



March 9, 2004

***A Look at the Role of the Medicare Non-Interference Clause***

**Competition vs. Price Controls:  
The Road to Lower Prescription Drug Prices**

**Introduction**

A key goal of Republicans in crafting the Medicare Modernization Act of 2003 was to help lower the price of prescription drugs for Medicare beneficiaries. And, in fact, the new Medicare law achieves this goal through an array of mechanisms, including increased private competition among private health plans, drug subsidies for certain beneficiaries, and language to encourage the use of high-quality, but also less expensive, generic pharmaceuticals.

Despite the wide bipartisan support for these mechanisms, one drug-pricing issue recently has reemerged. That is whether the federal government should set pharmaceutical prices for Medicare or – as the bill provides – leave drug discount negotiations to the private sector, as is the case with the federal employees’ health system and most employer-based health plans.<sup>1</sup> This paper examines that issue and the reasons why the law utilizes the latter approach to reducing drug prices.

**Medicare Modernization Act: History of the Non-Interference Clause**

The concept that prescription price discounts are best achieved through private competitive forces – and that government should not interfere – has, over the years, received longstanding support from lawmakers. It has been included in every Democratic and Republican Medicare proposal introduced since the 106<sup>th</sup> Congress. Some of those past bills include: the Medicare Expansion for Needed Drugs (MEND) Act of 2000, introduced by Senator Daschle; the

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<sup>1</sup>Congressional Research Service, “Comparison of Medicare Prescription Drug Provisions in P.L. 108-173 With Federal Employees Health Benefit Program, 5 U.S.C. §8901 *et seq.*,” Memorandum, February 9, 2004.

Seniors Prescription Insurance Coverage Equity (SPICE) Act of 2001, introduced by Senator Wyden; and the 21<sup>st</sup> Century Medicare Act of 2002, introduced by Senators Jeffords, Breaux, and Grassley.<sup>2</sup>

These previous bills each contained what is often referred to as a “non-interference clause,” and that language formed the basis for the legislation contained in the Medicare Modernization Act, as enacted. Specifically, House and Senate Medicare conferees worked to ensure that the new voluntary prescription drug benefit, administered under Medicare Part D, was structured in a manner that preserves the competition concept and prevents direct price controls. The new Medicare law states:

*“The Secretary of Health and Human Services (HHS) may not interfere with the price negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. In addition, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs” (§1860D-11).<sup>3</sup>*

Recently, some lawmakers began taking a different position toward this clause, claiming that it will hamper the government’s ability to obtain lower-priced drugs for seniors.<sup>4</sup> They argue that the federal government, due to its size, is in a better position than the private sector to achieve drug discounts.<sup>5</sup>

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<sup>2</sup>The non-interference language can be found on pg. 5, line 6 of the MEND Act (S.2541); pg. 61, line 13 of the SPICE Act (S. 1185); and pg. 86, line 19 of the Tripartisan bill.

<sup>3</sup>Similar language also is included under the new Medicare Advantage program administered by Medicare Part C.

<sup>4</sup>It is important to note the Medicare law potentially could result in *indirect* price controls due to the law’s provision that would permit importation of pharmaceuticals from Canada provided that the HHS Secretary deems the importation of such drugs safe and more cost-effective. By contrast, requiring the Secretary to negotiate pharmaceutical price discounts with manufacturers constitutes *direct* price controls, which the competition language – also commonly referred to as the “non-interference” clause – prohibits.

<sup>5</sup>The following legislation recently was introduced to modify various aspects of the Medicare Modernization Act, including repeal of §1860D-11: 1) The Defense of Medicare and Real Medicare Prescription Drug Benefit Act (S. 1992), introduced on December 9, 2003, by Senators Kennedy, Bob Graham, and Mikulski; 2) The Medicare Prescription Drug Savings Act of 2003 (S. 1950), introduced on November 24, 2003, by Senators Durbin, Dayton, and Levin; and 3) The Medicare Enhancements for Needed Drugs Act of 2004 (S. 2053), introduced on February 6, 2004, by Senators Snowe, Wyden, Feinstein, and Jeffords. Each of these measures includes language authorizing the HHS Secretary to negotiate contracts with manufacturers of covered Medicare Part D drugs.

