



### **Medicare Part D: Government Negotiation of Prescription Drug Prices**

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that would allow or require the federal government to negotiate prescription drug prices on behalf of Medicare Part D plan sponsors. The Academy supports the current structure of the Part D benefit that relies on the concept that drug price concessions are best achieved by negotiations by participating drug plan sponsors who themselves are motivated by the competitive need to provide the most cost-effective and clinically appropriate drug benefits possible. AMCP believes proposals to repeal the noninterference provision would introduce consequences that must be thoughtfully considered before action is taken.

It is important to note that the price of a drug is only one factor affecting the continued long-term viability of the program. The needs of patients and the ability of health care professionals to provide quality, safe and affordable health care are best served by having the government promote effective competition and encourage the use of innovative management techniques by purchasers, rather than directly intervening in competitive activities or engaging in micromanagement of otherwise functioning markets. The Academy also believes that the use of proven managed care strategies as part of an integrated program to provide a prescription drug benefit are working to give Medicare beneficiaries access to the medications they need in an effective and affordable manner.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (P.L. 108-73), which established the Part D drug benefit, is structured so that Part D plan sponsors negotiate prices with pharmaceutical manufacturers on behalf of Medicare beneficiaries. Section 1860D-11 (the “noninterference” provision) of MMA expressly forbids the Secretary of Health and Human Services (HHS) from negotiating with pharmaceutical manufacturers for the price of prescription drugs on behalf of Medicare beneficiaries and from establishing a list of preferred drugs.

#### **The Medicare Part D drug benefit program is working.**

The competitive model on which the Part D program was designed created incentives for qualifying plan sponsors to negotiate significant price discounts and provide the drug benefit as efficiently as possible. These incentives have proven to be strong and effective. The structure of the Part D drug benefit program offers beneficiaries a broad choice of options so that they can select a plan that offers the medications they need through pharmacies convenient to them. The plans offered under Part D are designed to attract enrollees through clinically sound formularies, affordable premiums and low cost-sharing requirements. The results are impressive:

- In 2013, over 60 percent of Medicare beneficiaries are enrolled in either a stand-alone Part D plan, or a Medicare Advantage (Part C) plan with prescription drug coverage (MA-PD).<sup>2</sup>
- For plan year 2013, each state offers beneficiaries a minimum of 23 choices of Part D plans, as well as multiple MA-PD plans. Monthly premiums range from a low of \$15 a month to a high of \$165 a month, including premiums for plans offering coverage beyond the standard benefit. This allows beneficiaries flexibility in finding the best plan to suit their needs.<sup>3</sup>
- A 2012 survey indicates that over 90 percent of beneficiaries are satisfied with the program.<sup>4</sup>

The ability of plan sponsors to effectively negotiate with pharmaceutical manufacturers to secure price concessions through well-established management tools has clearly been a major factor in the success of the Part D program. Giving the federal government the authority to negotiate drug prices would remove one of the principal competitive tools available to drug plan sponsors for managing the benefit.

In view of the program's success, there is no justification for switching from a model in which a diversity of private purchasers negotiates with manufacturers to one in which the government makes specific, universal purchasing decisions. Making such a fundamental change in the Medicare drug benefit poses its own risks to beneficiaries and the Medicare benefit and could undermine the long-term success of the program.

**Authorizing the federal government to negotiate the purchase price of drugs under the Medicare Part D program would inappropriately separate price negotiation from the formulary development process.**

AMCP supports the use of appropriately designed formularies as quality-enhancing, cost-effective managed care pharmacy tools. As outlined in the consensus document Principles of a Sound Drug Formulary System<sup>5</sup>, formulary systems are complex structures that are dependent on a variety of components whose interaction result in patients having access to the medications they need in a cost-effective, affordable manner. Effective use of formularies has mitigated the increase in the cost of medications without sacrificing patient access to necessary therapy, including access to medically necessary non-formulary drugs.

A formulary should only exist as part of a formulary management system, where formulary management serves as an integrated patient care process that enables health care professionals to work together to promote clinically sound, cost-effective pharmaceutical care. Formularies are developed in the context of an ongoing decision-making process in which medication experts determine which drugs meet the clinical needs of a defined patient population, taking into account scientific evidence relating to effectiveness and safety.

