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How Medicare Could Get Better Prices On Prescription Drugs

Increased formulary flexibility and value-based pricing are among the options that should be considered in the context of health reform.

by **Kevin Outterson and Aaron S. Kesselheim**

ABSTRACT: Congress may reform drug pricing policies under Medicare Part D as part of a larger health reform effort. Currently, the “noninterference” provision prevents the government from negotiating drug prices on behalf of Medicare Part D prescription drug plans. Commonly considered reform proposals borrow ideas from Medicaid, either through returning dual eligibles to Medicaid drug pricing or by imposing mandatory rebates across the Part D population. We examine a menu of other options, including value-based pricing; expansion of generic and therapeutically equivalent substitution; increased formulary diversity; importation; and limited antitrust waivers. These latter options may reduce federal spending without direct government price negotiations. [Health Aff (Millwood) 2009;28(5):w832-41 (published online 30 July 2009;10.1377/hlthaff.28.5.w832)]

AN \$80 BILLION INFORMAL AGREEMENT by the drug industry to support Medicare and Medicaid drug benefits has raised the profile of the costly Medicare Part D prescription drug program as Congress crafts broad health care reform legislation. The 111th Congress may address several aspects of Part D for legislative reform, including the “noninterference” provision in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2006, which says that the secretary of Health and Human Services (HHS) cannot “interfere with the negotiations” or “institute a price structure” for Part D drugs. Prohibiting such negotiations has been criticized as artificially raising Part D drug prices and increasing the costs of the program.¹ With the noninterference provision in place, price negotiations occur at the level of the individual Part D insurance plans, using private-sector purchasing strategies.

In this paper we evaluate several options to reduce federal spending on Part D drugs (Exhibit 1), focusing on the most feasible ideas. We first examine federal ne-

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**EXHIBIT 1
Medicare Part D Drug Price Reform Options**

Category/proposal ^a	Strengths	Weaknesses
Direct federal interventions		
Price controls	Large static savings	Administratively complex; political process vulnerable to lobbying; formidable political opposition
International reference pricing	Large static savings; administratively straightforward	Savings tend to dissipate over time as companies react; policy levers ceded to referenced reimbursement systems
Profit controls	Existing model in U.K.	Largely ineffective due to company reactions to profit-based measures (transfer pricing)
Federal negotiations	Direct federal role without a complicated administrative process	Horizontal inequity; unknown effectiveness; rent seeking
Binding arbitration	Evidence-based legal process	Companies have opposed similar processes in NICE and PBS
Public option plans	Limited scope, leaving the remainder of the market untouched	Political opposition; unknown effectiveness
Medicaid-based		
Mandatory rebates	Huge static savings with well-tested administrative model	Arbitrary rebate levels; company responses will erode savings over time
Return dual eligibles to Medicaid pricing	Significant static savings; known implementation model	One-time clinical cost of switching back
Other proposals		
Formulary design	Permits Part D plans to use commercial formulary designs; significant savings	Savings will take time; formulary restrictions have clinical effects; patients must make educated choices; opposition by patient advocacy groups
Generic and therapeutic substitution	Extends a proven savings model	Expansion to therapeutic classes and biosimilars may have clinical effects
Antitrust waivers	Low risk	Unproven
Importation	Some static savings	Secondary effects in foreign markets; potential safety questions; savings unlikely to persist; cedes policy levers to foreign reimbursement systems
Value-based pricing	Transformative information spillovers to U.S. health care market; significant existing international evidence base and U.S. commitment to fund additional studies	Some have tried to create tension between comparative effectiveness and cost-effectiveness; history of political opposition to NICE and PBS determinations; lag time for new studies

SOURCE: Authors' analysis.

NOTES: NICE is (U.K.) National Institute for Health and Clinical Effectiveness. PBS is (Australian) Pharmacy Benefits Scheme.

^aAll proposals share the potential for dynamic changes to research and development.

gotiations and other direct interventions in the Part D market; we then turn to approaches that avoid direct government price negotiations.

Direct Federal Negotiations

In the years since Part D was enacted, a number of reform proposals have sought

to overturn the noninterference provision. The most straightforward plan would simply remove the offending section from MMA. But the structure of Part D, replete with many private plans, poses difficult administrative and practical hurdles to successful federal price negotiation.² The Congressional Budget Office (CBO) concluded that HHS would have insufficient leverage to negotiate on behalf of plans, given that discounts are driven more by moving market share in competitive drug classes than by gross volume.³

In addition, the largest Part D contractors compete across many health insurance markets, and it is unclear how federally negotiated prices under Part D could be limited to Medicare. Negotiators would need to account for favorable price discrimination in other U.S. programs and protect low-cost federal acquisition programs such as the Section 340b public health program and the Federal Supply Schedule (FSS).⁴ A recent analysis projected \$21.9 billion in annual savings if Part D adopted FSS pricing.⁵ However, if Part D and FSS prices are linked, the FSS may no longer be able to achieve the same discounts. This dynamic effect might greatly reduce the net savings to the federal government.

