Medicare Rights Center

The Best Medicine:
A Drug Coverage Option Under Original Medicare

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Introduction

The inception of the Medicare outpatient prescription drug coverage (Part D) marked the first time in Medicare's 42-year history that a Medicare benefit has been provided entirely through private companies, without an option administered directly through Medicare.

Original Medicare provides coverage for hospital and outpatient medical services by enrolling all older adults and people with disabilities, regardless of health or financial status, into a single risk pool and providing a uniform premium subsidy and cost-sharing structure. Coverage is guaranteed for all "reasonable and necessary" medical services, with the exception of those excluded by law, such as most dental and vision care. People can go to practically any doctor or hospital in the country, and they can purchase supplemental insurance (Medigap policies) to cover their out-of-pocket costs.

By contrast, if people need Medicare prescription drug coverage under Part D, they can only get it by purchasing coverage, with the help of a premium subsidy from Medicare, from one of the dozens of competing prescription drug plans available in their area. This radically different structure has a profound impact on people with Medicare, which can be summarized as follows:

- **Higher Costs:** The delivery of the benefit through multiple plans fragments the negotiating leverage that would be available under a drug benefit run by Original Medicare. If Medicare could negotiate on behalf of all the 43 million people with Medicare, it could obtain lower prescription drug prices from manufacturers. The negotiations between private plans and drug manufacturers have failed to translate into affordable prices for people with Medicare at the pharmacy counter. The private delivery mechanism also results in higher administrative costs, which are passed on to consumers as higher premiums.

- **Gaps in Coverage:** The fundamental guarantee that access will be provided to all medically necessary drugs is undermined by the privatized structure of the benefit. Subject to statutory and regulatory parameters, companies that offer Part D plans have wide discretion to decide which drugs they will cover, what restrictions they will place on coverage and what differential cost-sharing they will impose on different drugs. As a result, there is wide variation in the formularies used by Part D plans and substantial failures to cover medically necessary drugs. This variation hinders doctors' efforts to comply with formularies, interrupts continuity of care in the transition between different treatment settings and necessitates reliance on an inefficient appeals system. The results are coverage denials and gaps in coverage that impair access to medically necessary drugs.

- **Instability:** The structure of the Medicare Part D premium subsidy creates instability in Part D premium rates from year to year. In addition, the premium assistance provided for people with low incomes is subject to similar instability, potentially forcing millions of vulnerable people with Medicare to switch plans every year. Formulary coverage, cost-sharing structures and supplemental benefits are also made unstable by the market pressures on competing plans.

- **Consumer Confusion and Marketing Fraud:** The multiplicity of plans and the wide variability in their formularies and cost-sharing structures generate confusion among

consumers, especially frail elderly and individuals with cognitive impairment and mental illness. The confusion renders people with Medicare vulnerable to coercive and deceptive marketing by private plans.

Providing older adults and people with disabilities the option to obtain prescription drug coverage directly through the Original Medicare program, without the insurance middleman, will provide a refuge from the rising costs, instability and gaps of the Part D plan marketplace. A Medicare-run drug benefit will provide stability and peace of mind to people with Medicare who have come to trust and rely on the program for all their other health care needs. It will reduce out-of-pocket spending for consumers through greater administrative efficiencies and maximized negotiating leverage with drug manufacturers.

Most importantly a Medicare-run drug benefit has an incentive to make the clinical effectiveness of prescription drugs the single most important determinant of formulary coverage because Medicare does not have to maximize profit, and it has a long-term interest in ensuring effective drug regimens that minimize individuals' need for other medical care.

Higher Costs

People with Medicare who are enrolled in Part D are directly affected by three types of costs imposed by Part D plans:

- monthly premiums;
- copayments or coinsurance during the initial and catastrophic coverage phases of the benefit; and
- retail prices charged during the deductible and coverage gap (doughnut hole) phases of the benefit.

In addition, the parameters of the standard benefit (the size of the deductible and the coverage gap and the copayments due for those eligible for the partial low-income subsidy) are determined by the growth in per capita Part D spending, and thus, by the ability of private drug plans to constrain rising prescription drug prices. More broadly, Congress' ability to improve the Part D benefit, for example, by closing the doughnut hole or expanding access to the low-income subsidy (known as Extra Help), is constrained by the cost of taking such measures, which will be high if not offset by the savings a drug benefit option under Original Medicare could achieve.

Numerous studies have documented that the retail prices charged by Part D plans—prices paid by enrollees in the deductible and doughnut hole phases of the benefit—are substantially higher than prices the Department of Veterans Affairs (VA) has been able to negotiate for its patients.

The latest in a series of reports by Families USA, issued in January 2007, found the VA had lower prices on all the top 20 drugs used by older adults than the prices charged by the Part D plans with the highest enrollment. For half of the drugs studied, the lowest price available under a Part D plan was at least 58 percent higher than the price charged by the VA. Among the higher priced plans, the price charged was at least twice the VA price for half of the drugs surveyed.[1]

[1] *No Bargain: Medicare Drug Plans Deliver High Prices*, Families USA, 2007 (www.familiesusa.org/assets/pdfs/no-bargain-medicare-drug.pdf).

The Families USA studies mirror the result of a study conducted by Consumers Union in October 2006. Using the top five most prescribed brand-name drugs, Consumers Union found that Part D prices in Broward County, Florida, were on average 54 percent higher than the VA price. A survey of prices available at pharmacies in Broward County found that 80 percent of the Part D plans charged a higher price for enrollees in the doughnut hole than the price charged by at least one local pharmacy for non-Part D customers.[2]

A report by the House Government Oversight Committee Minority Staff found Part D prices were on average 60 percent higher than what Canadian consumers pay, which are capped at the average price charged in seven industrialized countries.[3] This report also found that discounts obtained by Part D plans were within 3 percent of the prices available at discount retailers such as Drugstore.com and Costco.

These studies demonstrate the inability of the private Part D plans to provide enrollees with prices as low as the VA or the Canadian health system or even to come in below the prices available from discount retailers. While these prices represent what consumers would pay during the deductible or in the doughnut hole, they do not represent the prices actually paid by Part D plans for drugs, which are reduced by rebates and other payments made directly from manufacturers to Part D plans (or the pharmacy benefit managers [PBMs] contracted by Part D plans). These savings to the plan, however, are not translated into lower retail prices for their enrollees, who are paying the full price of drugs in the deductible or doughnut hole phases of the benefit.

In fact, in a recent rulemaking, the Centers for Medicare & Medicaid Services (CMS) acknowledged that "Part D sponsors are unable to actually apply discounts, rebates, and other price concessions at the point of sale. . . ." This inability is rooted in the pricing structure of the pharmaceutical market. Retail prices are set through negotiations between PBMs and pharmacies; in exchange for inclusion in the PBM's pharmacy network, pharmacies agree to limit their markup by establishing a price based on a percentage of a list price set by manufacturers. In exchange for preferable formulary placement, PBMs secure rebates and other remuneration from manufacturers, but these payments are not passed through to plan members as lower prices at the pharmacy counter.

To the extent rebate income is passed on to consumers, market dynamics encourage Part D plans to use these funds to lower premiums and copayments across the board in order to make the benefit more attractive, in particular for low-cost enrollees (healthier members who have few and cheaper prescription drug needs). This creates a dynamic in which consumers who need high-cost medicines wind up subsidizing coverage for healthier enrollees through the rebates generated by the high-cost drugs. Rebate data provided by plans to congressional investigators show that plans will receive $1 billion in rebates in 2007 for drugs their members purchased at full price during the coverage gap. Although the purchasers of these drugs will still be paying

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[2] *Not Low Enough: Medicare Part D 'Donut Hole' Prices Compared with Retail and VA Prices*, Consumers Union, October 2006 (www.consumersunion.org/pdf/RXReport06.pdf).