Due to the diversity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised document. Decisions on which drugs are included on a formulary are made by pharmacy and therapeutics (P&T) committees. P&T committees are responsible for developing, managing, updating and

administering a formulary. P&T committees are comprised of primary care and specialty physicians, pharmacists and other health care professionals. In order to keep a formulary current, P&T committees meet regularly to objectively appraise, evaluate and select drugs for the formulary and to review and update the appropriateness of a formulary system in light of new drugs and new indications, uses or warnings affecting existing drugs.

P&T committees' evaluations of medications are based first on safety and efficacy and then on cost-effectiveness. It is commonplace in the private sector for a P&T committee to determine clinically whether a drug under consideration for inclusion on a *formulary must be added to the formulary, may be added to the formulary, or should not be added to the formulary*. Once a therapeutic decision is made to add a drug to a formulary, price negotiations begin. Price or cost should never be the sole factor underlying P&T decisions.

Authorizing the federal government to negotiate prices for medications provided by Part D plan sponsors inappropriately separates the therapeutic evaluation from cost-effectiveness considerations. It would be easy to foresee a situation where the federal government would negotiate a low price for a medication that Part D sponsors have decided not to add to their formularies based on safety reasons. If the product is publicly listed as the lowest cost drug in its class, Part D sponsors may have no alternative but to add that medication to formulary based on public and government-driven demand. In such a situation, cost considerations would be overriding clinically sound therapeutic decision making which can jeopardize patient care.

Additionally, the federal government's imposition of a standard price for drugs under Part D would greatly impair the ability of Part D plan sponsors to design a competitive benefit offering that integrates clinically sound, evidence based medication choices with delivery systems and co-payment alternatives that provide beneficiaries with substantive choice. The ability of Part D sponsors to negotiate formulary placement and the price of drugs with manufacturers is a driving force in the Part D program's success in achieving the premium levels it offers beneficiaries and the government. The Academy believes that the formulary decision-making process that has proven successful in the competitive private sector should continue to be the basis for the purchase of drugs under the Medicare Part D program.

**The nonpartisan Congressional Budget Office (CBO) has stated that repealing the noninterference provision would have a negligible effect on federal spending.**

As noted above, plan sponsors under the current law's competitive structure have strong incentives to negotiate the deepest possible discounts. In addition, the overwhelming majority of plan sponsors participating in the Part D program have an established track record in the private sector of successfully negotiating prescription drug discounts for large populations. In an April 2007 cost estimate of legislation that would repeal the non-interference provision, the CBO estimated no savings to the federal government:

*CBO estimates that modifying the noninterference provision would have a negligible effect on federal spending because we anticipate that under the bill the Secretary would lack the leverage to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under current law. Without the authority to establish a formulary or other tools to reduce drug prices, we believe that the Secretary would not obtain*

*significant discounts from drug manufacturers across a broad range of drugs*<sup>6</sup>

**Even if, in the short term, the government was able to secure prices lower than the plan sponsors have been or would be able to do in the future, there are longer term adverse consequences that must be taken into consideration.**

Requiring the Secretary to directly negotiate with pharmaceutical manufacturers would likely result in de facto price controls: The term “negotiate” is not applicable in the context of the Medicare drug benefit as it implies some comparative equity among the parties. Allowing the federal government itself to directly “negotiate” on behalf of over 32 million Medicare beneficiaries would result in government setting prices, as pharmaceutical manufacturers would have little choice but to accept what the government offers. Examples are easily found in other parts of the Medicare program, in which the federal government’s approach has been the imposition of rigid pricing schedules for provider services under Medicare Parts A and B.

**It is questionable whether the experience of the Department of Veterans Affairs (VA) is an appropriate benchmark for comparison with Part D.**

The experience of the VA in negotiating discounted prices is often cited as an example of the types of discounts that might be available to Medicare should the Secretary of HHS negotiate on behalf of Medicare beneficiaries. It is true that the VA purchases pharmaceuticals at prices lower than the average obtained by Medicare drug plan sponsors. However, there are substantial differences between Medicare and the VA benefit.