■ **Negotiations for a public drug plan.** Another direct federal approach proposed in recent legislative sessions⁶ would require negotiations, but only for a publicly owned drug plan.⁷ Leading congressional Democrats support a “public plan option” for health reform generally; the public plan would negotiate prices, but only for itself. Successful negotiations would require a credible threat of formulary exclusion, which is difficult in a national public plan with a safety-net role.

■ **Other direct interventions.** Other direct federal interventions have also been discussed—including international reference pricing, price controls, profit limitations,⁸ and binding arbitration for sole-source Part D drugs.⁹ All of these proposals face strong political opposition in the United States, with the possible exception of the arbitration proposal.

Medicaid-Based Pricing: Dual Eligibles And Rebates

A second category of reforms borrows ideas from the Medicaid program. Medicaid receives substantial discounts on drugs, in both mandatory federal rebates and state-negotiated supplemental rebates. A House committee has estimated that Part D pays about 30 percent higher drug prices than Medicaid pays.¹⁰ Congress moved Medicaid patients who were also eligible for Part D (so-called dual eligibles) into Medicare Part D, meaning that such patients lost access to Medicaid rebates. Although patients’ experiences have been mixed, studies have revealed that certain high-risk patients had problems maintaining access after the switch.^{11,12} State budgets did not benefit, as state Medicaid savings were recovered by a federal charge called the “clawback,” which led to unsuccessful litigation by some states against the federal government before the Supreme Court.¹³

■ **Mandatory rebates.** Two Medicaid-based pricing proposals have recently been discussed. The greatest direct cost savings would come from applying the

Medicaid mandatory rebate scheme to Part D. The CBO estimated that a 15 percent mandatory rebate would reduce federal expenses by \$33 billion in 2010–2014 and \$110 billion in 2010–2019.² Mandatory rebates are economically similar to a federal tax on the patent-based drug industry, with the proceeds supporting Part D. This model has the benefit of simplicity, and it may be reasonable to require participating companies to directly support a system that has been so profitable for them. However, mandatory rebates would be prone to gaming by companies and politically expedient adjustments by Congress, which could revisit the relatively arbitrary rebate level in the future. All of the options would also reduce drug company profits.¹⁴

■ **Return dual eligibles to Medicaid pricing.** The second, perhaps more feasible, step would return the 6.2 million dual eligibles to Medicaid pricing, which could lead to substantial savings¹⁵—perhaps as much as \$2.8 billion annually.¹⁶ As Richard Frank and Joseph Newhouse have suggested, this step involves less risk, since major problems were not apparent under the prior regime.⁹

Reforms To Promote More-Effective Private Negotiations

Other possible reforms seek to improve private negotiations by Part D plans. We evaluate a menu of five options that could effectively give more negotiating power to Part D plans. These proposals retain the current framework of a competitive prescription drug marketplace, with less-intrusive government intervention.

■ **Formulary design flexibility.** Formulary design is a widely used private-sector tool for controlling health plans' drug costs. Medicare limited the freedom of Part D plans to control their formularies through rules such as the safe harbor guidelines established by the U.S. Pharmacopeia¹⁷ and MMA's requirement that Part D plans cover at least two drugs per class.¹⁸

The CMS went beyond the statute, requiring at least one drug in each subclass as well. In addition, the CMS has given special protections to six classes of drugs, requiring that "all or substantially all drugs" in the classes be included in the formularies.¹⁸ This rule effectively eliminates Part D drug price negotiations over anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. In other classes, Part D plans routinely exclude some drugs as part of the normal commercial formulary process.¹⁹ The 110th Congress solidified and expanded the protected classes. The July 2008 physician payment update legislation gave the CMS clear statutory authority to expand the protected drug classes and created a cumbersome process that delays competition within the classes.²⁰

These rules limit the negotiating power of Part D plans and make drugs in those classes more expensive. A Milliman study found that these six protected classes accounted for 16.8–33.2 percent of Part D drug costs by Part D plan administrators. Reversing this one rule would decrease prices in these classes by 9–11 percent, for a projected Part D savings of \$511 million per year.²¹ To ease the negative effect such restrictions can have on price negotiations, Congress could modify the

Medicare Part D rules to give private drug plans more freedom to control their formularies. More-flexible formularies would permit more-aggressive negotiations by Part D plans, because the plans would have more maneuvering room to negotiate for deeper discounts, as they do with some of their non-Medicare plans.²²

Because permitting tighter formularies for Part D plans could have real clinical and financial effects, modifications would have to be monitored closely. For example, tighter formularies might be adopted by Medicare Advantage Prescription Drug (MA-PD) plans as a device to discourage enrollment by beneficiaries with certain chronic conditions. In the absence of effective risk adjustments in Medicare contracts, experimentation with tighter formulary designs might be limited to stand-alone plans. In addition, formulary stability is important; rules should continue to prohibit changes that negatively affect a Part D formulary or drug tier structure within a plan year.²³ Patients will need to be aware of the changes in their plan well in advance of the annual enrollment period, but Medicare patients do not have a good track record in efficiently selecting Part D plans.²⁴ Plans could be required to give beneficiaries advance notice of any prospective formulary or tier design change affecting any drug purchased in the prior three years.