## Keeping the Non-Interference Clause Intact: What the Experts Say

Earlier this year, in response to a request by Senator Frist concerning the budgetary impact of striking the non-interference language, the Congressional Budget Office (CBO) stated:

*“We estimate that striking [the] provision would have a negligible effect on federal spending because CBO estimates that substantial savings will be obtained by the private plans and that **the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree.**”<sup>6</sup>*

The Senate Budget Committee pursued this statement further with CBO Director Douglas Holtz-Eakin during his testimony before the committee last month. During questioning, Chairman Nickles asked the CBO Director what the impact would be if Congress mandated government interference in the Medicare prescription drug benefit negotiations. Director Holtz-Eakin did not project any “appreciable savings,” adding further:

*“If you put in a provision and language into the bill as passed which said the Secretary ‘should’ or ‘must’ negotiate, we think there is the potential for savings in some drugs, presumably the nonpreferred drugs. . . .But given bottom lines, to the extent that you move down the prices on one drug, you probably move up the prices on the preferred drugs, and **on balance, you could raise costs.**”<sup>7</sup> [emphasis added]*

Therefore, the fundamental assumption— that drug prices uniformly would be reduced if the non-interference clause is eliminated and a government-negotiated pricing system is created — is not only incorrect, but it is possible that *some prescription drug prices could actually increase.*

During the recent markup of the Fiscal Year 2005 Budget Resolution, opponents of the non-interference clause again raised the argument for mandated federal negotiations, this time basing their argument on a March 3 letter from the CBO director in response to an inquiry from Senator Wyden. In his response, Director Holtz-Eakin reiterated the agency’s position that there would be “little, if any, potential savings” from the Secretary negotiating prices for most drugs. However, he did acknowledge that “there is potential for some savings,” – but only for “single-source drugs that do not face competition from therapeutic alternatives.”<sup>8</sup> Single-source drugs typically are breakthrough medicines, which include biotech drugs and innovative chemical

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<sup>6</sup>Letter to Senate Majority Leader Bill Frist from the Congressional Budget Office, January 23, 2004.

<sup>7</sup>Douglas Holtz-Eakin, CBO Director, U.S. Senate Committee on Budget Hearing, “The Budget and Economic Outlook: Fiscal Years 2005 to 2014,” January 27, 2004.

<sup>8</sup>Holtz-Eakin, Letter to Senator Wyden, March 3, 2004.

compounds. These are the most expensive to research and develop. However, it is important to note that CBO did not assume any savings. Holtz-Eakin also reiterated the agency's position that any proposal applied on a broad basis "*could generate no savings or even increase federal costs.*"

Over the years, CBO consistently has identified pharmacy benefit managers (PBMs) as a key feature for any Medicare prescription drug proposal, claiming that they are better equipped than the federal government to "constrain federal costs and total spending on outpatient prescription drugs."<sup>9</sup> PBMs contract with employer-sponsored health plans and insurers to help manage their prescription drug benefits. In turn, these entities negotiate drug prices with pharmacies and drug manufacturers. In some cases, they also provide administrative services such as processing drug claims for health plans. The CBO attributes savings to the health plan and PBM relationship because both the plans and PBMs risk profit loss if significant discounts are not achieved – a pressure that does not exist within the government. According to the General Accounting Office (GAO), "approximately 200 million Americans currently have their prescription drug benefits managed by a PBM."<sup>10</sup> And the role of PBMs recently was cited as one of the factors contributing to a slower growth in prescription drug spending.<sup>11</sup>

Similar cost savings also have been cited as a primary factor in keeping FEHBP expenses relatively low. For instance, the GAO issued a report last year that found PBMs negotiated savings of up to 53 percent from what would have otherwise been paid, on average, at retail pharmacies or through home delivery programs – a significant finding since Congress has tried to duplicate the success of the FEHBP in Medicare.<sup>12</sup> These findings are the basis for the Medicare conferees' decision to reject federal price controls and maintain pharmaceutical negotiations in the private sector.