[3] *New Medicare Drug Plans Fail to Provide Meaningful Drug Price Discounts*, U.S. House of Representatives Committee on Oversight and Government Reform—Minority Staff Special Investigations Division, November 2005 (http://oversight.house.gov/Documents/20051122163450-37554.pdf).

premiums to their plans, the rebates they generate with each purchase in the coverage gap are not used to lower the prices they pay at the pharmacy counter.[4]

Although the rebates and other remuneration that Part D plans receive from drug manufacturers are closely held secrets, the evidence is strong that they fall short of the discounts that government health care programs—Medicaid, the VA, health systems in other industrialized countries—have been able to secure, and, therefore, the price concessions a Medicare-administered drug benefit could be expected to achieve.

CMS researchers have acknowledged that the transfer of six million dual eligibles (people with both Medicare and Medicaid) from Medicaid drug coverage to Medicare Part D private plans increased spending on prescription drugs. Part D plans were unable to secure rebates equivalent to those received by state Medicaid programs that are either mandated by statute or secured through negotiations by states.[5] The transfer of coverage to Part D halted a downward spending trend caused by aggressive, multistate negotiations for lower Medicaid drug prices.[6] This research demonstrates the rise in government spending on prescription drugs and the subsequent windfall profits that some drug manufacturers reported from the involuntary shift of so many consumers from Medicaid to Medicare Part D coverage.

Using the estimates of CMS actuaries (who do have access to rebate information for Part D plans), Johns Hopkins University professor Gerard Anderson testified before Congress that Part D plan prices, including manufacturer rebates, are 22 percent higher than Medicaid prices and 31 percent higher than the rates negotiated by the VA.[7] Anderson's testimony also highlights projections from CMS actuaries that predict Part D plans will not be able to negotiate better prices from drug manufacturers in the future.

A recent report by the House Committee on Government Reform and Oversight confirms Anderson's analysis. Drawing on confidential information on manufacturer rebates provided by 12 major Part D plans, the committee found that manufacturer rebates will reduce Part D drug spending by just 8.1 percent in 2007, well below the 26 percent spending reduction that the federal government and states secure for the Medicaid program and the 50 percent average discount obtained by the VA. If Part D plans had been able to negotiate rebates on par with what Medicaid receives, taxpayers and plan enrollees would have saved $10.7 billion in 2007.[8]

The failure of Part D plans to negotiate price concessions from manufacturers on par with those achieved by government programs results in higher costs to taxpayers and higher premiums and

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[4] *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, U.S. House of Representatives Committee on Oversight and Government Reform, Majority Staff, October 2007. http://oversight.house.gov/documents/20071015093754.pdf

[5] "Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact," Poisal et al., *Health Affairs*, February 2007. http://content.healthaffairs.org/cgi/reprint/26/2/w242

[6] "National Health Spending in 2005: The Slowdown Continues," Caitlin et al., *Health Affairs*, January 2007 (http://content.healthaffairs.org/cgi/content/full/26/1/142).

[7] Statement by Gerard Anderson, director of the Center for Hospital Finance and Management, Johns Hopkins University, before the Oversight and Government Reform Committee, U.S. House of Representatives, February 9, 2007 (http://oversight.house.gov/Documents/20070209123654-09260.pdf).

[8] *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, U.S. House of Representatives Committee on Oversight and Government Reform, Majority Staff, October 2007. http://oversight.house.gov/documents/20071015093754.pdf

cost-sharing for people with Medicare drug coverage. Dean Baker of the Center for Economic and Policy Research estimates a potential savings of $42 billion in 2006 if the Part D benefit were able to secure the prices negotiated by the Australian government, which uses a national formulary to leverage lower prices in the same manner as a Medicare-run drug benefit could operate. According to Baker, "If Medicare had been allowed to bargain directly with the pharmaceutical industry, and could obtain prices as low as the Australian government does, the savings would be more than twice the size of the doughnut hole. This would allow for elimination of the doughnut hole, in addition to substantial savings for the federal and state governments."[9]

In addition, using estimates from the Congressional Budget Office, Baker estimates an additional $4.6 billion in potential savings in 2006 by eliminating administrative expenses, marketing costs and profits by Part D plans under a government-administered drug benefit. Data provided by Part D plans to the House Committee on Government Reform and Oversight showed that plans' administrative expenses, sales costs and profits totaled $4.3 billion in 2007, including profits of $1 billion. Together with CMS' costs of overseeing the program, the overall administrative cost of the privatized Part D structure is $4.6 billion in 2007, or 9.8 percent of total Part D costs. By contrast, Medicare administrative expenses for Part A (hospital insurance) and Part B (outpatient care) account for just 1.7 percent of total benefit costs.[10]

Supporters of the privatized Part D benefit have made much of the fact that revised estimates of the benefit's cost are lower than initial projections. The principal causes of these "savings," however, are the national dampening of prescription drug inflation—independent of Part D—and lower-than-projected enrollment in the benefit.[11]

The full impact of Part D private plans' failure to lower drug prices, however, has yet to be felt by consumers. Part D plans have been largely insulated from risk in the first two years of the Part D benefit through risk corridors that trigger payments to plans if losses exceed specified thresholds. This has enabled plans to use low premiums to attract market share, including that of dual eligibles automatically assigned by Medicare to lower-cost plans, and to pursue a strategy to "migrate" Part D enrollees to their private Medicare health plans (known as Medicare Advantage plans).[12] People with Medicare have also been largely insulated from sharp Part D premium increases as CMS used its demonstration authority to prevent the statutory formula from causing a precipitous drop in the subsidy for Part D premiums.

Finally, the benefit parameters—the size of the deductible, initial coverage limit and coverage gap (doughnut hole)—will rise with the escalating cost of drug treatment. The inability of Part D plans to restrain the growth in drug prices translates each year into an ever-larger coverage gap in the Part D benefit. The coverage gap in particular will grow very fast. Getting out of the

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[9] *Waste in the Medicare Drug Benefit: Why the Doughnut Hole Is Unnecessary*, Dean Baker, Center for Economic and Policy Research, July 2006 (www.cepr.net/documents/medicare_waste_2006_07.pdf).

[10] *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, U.S. House of Representatives Committee on Oversight and Government Reform, Majority Staff, October 2007. http://oversight.house.gov/documents/20071015093754.pdf

[11] Statement by Gerard Anderson, director of the Center for Hospital Finance and Management, Johns Hopkins University, before the Oversight and Government Reform Committee, U.S. House of Representatives, February 9, 2007 (http://oversight.house.gov/Documents/20070209123654-09260.pdf).

[12] "Plan A: Hook Them with Part D," Howard Gleckman, *BusinessWeek,* January 30, 2006.

coverage gap in 2006 requires $5,100 in total drug spending, but this rises to $5,596 in 2007 and $6,158 in 2008.[13] As a result, the total size of the coverage gap will rapidly increase over time and engulf more and more Americans if no legislative changes are made.[14]

A Medicare-run drug coverage option can serve as an alternative for consumers as the full impact of the privatized Part D benefit is felt by consumers in the coming years. The Medicare option can provide a true test of the private Part D plans' ability to control costs, pitting them not against earlier projections that were erroneously set too high, but against the demonstrated ability of a government-run benefit to deliver lower prices and administrative efficiency.