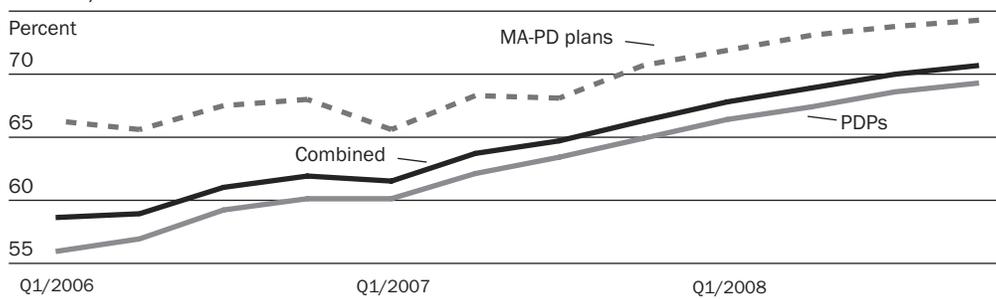
Current Medicare rules allow some midyear benefit alterations that could directly affect patient care, in the form of drug price changes at the point of purchase. These changes can occur without notice, even after a beneficiary has committed to a particular plan. Physicians and policymakers should be concerned about the potential risks this current arrangement may pose for patients. This proposal is not a national formulary; it simply permits more heterogeneity among private formularies.

■ **Extended generic and therapeutic substitution.** Substitution of generic drugs for their brand-name equivalents is well established as a way of reducing what consumers and health plans pay for prescription drugs without affecting clinical outcomes.²⁵ It is important to note that generic substitution strategies to date have been effective, and their history of success may limit future potential savings.²⁶

State generic substitution laws vary widely in their effectiveness, and consumers' willingness to switch voluntarily is less than optimal.²⁷ In some states, laws have been proposed to reduce the scope of generic substitution for certain classes of drugs. A federal generic substitution law is a possible response: it would preempt local legislative retrenchments and promote uniform generic access.

Some will argue that these changes are not needed, since Medicare Part D plans already have substantial and growing generic use rates (Exhibit 2), but expanded generic substitution would accelerate this trend. Medicare Part D plans vary greatly in generic use rates, ranging in 2008 from a high of 89.5 percent to a low of 49.1 percent.²⁸ These variations may represent consumers' preferences among the various plan designs, as patients who are unwilling or unable to accept particular generics choose higher-price plans. But given the clinical equivalence of nearly all brand-name and generic drugs,²⁹ there may still be room for improving generic

EXHIBIT 2
Quarterly Use Of Generic Drugs In Medicare Part D, As Percentage Of Paid Part D Claims, 2006–2008



SOURCE: Centers for Medicare and Medicaid Services, Medicare Part D Generic Drug Utilization Rates (2006–2008),

NOTES: MA-PD is Medicare Advantage prescription drug, PDP is prescription drug plan.

substitution rates.

Another way to achieve price savings would be to expand generic substitution laws to include different drugs within carefully selected therapeutic classes, including between similar biologic molecules. Congress is considering a form of therapeutic substitution legislation to permit “generic” biological molecules, known as “biosimilars” or “follow-on biologics.” Current law for generic entry of small-molecule chemicals is inadequate for more complex large-molecule biological products. The CBO estimates savings at \$9.2–\$12 billion over ten years if the federal law is changed to permit follow-on biologics.² However, it is important to remember the role of state generic substitution laws, as well, to aid in the uptake of follow-on biologics.

Therapeutic substitution can also occur with traditional, nonbiological drugs. The clinical implications of therapeutic substitution must be addressed, because not all drugs within a class are substitutable for all patients. In December 2008 the CBO described a proposed Medicaid therapeutic substitution program in two classes: proton-pump inhibitors and non-benzodiazepine hypnotic agents for treating insomnia.² Although the initial savings are projected to be quite small, this important trial of therapeutic substitution could be implemented and carefully evaluated for future expansions.

