced at the start of Part D in 2006 are attributable to this random assignment. Matching drug regimens with plan formularies is a more sensible approach, but random assignment of dual eligibles is written into the Medicare statute. A number of states use formulary criteria in assigning plans for members of their state pharmaceutical assistance commissions and through these efforts were able to match individuals with plans that covered their drugs, the same process that informed consumers use in their plan selection.

Random reassignment of people with Medicare receiving the low income subsidy is slated to occur on an annual basis, as plans that received auto enrollments in one year find their Part D premium is above the regional low income benchmark, which is based on average Part D premiums charged by Part D and MA plans in the area. CMS minimized the number of low income people subject to random reassignment by using its demonstration authority to change how the low income benchmark was calculated in 2007. As CMS phases-in the benchmark setting formula set by statute, millions of low income subsidy recipients are likely to be randomly reassigned to new plans, with different formularies, on an annual basis. Congress should amend the law to require CMS to match drug regimens and formularies in effecting these reassignments.

Low Income Subsidy

Changing Part D plans, either on a voluntary basis or by random reassignment, often interrupts access to affordable medicines for low income individuals because systems problems prevent the record of enrollment in the low income subsidy from

traveling with the individual when they change plans. This means that the individual may face a $265 deductible or a high copayment instead of the copayments of $5 or less that are set by statute. For individuals living on low, fixed incomes this can put vital medicines for treating hypertension or controlling seizures out of reach.

Although this problem is rooted in the systems problems it is compounded by a persistent failure of Part D plans to comply with CMS guidance requiring plans to accept "best available evidence" of enrollment in the low income subsidy. What this policy should mean is that an individual can present her Medicaid card or LIS award letter from SSA at the pharmacy, the pharmacist will inform the Part D plan customer service center of the customer's LIS status, and the plan customer representative will fix it so the electronic billing transaction between plan and pharmacy charges the appropriate copayment for an LIS recipient. However, our clients often experience a flat out refusal by plan customer service representatives to charge the appropriate copayment, even when a pharmacist or MRC case worker explains the requirements laid out in CMS guidance. Improved oversight and enforcement by CMS are needed in this area as well.

Part D Appeals

Part D plans are given wide latitude to decide what drugs they will cover and what restrictions they will place on the drugs they do cover. To protect access to medically necessary drugs, Congress established an appeals process. Since the start of the Part D benefit, the Medicare Rights Center has helped hundreds of individuals navigate the appeals system and obtain coverage for the medicines they need. In our experience, the Part D appeals system is cumbersome, unfair and vulnerable to obstructionist tactics by Part D plans.

The appeals process usually breaks down before it starts, when the consumer obtains a rejection at the pharmacy counter. Many consumers are never notified of their appeal rights because CMS has failed to articulate and enforce regulations that would ensure people with Medicare are notified of their rights. We recommend that Congress direct CMS to require that Part D plans and their pharmacies provide a written explanation at the pharmacy of why coverage of why their prescription has been denied, an explanation of their appeals rights and the necessary contact information to begin the appeals process. Without such notice, the Part D appeals process will remain little more than a fiction.

After having a prescription rejected at the pharmacy counter, a consumer must then call the Part D plan to obtain an exception, also known as a coverage determination. At that point, the consumer must convince her doctor to write to the plan to explain why the prescribed drug is medically necessary. Not only are doctors not paid for this task, they often must deal with plans that refuse to explain the criteria used for obtaining coverage. In fact, only last week did CMS clarify that Part D plans must provide this information to doctors.

If the plan affirms its initial denial of coverage, consumers must ask the plan a second time for coverage "redetermination," often after they have already engaged in a back-and-forth between their doctor and the plan for more information. CMS statistics show that plans deny 95 percent of redeterminations but that a majority of these redeterminations are overturned through independent review. We recommend that Congress simplify the appeals process by requiring the initial rejection at the pharmacy to count as the first coverage determination. Consumers would ask their plans one time for a

coverage "redetermination," before proceeding to an independent review. Congress can also help secure the participation of doctors in the appeals process by allowing them to represent their patients at the redetermination and independent review stages without securing an appointment to represent their clients.

The Medicare Rights Center wins most of the cases once we obtain an independent review of the plans' coverage denial, with the exception of appeals for coverage of drugs prescribed for off-label indications, indications other than those approved by the Food and Drug Administration. CMS' interpretation of the statute defines a medically accepted indication only as one that is specified on the label or an off-label use that is referenced in one of three medical compendia. If the prescription is off-label but not included in the specific compendia, Medicare Part D will not provide coverage, even if the usage has been shown effective in peer-reviewed clinical literature, the standard that applies for Part B drugs. We urge Congress to clarify the Part D statute so that the definition of medically accepted indication is consistent with Part B and our clients can obtain coverage for drugs that have proven effective in treating their condition. The story of one of our current clients shows why Congressional action is necessary.

> Mr. H, a U.S. Air Force veteran, was severely injured in a tornado in 1997. As a result, he had to undergo removal of his left eye, removal of portions of the left frontal lobe of his brain, and extensive cranial facial reconstruction.
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> Mr. H has worked to manage his pain with his prescribing physician, a board-certified pain management specialist. For six years, under the supervision of his physician, Mr. H successfully used Actiq, a medicine approved by the FDA for treatment of breakthrough pain for cancer patients, to manage his migraines and reduce his risk of seizing. Before

the enactment of Medicare Part D, Mr. H received coverage for Actiq under his state's Medicaid program, TennCare. Initially, his Part D plan covered Actiq, but in October 2006 Mr. H was suddenly told by his pharmacist that the drug would no longer be covered. Because Actiq was being prescribed for an off-label indication, it was not considered a medically accepted indication under Part D.

Mr. H's doctor prescribed Fentora, also approved for treating cancer-related pain, as a replacement. Recently published peer-reviewed literature has demonstrated that Fentora is a safe and effective method of treating neuropathic pain and the drug has proven successful at easing Mr. H's pain. Initially, Mr. H's Part D plan covered Mr. H's Fentora prescription, but in January 2007, the plan ended this coverage without prior notification to Mr. H or a transition fill.

Since Humana stopped covering his Fentora prescription, Mr. H has been forced to go without treatment because he cannot afford to pay out-of-pocket. When Mr. H had access to his Fentora prescription, he experienced only one seizure per month; without this prescription, he now experiences approximately four seizures every week. As a result, Mr. H must now make frequent trips to the emergency room. This pain hampers every aspect of his life, including his ability to interact with his family and complete daily tasks.

Because Medicare Part D regulations do not allow for consideration of peer-reviewed medical literature, Mr. H's appeals to for coverage to both his plan and the independent review entity were unsuccessful. On Mr. H's behalf, MRC has submitted a request for review of this decision by an Administrative Law Judge, and we are currently waiting for a hearing to be scheduled.

We believe the experience of people with Medicare over the first year-and-a-half of the Part D benefit should guide Congress' efforts to improve consumer protections. We recommend that Congress take action to streamline the Part D appeals process and ensure access to medically necessary drugs, including for off-label uses that have proven

to be clinically effective. Enrollment protections for people with Medicare, including the removal of lock-in for Part D and the Medicare Advantage program, should also be enacted. Finally, Congress should direct CMS to exercise its oversight and enforcement responsibilities so that the protections afforded people with Medicare on paper are in fact provided by the Part D plans. The Medicare Rights Center stands ready to work with members of both parties on making stronger Part D consumer protections a reality.