Gaps in Coverage

The fundamental guarantee Congress made to people with Medicare that access will be provided to all medically necessary drugs is undermined by the privatized structure of the benefit. Subject to wide statutory and regulatory parameters, Part D plans have wide discretion to decide which drugs they will cover, what restrictions they will place on coverage and what differential cost-sharing they will impose on each drug they cover. As a result, there is wide variation in the formularies used by Part D plans and substantial failures to cover medically necessary drugs affordably or at all. Since most enrollees are subject to plan lock-in (that is, they can change their drug plan only once a year), they often find out midyear that their plan does not cover what they need or covers it at a very high out-of-pocket cost.[15] Members cannot then change to a plan that is better suited to their changing medical needs. Problems accessing needed medications often lead to higher costs for Medicare Parts A (inpatient care) and B (outpatient care).

Coverage for People with Life-Threatening Conditions

Below are examples of how the privatized Part D benefit has failed to meet the needs of people with life-threatening conditions:

Cancer. Avalere Health, a health care research group in Washington, DC, examined how the choice of a drug plan affects cancer patients. Researchers looked at how each of a dozen Part D

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[13] "Medicare Part D Benefit Parameters for Standard Benefit: Annual Adjustments for 2007," Office of the Actuary, Centers for Medicare & Medicaid Services (CMS), May 22, 2006 (www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/2007_Part_D_Parameter_Update.pdf) and "Part D Payment Notification," Abby Block, Centers for Medicare & Medicaid Services (CMS), April 2, 2007 (www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/PartDAnnouncement2008.pdf).
The Part D benefit parameters are currently pegged to increases in national drug spending, which are higher because of Part D's takeover of drug coverage for dual eligibles. Year-to-year increases in Part D drug spending will not be used to adjust benefit parameters until the 2009 plan year.

[14] *Falling into the Doughnut Hole: How Congress and the Drug Industry Created a Trap for American Seniors and People with Disabilities*, Jeff Cruz and Roger Hickey, Institute for America's Future, June 2006 (www.house.gov/berry/issues/0607-DoughnutHole.pdf).

[15] People with Medicare and Medicaid and people with Medicare who meet other specific criteria are not subject to lock-in.

plans covered drugs prescribed for seven standard treatments for breast, colon and lung cancers, and lymphoma.[16]

Although nearly all the necessary drugs were covered by the 12 plans, the patient's cost varied significantly. The most expensive plan for drugs used to treat metastatic colon cancer was nearly 29 times as much as the lowest-cost plan for the same drugs. The most expensive plan covering a drug regimen for low-grade lymphoma was almost 7 times more than the cheapest one, also for the same drugs. Researchers substituted cheaper generic drugs when available and also took into account each plan's monthly premiums, copayments and the full drug price the member pays during the coverage gap. They used a proprietary database to determine how much each of the seven treatment regimens would cost under each plan—a sophisticated system most people with Medicare could not navigate.

In addition to the dramatic differences in plan costs, researchers discovered that a plan where a member has a set copayment for a prescription—$20, for example—is not always less expensive than paying a percentage of the full drug price. "In some cases, the copay amount charged by the plan equaled or exceeded the baseline negotiated price as cost-sharing. This resulted in the beneficiary paying the full negotiated price as cost-sharing."[17] As an example, they found that the copayment amount under some plans for Proventil, a common asthma medication used in the treatment protocol for metastatic colon cancer, was greater than the drug's full price.[18]

Although the study found that most cancer drugs are covered by most Part D plans, figuring out which plan is the best bargain is extremely difficult. People with Medicare cannot assume that a plan with low monthly premiums and copayments will be the least expensive in the long run. And the authors caution that one of the greatest obstacles in choosing the right plan is the unknown—that no one can know before enrolling that he or she may need treatment for cancer in the coming year.

HIV/AIDS. Late last year, the HIV Medicine Association and the American Academy of HIV Medicine asked its members, who include most of the country's HIV/AIDS care providers, about their Medicare patients' access to medications since joining private drug plans. The survey was released in April 2007 and found that 83 percent of the 377 responding providers said that their patients had trouble getting their medicine from their Medicare private drug plan.[19] Of those who reported problems

- 80 percent said at least one of a patient's drugs was subject to prior authorization;
- 76 percent said the plan did not cover at least one of a patient's drugs;
- 73 percent said patients could not afford their share of the cost;
- 46 percent said patients had difficulty getting enrollment cards;
- 44 percent said their patients' drugs were subject to quantity limits.

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[16] *Cost-Sharing for Cancer Patients in Medicare: Seven Case Studies*, Catherine Harrison and Khoa Nguyen, prepared by Avalere Health LLC, October 2006 (www.avalerehealth.net/research/docs/ACS_Cost_Sharing_For_Cancer_Patients.pdf).
[17] *Cost-Sharing for Cancer Patients in Medicare: Seven Case Studies*
[18] *Cost-Sharing for Cancer Patients in Medicare: Seven Case Studies*.
[19] "HIV Medical Provider Medicare Part D Survey," HIV Medicine Association and the American Academy of HIV Medicine, April 2, 2007 (www.aahivm.org/images/stories/pdfs/medpartd__provider_survrept_2007.pdf).

As a result of these problems, 75 percent of providers reported that their patients could not get their medications, including 65 percent who said that their patients missed taking antiretrovirals as well as other drugs. These lapses in coverage occurred even though Medicare required Part D plans to cover all but one antiretroviral medication and cover them without restrictions.

HIV disease can be effectively controlled through strict compliance with a regimen of several daily doses of three or more expensive drugs. The availability of these drugs means that, for most patients, an HIV diagnosis is not a death sentence. But when patients have to skip their medications, providers report serious consequences:

- 60 percent said that their patients had extra or unscheduled medical appointments because of Part D-related problems;
- 28 percent said that patients experienced other adverse health effects due to Part D.

Mental Illness. A survey of U.S. psychiatrists by the American Psychiatric Institute for Research and Education found similar problems during the first four months of the Part D program among mentally ill patients with both Medicare and Medicaid.[20] This group is particularly vulnerable to Part D's shortcomings. They are more likely to be poorer, members of a minority group, sicker, use more drugs and live in a nursing home.[21]

Treatment of mental illness involves a "trial-and-error process" to find the most effective medication and dosage, according to a recent analysis in the journal *Health Affairs*. And once an appropriate regimen is found, switching to drugs available under a new Part D plan can undermine the treatment and—unlike other chronic health problems—can have immediate adverse effects, including functional impairment and increased use of health care services.[22]

According to the 1,183 psychiatrists who responded to the survey, 53.4 percent of their patients with Medicare and Medicaid had problems getting their medications from their new Part D plans. Among the most common problems

- 22.3 percent could not get prescription refills for drugs that they had been taking prior to Part D because of coverage restrictions or excessive copayments;
- 24.2 percent could not get benzodiazepines because Medicare law excludes them from Part D coverage;
- 23.6 percent could not afford the copayments required to purchase prescriptions;
- 18.3 percent were required to switch to different drugs because the drugs they had been taking were not on their Part D plan's formulary.

The Institute's study found that almost one out of four patients stopped taking their medication as a result of a problem obtaining it under their new Part D private plan. The Part D problems

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[20] "Medication Access and Continuity: The Experiences of Dual-Eligible Psychiatric Patients During the First 4 Months of the Medicare Prescription Drug Benefit," Joyce C. West, Ph.D., M.P.P.; Joshua E. Wilk, Ph.D.; Irvin L. Muszynski, J.D.; Donald S. Rae, M.S.; Maritza Rubio-Stipec, Sc.D.; Carol L. Alter, M.D.; William E. Narrow, M.D., M.P.H.; and Darrel A. Regier, M.D., M.P.H., *American Journal of Psychiatry*, May 2007 (http://ajp.psychiatryonline.org/cgi/reprint/164/5/789).

[21] "Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare," Nancy E. Morden and Louis P. Garrison, Jr., *Health Affairs*, March 2006 (http://content.healthaffairs.org/cgi/content/abstract/25/2/491).