Generic utilization can also be supported by reference-based copayment structures. This copayment is the difference between the generic and brand-name price when a generic is available. In January 2009 the CMS proposed a ban on reference-based copays³⁰ and other variable copayments, to take effect in 2010. The rule was finalized in the 2010 Call Letter issued 30 March 2009.³¹ Consumer groups such as AARP complained about reference-based copays in Part D plans, even though they apply only when a generic is available but not chosen by the patient. In this circumstance, the additional financial burden is probably justified, especially if the patient is clearly informed of the lower-cost generic option at the pharmacy.

■ **Limited antitrust waivers.** Antitrust laws prohibit joint negotiations by Medicare drug plans—such plans must all negotiate individually or through pharmacy benefit managers (PBMs). Such arrangements limit the market power of Part D plans. To address this problem, Congress could give private plans limited waivers from state and federal antitrust laws, allowing them to voluntarily band together in negotiating groups to seek lower drug prices. The waiver groups could be limited to no more than one-quarter of the Part D market, allowing a reasonable size to negotiate better discounts, without creating a monopsony, where a single buyer would have disproportionate leverage.

Although this option is straightforward in theory, it is hard to know in advance whether companies would use it. The larger companies might prefer to continue to negotiate independently. But smaller plans lacking market power might find this option attractive, especially if the joint negotiations were facilitated through their PBMs. Frank and Newhouse suggest that the market for Medicare prescription drug plans (PDPs) might be too fragmented, leaving some plans with “weaker than anticipated” negotiating power.⁹ If so, limited antitrust waivers might be able to recalibrate the market.

■ **Importation.** For several years, Congress has considered various proposals to import lower-price drugs from countries with well-regulated pharmaceutical markets, such as Canada, Australia, and western Europe. Such a system was most recently proposed in 2009, permitting imports by individual patients and drug wholesalers from an FDA-approved set of sources.³² Additional legislation might not even be necessary, as HHS could use existing statutory authority to certify the safety of imports.³³ Alternatively, Part D plans could agree to waive the right to import certain drugs in exchange for price discounts from the manufacturer. This waiver option reduces prices without invoking potential problems with importation.³⁴

However, importation plans raise important questions, such as sustainability and the long-term dynamic effects on global prices and research and development (R&D).³⁵ Arbitrage or parallel trade involves moving identical products from low-price to higher-price markets, earning a profit on the difference. Over time, companies react to parallel trade to limit its scope and profitability. Also, although questions are often raised about safety, a fully regulated importation process will be much safer than the unregulated Internet and personal channels that some patients use now.

■ **Value-based pricing.** As a direct result of the quality movement in health care, Medicare is exploring important changes in how to pay for health services, including comparative effectiveness and value-based pricing incentives.³⁶

Comparative effectiveness studies may include head-to-head trials of competing drugs, expanding the scope of evidence-based medicine. The American Recovery and Reinvestment Act of 2009 (the so-called stimulus bill) provided \$1.1 billion to fund research comparing the effectiveness of health care treatments. It also established the Federal Coordinating Council for Comparative Effectiveness Re-

search, which will conduct this research along with HHS, the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality (AHRQ).

Value-based pricing for drugs adds the element of pharmacoeconomic analysis to comparative effectiveness data. It may require greater reimbursement for outstanding drugs with clear benefits over existing therapies, and less for drugs with limited usefulness or complicated side-effect profiles.³⁷ Although value-based pricing does not necessarily lower the price of prescription drugs, its goal is to identify and encourage the use of more cost-effective medicines. A limited domestic test of value-based reimbursement in Part D could be an important step forward, as recently proposed by the Medicare Payment Advisory Commission (MedPAC).³⁸

These U.S. efforts do not proceed in a vacuum. For the past decade, the National Institute for Health and Clinical Excellence (NICE) in England has performed comparative pharmacoeconomic and clinical analyses of drugs.^{39, 40} Other programs include the Australian Pharmaceutical Benefits Scheme⁴¹ and Oregon's Drug Effectiveness Review Project.⁴² A sizable international evidence base already exists, and the United States should examine the lessons learned in England and Australia.⁴³ These results could inform the organization of the Part D plans in their formularies, payment tiers, and step-therapy options, with spillover benefits well beyond Medicare. A value-based reimbursement system could create and apply information in transformative applications for public and private health care markets.⁴⁴

Concluding Remarks

If Congress reforms Part D, it may be tempted to pursue interventions such as direct repeal of the noninterference provision or mandatory rebates. Restoring dual-eligible pricing is the better Medicaid-based strategy, especially if it can be done without harming patients, the states, and providers. One option would be to adopt dual-eligible pricing without actually moving dual eligibles' prescription drug financing back to Medicaid. In addition, more market-based reforms include greater formulary flexibility, expanded generic and therapeutic substitution, anti-trust waivers, drug importation, and value-based reimbursement. Each of these reforms also suffers from various weaknesses, but they may be worth considering as positive steps toward achieving lower prices for prescription drugs within Medicare Part D and encouraging enrollees and their physicians to use effective, yet less expensive, medicines.

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