The VA is able to hold prices down because there is a comparatively limited network of VA pharmacies. Three-quarters of its prescriptions are delivered by mail, through a dedicated warehouse and distribution network. The VA, through its health care system, both purchases and distributes prescription drugs. In contrast, the Medicare program is an insurer that pays for care that is delivered to covered beneficiaries at a myriad of sites by a myriad of professionals operating without a centralized system’s oversight and guidance.

Two fundamental factors operate in tandem and are unique to the VA:

- **The closed system of patient care under the VA system.** The VA is a direct provider of health care. Its physicians, pharmacists and other health care providers reach consensus on patient protocols for therapy, including prescription drugs. The fact that patients obtain full health care services through the VA’s integrated system fosters collaboration among those providing care to the veterans and adherence to the VA formulary.
- **The federal statutory ceiling price available to the VA and the statutory authority granted to the VA to purchase drugs under the Federal Supply Schedule.** The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) introduced the Medicaid best price practice. The provision made it illegal for a manufacturer to sell a medication to any other purchaser at a price less than what it charged Medicaid. The ramifications for the VA were immediate and profound: the VA lost its price advantage, and prices increased significantly for

the VA, just as they did in the private market.<sup>7</sup> Congress responded by enacting the Veterans Health Care Act of 1992, which not only exempted the VA from the best price requirement, but established a system of price ceilings and authorization for the VA to purchase drugs off the federal supply schedule. This not only reinvigorated the VA's ability to use market tools to negotiate lower prices, but it also imposed a statutory price ceiling on VA drug purchases of 76% of the nonfederal average manufacturer price, and allowed the VA to access Federal Supply Schedule prices, if lower. Much of the VA's comparative price advantage comes from the 'price control' elements of this pricing scheme.

To expediently provide a national program based on widely employed best practices in the private sector, the Part D benefit was structured upon a competitive approach that would encourage vigorous competition among qualifying private drug plan sponsors. The twofold objectives were to serve the medication needs of Medicare beneficiaries with maximum flexibility for patients, plus manage the cost requirements of the federal government. In giving drug plan sponsors the responsibility for administering the benefit, Congress cited the success of private-sector managed care organizations in using a broad range of innovative and integrated strategies to effectively manage prescription drug benefits for given patient populations, including the securing of price concessions from manufacturers and the use of clinically appropriate formulary systems, based on standards outlined in the law. Neither a clinical nor a financial case has been made to justify fundamentally undermining the structure established by MMA. Accordingly, AMCP opposes repeal of the noninterference provision.

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*The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's more than 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.*

## BIBLIOGRAPHY

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<sup>1</sup>SEC. 1860D–11. (i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

<sup>2</sup>Kaiser Family Foundation, The Medicare Prescription Drug Benefit Fact Sheet (November 2012). <http://www.kff.org/medicare/upload/7044-13.pdf> (accessed January 7, 2013).

<sup>3</sup>Kaiser Family Foundation fact sheet (November 2012).

<sup>4</sup>Modern Healthcare, Poll Finds Seniors Happy with Part D (October 2012). <http://www.modernhealthcare.com/article/20121003/NEWS/310039963> (accessed January 7, 2013).

<sup>5</sup>Principles of a Sound Drug Formulary System, consensus document endorsed by AMCP, Alliance of Community Health Plans, American Medical Association, American Society of Health-Systems Pharmacists, Department of Veterans Affairs, Pharmacy Benefits Management Strategic Healthcare Group, National Business Coalition on Health, U.S. Pharmacopeia (October 2000).

<sup>6</sup>Congressional Budget Office Cost Estimate, S. 3 Medicare Prescription Drug Price Negotiation Act of 2007 (April 16, 2007). <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/80xx/doc8006/s3.pdf> (accessed January 7, 2013).

<sup>7</sup>Government Accountability Office. Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions (GAO/HRD-91-139) (September 1991). <http://archive.gao.gov/t2pbat7/144939.pdf> (accessed January 7, 2013).