[22] "Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare."

endangered the lives of over a quarter of the patients. The surveyed psychiatrists reported that among these patients

- 21.7 percent experienced increased suicidal behavior;
- 19.8 percent had to make hospital emergency room visits;
- 14.5 percent reported an increase in violent behavior;
- 11 percent required psychiatric hospitalization.

Researchers found that patients forced to switch medications had the highest rates of hospital emergency room visits.

These problems occurred despite the fact that drug plans are not allowed to interrupt drug treatment that has successfully stabilized patients with schizophrenia, depression or seizure disorders. The survey found that drug plans used prior authorization and other restrictions that they were specifically prohibited from applying to these types of medicines.

Some problems can be expected when a new program begins, particularly one involving millions of Americans. But the drug plans' disregard for program requirements and the government's inability to enforce them have continued through the end of the drug benefit's first year, according to the researchers' latest data. Follow-up studies conducted through 2006 continue "to show significant rates of medication access problems."[23]

Getting Coverage Through the Part D Appeal Process

The Bush administration's response to reports of problems getting medically necessary drugs through Part D has typically been to emphasize that people can appeal coverage denials and that plans should cover all medically necessary drugs. But nearly two years after the Part D program began, the appeals system is hopelessly dysfunctional. Plans' customer service representatives regularly misinform consumers about the appeals process while plans delay the appeals process or issue denials, disregarding both Medicare requirements and the urgent medical needs of people with Medicare.

First, many members of Part D plans do not know they can appeal the denial of drug coverage by their plan even though Medicare rules require plan representatives to tell members at the time coverage is denied that they can appeal.

The problem begins with plans' customer service representatives, who do not inform members that they have a right to appeal or tell them they cannot appeal. When plan representatives do mention the appeals option, they do not provide appeals forms, fax numbers for appeals requests or other information needed to begin the appeals process.[24]

Second, if an individual is able to file an appeal, the process too often gets bogged 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

[23] "Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare."
[24] "Medicare Part D Appeals System Breaks Down," Medicare Rights Center, March 2006 (www.medicarerights.org/appealsbrief_final.pdf).

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 failed to acknowledge four requests faxed by a counselor at the Medicare Rights Center on behalf of a client; many plans never respond, even though the law requires a response within seven days.

A September 2006 Kaiser Family Foundation national survey of doctors with patients enrolled in Part D found that nearly half reported they had been asked for help in an appeal for coverage. Nearly two-thirds of doctors said it was a burden helping patients obtain coverage or otherwise navigate Part D.[25] By contrast, only one-third of doctors working for the Department of Veterans Affairs (VA) report difficulty getting nonformulary drugs approved. The VA approves prescriptions for nonformulary drugs 84 percent of the time, and less than one-half of 1 percent of VA patients expressed a concern about access to medications.[26] By contrast, 12 percent of older adults enrolled in Part D report problems getting their drugs covered or affording their medicines.[27]

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 by the Qualified Independent Contractor (QIC), which should provide an objective review of the prescription drug plan's initial decision.

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,[28] the Medicare Rights Center generally wins its appeals to the QIC. 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. The only data provided by CMS on the Part D appeals system shows that the QIC reversed plans' decisions on over half of the cases concerning utilization management restrictions (prior authorization, step therapy or quantity limits) and nearly one-third of cases concerning drugs excluded from formularies.[29] Individual plans were reversed on over half the cases that were appealed to the QIC, according to the quality rankings available on CMS' prescription drug plan finder.

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 Medicare. Without a persistent 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.

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[25] Kaiser Family Foundation National Survey of Physicians, September 2006 (www.kff.org/kaiserpolls/7554.cfm).
[26] "VA Drug Formulary: Better Oversight Is Needed but Veterans Are Getting Needed Drugs," General Accountability Office, December 2001.
[27] "Seniors and the Medicare Prescription Drug Benefit," Kaiser Family Foundation/Harvard School of Public Health, December 2006 (www.kff.org/kaiserpolls/upload/7604.pdf).
[28] *Off-Base: The Exclusion of Off-Label Prescriptions from Medicare Part D Coverage*, Medicare Rights Center, August 2007 (www.medicarerights.org/Off-label_PartD_Coverage.pdf).
[29] "Part D Reconsideration Appeals Data," Centers for Medicare & Medicaid Services (CMS), September 21, 2006 (www.centeronaging.uiowa.edu/News/MedicareDrugBenefits/What%20to%20Know/PartDReconsiderationAppealsfactsheet9%5B1%5D%5B1%5D.21.2006(2).pdf).

Instability

The system of private plans under Part D provides an unstable, unpredictable benefit for people with Medicare. Plans can and do increase drug prices sharply during the course of the year, after people are locked into their plan selection. Formulary coverage, copayments and coverage restrictions change on an annual basis. Premiums fluctuate annually under a dynamic that amplifies the difference between high- and low-cost plans. People with low incomes who qualify for Extra Help (a federal program to help cover the out-of-pocket costs incurred by people with Medicare drug coverage) are the most subject to changes in coverage as many are annually randomly reassigned among the plans with premiums low enough to qualify for a full subsidy.

Although CMS has provided a web-based tool to help people with Medicare compare drug prices charged by plans, persistent and sometimes dramatic price changes mean the tool is of little use in predicting the prices a plan will charge. A February report by Consumers Union found that nearly all plans raised their drug prices from January to February, after enrollees were locked into the plan for the year, and nearly a quarter of plans raised prices by more than 5 percent. The report found plans changed prices multiple times during the course of the year and almost always raised prices from one year to the next.[30] Most plans peg the prices they charge at the pharmacy to the list price provided by drug manufacturers. As a result, every price increase is passed on directly to the consumer.[31]

Plans can change formularies with the calendar year. Enrollees have from November 15 to December 31 to change plans if, after leafing through voluminous formularies, they discover that their current plan has changed how it covers their drugs. Savvy consumers may know they have to check at the end of each year to make sure their plan will still have the drugs they take on its formulary. Few realize they also have to check whether the plan will impose new restrictions on the coverage. These restrictions, known as cost-utilization management tools, include requiring prior authorization or step therapy before a prescribed drug on the formulary will be covered, or quantity limits on how much of the drug the plan will cover. The 10 most popular plans changed restrictions for the 152 most commonly used drugs from 2006 to 2007, according to the Kaiser Family Foundation, an independent health care research organization.[32]

Its study found that 9 of the 10 plans added new quantity limits for these drugs. Step therapy requirements—in which a patient must try an alternative drug before the desired medication will be covered—increased in four plans. Prior authorization requirements increased in three.

The Kaiser report also found that while 9 of the 10 plans covered more of the 152 sample drugs in 2007 than before, the patient's share of the cost increased. Seven of the 10 plans increased the

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[30] *Medicare Part D Plans: A Cost Rollercoaster for Seniors*, Consumers Union, February 2007 (www.consumersunion.org/2006%20mini-report%20on%20Medicare%20Prescription%20Drug%20Plans%20-%20Final.pdf).

[31] *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, U.S. House of Representatives Committee on Oversight and Government Reform, Majority Staff, October 2007. http://oversight.house.gov/documents/20071015093754.pdf

[32] *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings*, Jack Hoadley, Elizabeth Hargrave, Katie Merrell, Juliette Cubanski and Tricia Newman, Kaiser Family Foundation, November 2006 (www.kff.org/medicare/upload/7589.pdf).

number of drugs placed in the "specialty tier." Drugs placed in this tier are the most expensive drugs and cannot be subject to appeals to lower cost-sharing.[33]

People with Medicare can also face drastic changes in how their Part D plan structures their coverage. Humana PDP Complete, for example, had the highest enrollment in 2006 of plans that offered coverage through the doughnut hole for both generic drugs and brand-name drugs. But, after losing money on the plan, Humana PDP Complete dropped coverage of brand-name drugs during the coverage gap for 2007.[34] At the same time, the plan's average monthly premium has increased from $57.83 in 2006 to $80.43 in 2007,[35] a cost members in the doughnut hole will have to continue paying while bearing the full cost of their brand-name medicines.