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<sup>9</sup>CBO, "Issues in Designing a Prescription Drug Benefit for Medicare," October 2002.

<sup>10</sup>General Accounting Office (GAO), "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," January 2003.

<sup>11</sup>Centers for Medicare and Medicaid Services, "2003 Expected to Mark First Slowdown in Health Care Cost Growth in Six Years," Press Release, February 11, 2004. The CMS health care spending projection data found that while prescription drug spending is still estimated to be the fastest-growing sector, its growth is expected to decline. For instance, prescription drug spending is expected to be 13.4 percent in 2003, 12.9 percent in 2004, and 12.4 percent in 2005. According to the report, "the deceleration is due to slower growth in drug prices, the scheduled expiration of patent protection for several top-selling drugs, and increased use of multi-tiered copays that have slowed demand."

<sup>12</sup>GAO, January 2003, pg. 4.

## **Gasoline Shortages: The Lessons of Government Interference**

Whether it is oil, pharmaceuticals, or other goods and services, the history of government interference is instructive in understanding the perverse effects of price controls and their impact on supply and demand in the market. On a few occasions, the federal government has been impatient with the market's timing and has established price-setting policies that have impacted certain industries.<sup>13</sup> A relevant example is from the 1970's, when the federal government tried to control domestically produced crude oil prices as a way to lower the price of gasoline for Americans – a policy that grossly distorted the market. While prices were reduced temporarily, domestic exploration and production were depressed, putting upward pressure on prices when the controls were lifted. Demand for gasoline artificially increased, and consumers experienced shortages. Ironically, Americans became even more dependent on foreign oil.

As the gasoline-price experience demonstrates, government price-setting policies adversely affect access. In the case of prescription drugs, the response may be a reduction in investment of innovative pharmaceutical research and development. Our foreign neighbors provide a window through which to view the consequences of pharmaceutical price-control policies. A recent study found that in countries in which governments control the price of pharmaceuticals, manufacturers in some cases delayed the launch of a new drug product rather than accept a low price.<sup>14</sup> Medicare beneficiaries could face similar access problems if the federal government intervened and negotiated pharmaceutical prices.

## **The Myth of the VA as a Model for Medicare Price Setting**

Some lawmakers have tried to draw analogies between the Medicare prescription drug program and the Veterans Affairs (VA) pharmacy system, arguing that the Medicare program should adopt the VA drug-pricing structure because it would result in lower drug prices for beneficiaries. However, the GAO and the Congressional Research Service (CRS) are among the observers who suggest that there would be severe market consequences for Medicare and the private sector if such a policy were implemented.

The VA pharmacy benefit is based on a federal procurement model, allowing the veterans health system to enter into agreements with certain drug manufacturers as a way to reduce prices for our nation's veterans served by the program. For instance, manufacturers that sell brand-name drugs listed on the Federal Supply Schedule (FSS) must offer the VA a price that is at least 24-percent lower than the non-federal average manufacturer price. In addition, the VA is

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<sup>13</sup>James L. Williams, "Oil Price History and Analysis," WTRG Energy Economics Newsletter, October 19, 2003.