Many of Humana PDP Complete's enrollees who realized the change was coming switched to a plan offering full gap coverage offered by Sierra Health Services. However, in February the insurance company announced that it was experiencing losses on the product, which attracted many enrollees taking expensive medicines, and will no longer offer a plan with brand-name gap coverage in 2008.[36] Enrollees in the SierraRx Plus plan will have to search again for a plan offering full coverage in the gap but they will find none. Given the financial record of such plans, no Part D plan will offer full coverage of brand-name drugs in the doughnut hole in 2008.[37]

The formula used for setting enrollees' Part D premiums amplifies increases imposed by the plan. Medicare pays roughly 75 percent of the cost of providing Part D coverage, with the government's contribution based on the national average premium. Consumers who choose a plan with a premium above the national average pay the difference; those in plans costing less than average have their premiums further reduced by the difference. The national average is weighted toward enrollment. As consumers gravitate toward low-premium plans, Medicare's contribution declines and people in higher-cost plans pay an increasing share of their premiums. The national average premium moves closer to the premium of low-cost plans.

While this system may drive enrollees to companies that can deliver low-cost plans through greater efficiencies and ability to negotiate drug prices, it can also function to split the risk pool, making people who need high-cost drugs pay higher premiums for plans that adequately cover these drugs, while consumers with lower-cost drug regimens (generally healthier people) enroll in low-premium plans that cover their drugs but erect barriers to more expensive medicines. In 2006 CMS used its demonstration authority to moderate premium increases under Part D for 2007, keeping the subsidy level from dropping sharply by giving less weight to the low-premium plans that have attracted the lion's share of enrollment. For the 2008 plan year, CMS began to phase in calculation of the national average premium according to the statutory formula.[38]

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[33] "2008 Call Letter," Centers for Medicare & Medicaid Services (CMS), April 19, 2007.
[34] "Few Private Insurance Plans Provide Brand-Name Prescription Drug Coverage During Medicare 'Doughnut Hole,'" Kaiser Daily Health Policy Report, April 2007.
[35] *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings*, Jack Hoadley, Elizabeth Hargrave, Katie Merrell, Juliette Cubanski, Tricia Neuman, Kaiser Family Foundation, November 2006 (www.kff.org/medicare/upload/7589.pdf).
[36] "Insurer: Covering Drugs During Medicare Gap Too Costly," Bob Moos, *The Dallas Morning News*, April 8, 2007 (www.dallasnews.com/sharedcontent/dws/bus/stories/040907dnbusmedicare.3a0ff59.html).
[37] "CMS Release of Part D 'Landscape' for 2008," Avalere Health LLC, September 28, 2007.
[38] "Notification of Changes in Medicare Part D Payment for Calendar Year 2008," Centers for Medicare & Medicaid Services (CMS), April 2008.

The most vulnerable Part D enrollees, those with very low incomes, are potentially subject to annual disruptions in their prescription drug coverage if they are randomly reassigned to a different Part D plan when their plan's premium goes above the amount Extra Help will cover. In 2006, CMS randomly assigned about 5.5 million people with Medicare and Medicaid (dual eligibles) to Part D plans that qualified for a full premium subsidy (plans with premiums at or below the average beneficiary premium in their region) without regard to whether the assigned plan covered a dual eligible's drugs.

This random assignment, which is mandated by statute, contributed to the disruptions in coverage that accompanied the kick-off of Part D in 2006, forcing 37 states to step in to provide backup coverage through Medicaid for their residents with dual eligible status. The disruptions were predictable. The U.S. Department of Health and Human Services' Office of Inspector General (OIG) found that Part D plan formularies varied greatly in their coverage of the 178 drugs commonly used by people with both Medicare and Medicaid. As a result, the OIG found that 30 percent of the randomly assigned dual eligibles, or roughly 1.6 million individuals, were assigned to plans that included less than 85 percent (151 or fewer) of the 178 commonly used drugs.[39]

No follow-up study has been conducted to determine how the mismatch between drug regimens and formulary coverage was handled—whether plans accommodated drug regimens through the appeals process or whether drug regimens were changed to comply with formularies or whether people just went without their medicine.

In addition, Consumers Union found that people with Extra Help may be randomly assigned to plans with widely varying costs to the taxpayer and coverage to the consumer. Often they are assigned to plans where the cost of a package of commonly prescribed drugs is higher than it is in plans that are not eligible to receive randomly assigned people with Extra Help.[40] A follow-up survey found that one company, WellCare, charged copayments that were at least $2,800 higher for five commonly used drugs in states where its WellCare Classic plan was eligible to receive random assignment of low-income people with Medicare. In addition, these plans did not cover many of these drugs at all—including treatments for dementia, hypertension and depression—which resulted in low-income people with Medicare having to pay the full price for these drugs.[41]

To avoid a repeat in 2007 of the disruptions experienced in 2006, CMS used its demonstration authority to minimize the number of people getting low-income assistance who would be randomly reassigned to new plans. CMS altered the formula to prop up the regional average premiums, increasing the number of plans qualifying for a full premium subsidy and reducing to around 270,000 the number of individuals subject to random reassignment. In 2008, as CMS

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[39] *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, Daniel R. Levinson, Department of Health and Human Services' Office of Inspector General, January 2006 (http://oig.hhs.gov/oei/reports/oei-05-06-00090.pdf).

[40] *Medicare Should Stop Randomly Assigning Low-Income Seniors to Costly Drug Plans with Poor Coverage, CU Says*, William Vaughan, Consumers Union, July 25, 2007 (www.consumersunion.org/pub/core_health_care/004744.html).

[41] Letter to Acting CMS Administrator Kerry Weems from William Vaughan, senior policy analyst for Consumers Union, October 3, 2007.

phases out this demonstration, the agency predicts 1.6 million people with Medicare who get low-income assistance will be subject to random reassignment.[42]

Consumer Confusion and Marketing Fraud

The privatized Part D benefit is predicated on the belief that consumer choice drives costs down as companies compete for members. Yet the benefit lacks the one choice overwhelmingly desired by people with Medicare—a drug coverage option under the Original Medicare program.[43] Instead, consumers are forced to choose from an array of private plans, with over 50 plans in most markets (not including drug coverage from Medicare private health plans), each of which covers different drugs, imposes different restrictions on its coverage and charges different copayments and premiums.

Vital consumer information on coverage restrictions imposed by the plans is lacking, information on plan performance is hard to find and hard to understand, and information on drug pricing is unreliable.[44] In addition, since no one can know what health problems they may get in the upcoming year, Part D defies the very nature of insurance, which is to protect people from an unknown future. Instead people are forced to pick their drug insurance plan based on their current health needs and the prices at the time they are comparing plans—both of which can and do change throughout the year, after most people are locked into the plan they chose until January of the following year.

In addition, people with Medicare, most of whom are over the age of 65, are expected to use the internet to compare their drug plan choices. Yet a 2005 Kaiser Family Foundation survey found that only 31 percent of Americans over the age of 65 have ever gone online.[45]

Despite efforts by CMS to limit the number of plan offerings by individual companies, the number of plans actually increased from 2006 to 2007.[46] Research by the Medicare Payment Advisory Commission (MedPAC) reveals that few Part D enrollees conducted the plan comparisons necessary to determine if a plan covered all their drugs and provided the lowest out-of-pocket spending.[47] Instead, consumers tended to rely heavily on brand recognition and advice from plan representatives.[48] Given the opportunity to change plans at the end of 2006, few Part D

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[42] "CMS Report's 'Dirty Little Secret': 1.6 Million Low-Income Beneficiaries Will Be Forced into New Drug Plans," Families USA, August 2007.
[43] "Seniors and the Medicare Prescription Drug Benefit," Kaiser Family Foundation/Harvard School of Public Health, December 2006 (www.kff.org/kaiserpolls/upload/7604.pdf).
[44] *The Knowledge Gap: Drug Plans Fail to Provide Critical Information to People with Medicare*, Medicare Rights Center, February 2006 (www.medicarerights.org/CHABrief2.2.2006.pdf).
[45] *E-Health and the Elderly: How Seniors Use the Internet for Health Information*, Kaiser Family Foundation, January 2005 (www.kff.org/entmedia/upload/e-Health-and-the-Elderly-How-Seniors-Use-the-Internet-for-Health-Information-Key-Findings-From-a-National-Survey-of-Older-Americans-Survey-Report.pdf).
[46] "Status Report on Medicare Part D Enrollment in 2006: Analysis of Plan-Specific Market Share and Coverage," Juliette Cubanski and Patricia Neuman, *Health Affairs* Web Exclusive, 2007. (http://content.healthaffairs.org/cgi/reprint/26/1/w1?ijkey=rqXm20BRs2tTc&keytype=ref&siteid=healthaff).
[47] *Report to the Congress: Increasing the Value of Medicare,* Medicare Payment Advisory Commission (MedPAC), June 2006 (www.medpac.gov/publications/congressional_reports/Jun06_EntireReport.pdf).
[48] *Report to the Congress: Increasing the Value of Medicare.*

enrollees took it and fewer still looked at the changes to their coverage to determine if it was still suitable.

This may be due to what Swarthmore College psychologist Barry Schwartz calls "The Paradox of Choice" in his book by the same name: "As the number of choices keeps growing, negative aspects of having a multitude of options begin to appear," he writes. "As the number of choices grows further, the negatives escalate until we become overloaded. At this point, choice no longer liberates, but debilitates."[49]

Consumers who did seek out crucial coverage information from their plans often had difficulty getting it. Information on coverage restrictions in particular was difficult to obtain from plans or inaccurate. The performance indicators used by CMS to rank plans' performance on customer service—complaints, how appeals are decided—are buried on the Medicare.gov web site and are of little use in determining which plans fail to meet minimum standards.[50] A number of plans also failed to send out timely notices of changes to their coverage for the 2007 plan year.[51]

People with Medicare are also vulnerable to "bait and switch" tactics if they choose a plan based on their overall annual costs, including premiums and costs for the drugs they take. Using data drawn from Medicare.gov, the same web site savvy consumers must use to compare plans, Consumers Union found that one-quarter of plans surveyed raised prices by 5 percent or more on commonly used drugs from February to September of 2007. As a result, plans that appeared to be among the best deals at the start of the year slid way down the scale by midyear. One plan, which raised prices by $676 on the five drugs sampled, went from being the third cheapest plan in February to fourteenth on the list in September.[52]

Consumer choice is made more difficult by the aggressive and deceptive marketing practices employed by both drug and Medicare private health plans. The year 2007 saw a surge of complaints of marketing abuse by both Medicare private health ("Medicare Advantage") and prescription drug plans.[53] Aggressive marketing tactics have been employed by insurance companies seeking to maximize their Part D market share as an entryway their more lucrative line of Medicare private health plan products.

The use of seasonal agents and independent brokers working on commission has created financial incentives to enroll people with Medicare into plans, particularly Medicare private health plans, with little regard to suitability of the plan for the individual. Sales agents are often minimally trained and conduct their sales in face-to-face settings, often in a person's home, in which potential plan enrollees are even more susceptible to manipulation than over the phone.

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[49] *The Paradox of Choice: Why More Is Less*, Barry Schwartz, Ecco: 2004.
[50] Statement by William Vaughan, senior policy analyst, Consumers Union. Testimony before the Subcommittee on Health of the House Committee on Ways and Means, May 4, 2006. http://www.consumersunion.org/pub/0504%20Statement%20of%20CU.pdf
[51] "Lawmakers, Others Eager for Part D Enrollment Numbers," Jeffrey Young**,** *The Hill,* January 2007 (http://thehill.com/business--lobby/lawmakers-others-eager-for-part-d-enrollment-numbers-2007-01-03.html).
[52] "Medicare Part D Plans Continue to Hike Drug Costs After Seniors Sign Up for Coverage," Consumers Union, October 1, 2007 (www.consumersunion.org/pub/core_health_care/004934.html).
[53] *After the Gold Rush: The Marketing of MA and Part D Plans*, Medicare Rights Center, January 2007 (www.medicarerights.org/CHA-MRC-brief_goldrush.pdf).

Lock-in rules that allow individuals to change plans only once a year heighten the consequences of aggressive and deceptive marketing to people with Medicare. The limited enrollment season promotes the use of aggressive tactics as well as unsupervised independent brokers focused on maximizing enrollments and has led to targeting low-income people with Medicare. After family members and friends, insurance agents were found to be the most frequent source of information for prospective Part D enrollees,[54] making the lack of adequate oversight of agent activities particularly problematic.

The limited enrollment window and a target population notorious for "stickiness" (an unwillingness to change its insurance coverage) when it comes to insurance coverage create added pressure on plan sponsors seeking to maximize market share. This inertia among the target population means that, as companies roll out additional plan options, enrollment grows primarily by "stealing" customers from competitors or from themselves, as plan sponsors try to encourage their stand-alone drug plan (PDP) enrollees to switch to their Medicare private health plan products.

The limited enrollment window also makes it more economical for companies to use independent brokers, paid on commission and with minimal company oversight, rather than a salaried sales force that has limited ability to enroll new plan members during most of the year. These factors create a marketing climate that is "ripe for abuse."[55] The Special Enrollment Periods that allow monthly plan switches by people who have both Medicare and Medicaid (dual eligibles) make older adults with low incomes—who have historically been vulnerable to aggressive marketing of dubious financial products like high-interest second mortgages—the principal target of brokers selling stand-alone drug and Medicare private health plans outside the annual Open Enrollment Periods.

The resulting consumer marketing fraud and abuse have led state insurance commissioners around the country to beg Congress for the right to police the plans and protect their citizens. Kim Holland, Oklahoma state insurance commissioner, testified before Congress that "Since the roll-out of Medicare Part D in November of 2005, the Oklahoma Insurance Department has responded to an unacceptable number of complaints caused by the inappropriate and sometimes fraudulent marketing of Medicare Part C (private Medicare plans providing health coverage) and Part D products by certain insurance companies and their sales producers. We have received hundreds of complaints from confused, unhappy and frightened citizens who have been mislead or deceived during a sale."[56]

At the same hearing, Jim Poolman, insurance commissioner from North Dakota, added, "Clearly these [insurance] companies need more rigorous oversight and CMS is not prepared or seemingly unable to do the job. With all due respect, I find it highly unlikely, based on our

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[54] *Report to the Congress: Increasing the Value of Medicare*, Medicare Payment Advisory Commission (MedPAC), June 2006 (www.medpac.gov/publications/congressional_reports/Jun06_EntireReport.pdf).
[55] "Seniors and Medicare Prescription Drug Benefit," Kaiser Family Foundation/Harvard School of Public Health, December 19, 2006 (www.kff.org/kaiserpolls/pomr121906pkg.cfm).
[56] Statement by Kim Holland, insurance commissioner, state of Oklahoma, before the Oversight and Investigations Subcommittee, Energy and Commerce Committee, U.S. House of Representatives, June 26, 2007 (http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.062607.Holland-Testimony.pdf).

experience during this situation, that CMS will be able to 'do better,' as Ms. [Acting Administrator Leslie] Norwalk suggests in a recent press release."[57]

In this environment, it is no surprise that plan selection is often based on shortcuts—brand recognition, premium costs—that leave consumers in unsuitable plans of which they often do not understand the basic features.