<sup>14</sup>Patricia M. Danzon, Y. Richard Wang, and Liang Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s." National Bureau of Economic Research, July 2003.

authorized to enter into multi-year contracts for other select drugs, resulting in a price that is even lower than the FSS discounted rate.<sup>15</sup>

In October 2000, the GAO issued a report that examined the impact of expanding the VA pharmacy benefit to Medicare. The report concluded that such a scenario would result in negative ramifications for the entire health care system, and that initial savings to Medicare would be short-term.<sup>16</sup> The GAO noted that the ramifications are due to risk segmentation in the market. For instance, the VA's pharmacy program serves a relatively small population of approximately 3.5 million veterans – a group which represents just 1 percent of total drug spending nationwide.<sup>17</sup> As a result, profit loss among pharmaceutical manufacturers is limited.

However, if the Medicare program were to implement a pricing system similar to the VA's, then the potential for market distortion would be much greater. The Medicare program currently covers 41 million seniors and disabled individuals – a group which represents 14 percent of the total population *but 40 percent of total U.S. drug consumption*. GAO concluded that manufacturers would respond almost immediately with price increases throughout the private sector as a way to prevent profit erosion. This, in turn, would raise health insurance rates for non-Medicare beneficiaries, and furthermore, create only temporary price reductions for Medicare since the federal supply rate is based on a manufacturer's "most-favored" rate in the private sector.<sup>18</sup>

Expansion of the VA pharmacy benefit also presents logistical concerns.<sup>19</sup> The VA is not only the sole system purchaser of pharmaceuticals but also its sole distributor. The VA pharmacy program implements a national formulary which all VA physicians are required to follow. Once a prescription is determined necessary, it is then submitted electronically to a national acquisition site. The repository then distributes the drugs only to VA pharmacies and hospitals, and in some cases, directly to veterans through a mail-order program.

The Medicare program, by design, is vastly more de-centralized. First, Medicare participating physicians are not government doctors working in government facilities, and not all

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<sup>15</sup>General Accounting Office, "Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes," August 2000. [Note that the VA pharmacy program has not changed substantially since this report was issued, and so its observations can still be considered relevant.]

<sup>16</sup>GAO, August 2000, p. 5.

<sup>17</sup>Interview with Thomas Scully, former Administrator of the Centers for Medicare and Medicaid Services, March 4, 2004.

<sup>18</sup>GAO, August 2000, p. 6.

<sup>19</sup>Interview with Congressional Research Service, VA division, February 19, 2004.

have the capability to submit prescriptions electronically. And even if they could, to whom would the prescriptions be transferred?

Second, the Medicare law expressly prohibits the creation of a national formulary, leaving such important decisions to the individuals and their physicians and health plans. The culture of standardization in the military and the VA is not shared by the vast majority of Americans within the private health care system, whether paid for by Medicare or personal insurance.

Third, when the new drug benefit begins in 2006, it will afford beneficiaries the opportunity to fill prescriptions at a range of locations, including their local pharmacy, a nearby outpatient clinic, an HMO facility, or even through a mail-order-delivery program. These options are the same as the options available in most of the private sector, and indeed, the Medicare law was structured to fit within that environment.<sup>20</sup> Proponents of a “VA-like” program must ask themselves what the impact would be on choice, access, convenience, and timeliness of prescription drugs for millions of Medicare beneficiaries if the VA pharmacy system were applied to the Medicare program. Undoubtedly, it would raise questions about the imposition of a one-size-fits-all national health care system that would be resisted by many.

## **Conclusion**

The Congressional Budget Office and the General Accounting Office have presented compelling evidence in support of private-sector drug negotiations. Given the data, the vast experience of private health plans, and the number of patients involved, Congress’ decision to include the non-interference Medicare language was justified. History reminds us that when government officials intervene in the market and control prices, there are consequences: supply and demand become distorted; access is hindered; and innovation is stifled. The difference between price controls on gasoline and price controls on pharmaceuticals is clear – while one left Americans standing in line to fill up their cars for transportation needs, the other potentially could leave Americans waiting for new medical advances to save and improve lives.

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<sup>20</sup>Interview with Thomas Scully, former Administrator of the Centers for Medicare and Medicaid Services, March 4, 2004.