The Solution

A Medicare-administered prescription drug benefit has the potential to lower drug prices for people with Medicare and to reduce the overall cost to Medicare of drug coverage. A national, evidence-based formulary for a Medicare drug plan can help guide doctors to prescribe in a way that improves health care outcomes, reduces costs and facilitates a fair and efficient appeals system.

People with Medicare will be able to turn to the Medicare option for drug coverage to find a stable, nationally uniform premium and consistent formulary coverage and prices over the course of the year and from year to year. The Medicare drug plan will provide a simple, high-quality and affordable option for people with Medicare seeking a refuge from the confusion, misinformation and predatory marketing practices that currently characterize the market for private Part D and Medicare private health plans.

In fact, according to a Kaiser Family Foundation survey, two-thirds of older adults support providing a drug benefit administered directly through Medicare.[58]

Despite these benefits, policymakers face a number of challenges in creating a Medicare-run drug coverage option in the context of a pre-existing system of private Part D plans established by the Medicare Prescription Drug and Modernization Act (MMA). These challenges include:

- setting a nationwide premium for the Medicare drug plan that is low enough to qualify for a full premium subsidy for people receiving low-income assistance without raising costs to Medicare;
- providing meaningful and affordable coverage in the doughnut hole when private Part D plans have abandoned this option because it served as a magnet for people with high drug costs;
- creating a level playing field with private drug plans while allowing the Medicare drug coverage to serve as a refuge for consumers ill-equipped to navigate the marketplace of competing plans; and
- establishing a formulary for the Medicare drug plan that guarantees access to medically necessary drugs while containing costs.

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[57] Statement by Jim Poolman, insurance commissioner, state of North Dakota, before the Oversight and Investigations Subcommittee, Energy and Commerce Committee, U.S. House of Representatives, June 26, 2007 (http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.062607.Poolman-Testimony.pdf).

[58] "Seniors and the Medicare Prescription Drug Benefit," Kaiser Family Foundation/Harvard School of Public Health, December 2006 (www.kff.org/kaiserpolls/upload/7604.pdf).

Formulary

The linchpin to meeting all these challenges is the establishment of an evidence-based, cost-effective formulary.

Resources already exist that can assist the Centers for Medicare & Medicaid Services (CMS) in assessing clinical information for creating a formulary. These resources include the Agency for Healthcare Research and Quality (AHRQ), the Department of Veterans Affairs (VA), the Oregon Health and Science University's Drug Effectiveness Review Project and state Medicaid programs, and the Food and Drug Administration. However, the funding necessary for AHRQ to conduct necessary research on comparative effectiveness is lacking, although MedPAC has recently recommended increasing the government's capacity in this area.[59]

An advisory committee established by CMS whose members are free of ties to pharmaceutical manufacturers, insurance companies and pharmacy benefit managers should be empowered to evaluate clinical evidence needed for formulary development. Because of the dearth of high-quality comparative research on prescription drugs, the committee should be empowered to request such research and additional clinical data from manufacturers. Clinical evidence should determine whether drugs should be included on formularies because they are safer, more effective or improve patient compliance with drug regimens.

One example of how effective an evidence-based formulary can be is the VA. The VA actually has more drugs (4,778) on its formulary than are potentially covered under Medicare Part D (4,300—and not all plans cover all these drugs).[60] In addition, the VA covers nonformulary drugs prescribed according to evidence-based guidelines, bringing the total number of drugs dispensed by the VA to 6,194.[61] By contrast, people with Medicare must navigate a complex appeals process to obtain coverage of nonformulary drugs,[62] and Part D plans deny 95 percent of appeals at the second level of appeals (redetermination).[63]

The Institute of Medicine concluded in 2000 that the VA formulary is "not overly restrictive."[64] This finding is supported by statistics that show the VA does a better job of using prescription drugs to control their patients' diabetes, high cholesterol and hypertension than private Medicare plans.[65] It is also supported by the fact that veterans are overwhelmingly satisfied with the care

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[59] *Report to the Congress: Promoting Greater Efficiency in Medicare*, Medicare Payment Advisory Commission (MedPAC), June 2007 (www.medpac.gov/documents/Jun07_EntireReport.pdf).
[60] "Can Government Price Negotiation Work for the Medicare Drug Benefit?" Michael A. Valentino, U.S. Department of Veterans Affairs, January 2007 (www.aei.org/events/filter.all,eventID.1447/summary.asp).
[61] "Can Government Price Negotiation Work for the Medicare Drug Benefit?"
[62] *Medicare Part D Appeals System Breaks Down*, Medicare Rights Center, March 2006 (www.medicarerights.org/appealsbrief_final.pdf).
[63] "Part D Reconsideration Appeals Data," Centers for Medicare & Medicaid Services (CMS), September 21, 2006 (www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=1972&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date).
[64] "Description and Analysis of the VA National Formulary," Executive Summary, National Academy of Sciences, 2000 (http://books.nap.edu/execsumm_pdf/9879.pdf).
[65] "Can Government Price Negotiation Work for the Medicare Drug Benefit?"

they receive from the VA, and there is no evidence of a decline in use of the VA drug benefit since the inception of Medicare Part D.[66]

In addition, the VA's use of an evidence-driven formulary has held down drug prices. The average price per prescription has actually declined over the last two years,[67] a time period when the prices of brand-name drugs most used by older adults rose 12 percent.[68] For many commonly prescribed drugs, VA prices have cost half as much or less than the prices available under Part D plans.[69] The VA rate of generic utilization—68 percent of prescriptions filled—is well above the Part D rate of 59 percent.[70]

Evidence-based formularies can save lives as well as money. With newer drugs, there is less information available about long-term safety effects. Safety problems with new drugs often do not emerge until after the drug is already available and has been marketed to consumers for a few years. For example, Merck spent $160.8 million in 2000 promoting its blockbuster painkiller Vioxx, approved in 1999, making it the most heavily advertised drug that year. Subsequently, retail sales of the drug quadrupled from $329.5 million in 1999 to $1.5 billion in 2000,[71] reaching $2.3 billion in 2003.[72] Then in 2004, Vioxx was pulled off the market after another long-term study showed it posed serious risks for heart attack and stroke.[73] By the time the drug was withdrawn, it had been taken by an estimated 80 million people.[74] The drug is estimated to have caused 27,785 heart attacks and deaths between 1999 and 2003.[75]

Using research from the Oregon-based Drug Effectiveness Review Project, Medicaid programs in Oregon and Washington removed Vioxx from their formularies before Merck pulled the drug from its market.[76] Similarly, the Department of Veterans Affairs strictly limited the use of Vioxx and other drugs in its class to those with medical conditions warranting a prescription, limiting exposure to drugs that still lacked adequate safety data.[77] A similar formulary under Medicare that is, like the VA's, based on clinical efficacy and necessity, would help protect the health of patients and—as the case of Vioxx shows—save lives.

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[66] "Can Government Price Negotiation Work for the Medicare Drug Benefit?"
[67] "Can Government Price Negotiation Work for the Medicare Drug Benefit?"
[68] "Trends in Manufacturer Prices of Prescription Drugs Used by Older Americans," AARP, March 2007 (www.aarp.org/research/health/drugs/aresearch-import-869-2004-06--IB69.html).
[69] *No Bargain: Medicare Drug Plans Deliver High Prices,* Families USA, January 9, 2007 (www.familiesusa.org/resources/publications/reports/no-bargain-medicare-drug.html).
[70] *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, U.S. House of Representatives Committee on Oversight and Government Reform, Majority Staff, October 2007.
[71] *Prescription Drugs and Mass Media Advertising, 2000*, National Institute for Health Care Management Foundation, November 2001 (www.nihcm.org/~nihcmor/pdf/DTCbrief.pdf).
[72] "Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-analysis," *The Lancet*, December 2004.
[73] "FDA Estimates Vioxx Caused 27,785 Deaths," *Consumer Affairs*, November 4, 2004 (www.consumeraffairs.com/news04/vioxx_estimates.html).
[74] "FDA Estimates Vioxx Caused 27,785 Deaths."
[75] "FDA Estimates Vioxx Caused 27,785 Deaths."
[76] "Recasting the Lowly Formulary," Minnesota Medical Association, April 2006 (www.minnesotamedicine.com/publications/MNMed2006/April/quality-smith.htm).
[77] "Recasting the Lowly Formulary."

Price Negotiation

In 2004, Professor Gerard Anderson of Johns Hopkins University spoke before the U.S. Senate Finance Committee that if the Centers for Medicare & Medicaid Services (CMS) negotiated drug prices down to the level of what other industrialized nations pay, it could close the coverage gap (or doughnut hole) at no additional cost.[78]

Now that the privatized drug benefit is already in effect, however, CMS' initial negotiating leverage with drug manufacturers could be substantially weakened by the fragmentation of the Medicare population into multiple Part D plans. Instead of facing a drug plan with purchasing power of 43 million people with Medicare, drug manufacturers will be negotiating with a Medicare drug plan that has no initial members and whose potential membership base is already enrolled in a plethora of private Medicare plans.

Policymakers have a number of options to maximize the Medicare plan's negotiating leverage:

- **Broaden the impact on manufacturers of inclusion in the Medicare-plan formulary.** For example, private Part D plans could receive automatic approval of their formularies if they adopt the Medicare plan formulary. This would create an incentive for plans to mimic the Medicare plan formulary and increase the impact on market share of inclusion in the Medicare plan formulary. The Medicare plan formulary can also be used as the basis for educational efforts directed at doctors to maximize cost-effective and evidence-based prescribing. Currently, the wide variation in formulary coverage among Part D plans makes it difficult for doctors to know whether the drugs they prescribe to patients enrolled in Part D will be covered.[79] A Medicare-plan formulary that serves as a widely used reference for prescribing would have a major impact on market share of competing drugs, maximizing Medicare's negotiating leverage.
- **Take steps to maximize enrollment in the Medicare drug plan.** While preserving a choice of plans for people with Medicare and a level playing field for the private plans, enrollment and premiums for the Medicare drug plan should be designed to maximize leverage with drug manufacturers. **Having the Medicare drug plan serve as the default option for individuals newly eligible for Medicare and for low-income people with Medicare facing annual reassignment would help boost the number of enrollees in the Medicare plan (see below).**

Premiums

Some 40 percent of Part D enrollment consists of people receiving low-income assistance, who pay nothing for their Part D premium if they enroll in a plan with a premium below a regional benchmark (set at the average Part D premium charged by Part D and Medicare private health plans in the region). If Medicare is to become a viable coverage option for low-income people with Medicare—the population most in need of the stability and formulary coverage that a

[78] Statement by Gerard Anderson, director of the Center for Hospital Finance and Management, Johns Hopkins University, before the Oversight and Government Reform Committee, U.S. House of Representatives, February 9, 2007 (http://oversight.house.gov/Documents/20070209123654-09260.pdf).
[79] "Identifying Widely Covered Drugs and Drug Coverage Variation Among Medicare Part D Formularies," Tseng et al., *Journal of the American Medical Association*, June 2007.

Medicare option can provide—the premium for the Medicare drug plan must be set at or below regional low-income benchmarks. If the Medicare plan's premium is to be uniform nationwide, it must be set at or below the lowest regional low-income benchmark. Policymakers have two basic options to take to achieve this goal:

- **Set the beneficiary premium by statute and allow the subsidy (the share of premiums and drug costs that Medicare pays for private Part D plans) to rise above the statutory formula.** This policy guarantees that the Medicare drug plan is available to people with Medicare who receive low-income assistance, but it could raise costs to taxpayers and give an advantage to the Medicare plan (through higher subsidies) over private Part D plans.

- **Base the enrollee's premium on the actuarial cost of providing drug coverage, providing a subsidy to the Medicare drug plan that is equivalent to the subsidies provided to private Part D plans.** A Medicare drug plan that is able to limit costs through an evidence-based formulary and price negotiations and that can attract both low- and high-cost members should be able to achieve this goal. There should also be savings from the Medicare-administered drug plan not having as high an overhead cost as the private Part D plans do (marketing costs of competing with dozens of other plans, salespeople to sell their policy, profit margins, etc.).

  A level playing field would also require payments to Medicare private health plans to be set at costs under Original Medicare. Medicare private health plans use overpayments to buy down their Part D premiums, artificially lowering the low-income benchmark and gaining a market advantage at taxpayer expense.

Enrollment

A Medicare drug plan with a premium accessible to people receiving low-income assistance should prove a popular option, generating the enrollment necessary to create negotiating leverage with drug manufacturers.

Policymakers may want to consider a number of other steps that would allow Medicare to serve as a refuge for people with Medicare who are ill-equipped to deal with the current marketplace because of cognitive impairments or who simply want the stability and reliability of a Medicare drug plan.

- The Medicare drug plan could serve as the default option as people become eligible for Medicare. This is how competition between Original Medicare and Medicare private health plans is structured: consumers are in the Original Medicare program and have to make an active choice for the private option.
- The Medicare plan can also become the default option for people receiving low-income assistance during the annual reassignment among plans that meet the benchmark for a full premium subsidy. This vulnerable population in particular deserves a stable home.

Doughnut Hole Coverage

If the Medicare drug plan is the only plan providing drug coverage of both brand-name and generic drugs in the doughnut hole, as is likely, it will attract the lion's share of people with high

drug costs. This dynamic, known as adverse selection, will drive up the cost (the premium) of the Medicare drug coverage option, further discouraging enrollment of all but the sickest, costliest people with Medicare. As a result, it is unlikely to be cost-effective either for taxpayers or for people who need comprehensive gap coverage for Medicare to be the sole provider of such coverage.

Policymakers should eliminate the coverage gap from Part D for both private plans and the Medicare option. It is time for the Medicare Part D benefit to come into line with every other type of insurance coverage. No other benefit stops coverage for a while in the middle of the year. This benefit structure, designed solely to keep the projected cost of the drug benefit under an arbitrary threshold, can have adverse health effects on members who cannot take their prescriptions anymore because they suddenly have to pay 100 percent of their cost. Such gaps in care can lead to higher costs to the rest of the Medicare program.[80]

Conclusion

Just as the cost to taxpayers of hospital and medical care through the Original Medicare program is cheaper than through private Medicare health plans (Medicare Advantage), a Medicare-administered prescription drug benefit can lower the cost of drug coverage. People with Medicare will be able to turn to the Medicare option for drug coverage to find a stable, nationally uniform premium and reliable formulary from year to year.

People with Medicare should have the option of being able to use their red, white and blue Medicare card in any pharmacy in the country. Those who profess to believe in choice should not take this option away from older Americans and people with disabilities.

[80] "Increase Copays and Increase Medical Spending?" Jason Shafrin, *Healthcare Economist*, February 16, 2007 (http://healthcare-economist.com/2007/02/16/increase-copays-and-increase-medical-spending).