Medicare Negotiation of Prescription Drug Prices

The Democratic House leadership has stated it intends to pass a modification to the Medicare prescription drug program to permit, or perhaps even require, the Secretary of Health and Human Services (HHS) to directly negotiate prices for Medicare Part D-covered drugs with pharmaceutical manufacturers. The leadership notably points to the U.S. Department of Veterans’ Affairs (VA) and its authority to negotiate prices on behalf of veterans receiving outpatient drugs under the VA prescription drug program. This memorandum provides a brief overview of this issue to form the basis of a discussion for CHCC members. The memo provides some background on the competing positions and identifies available data and also areas where more information is likely needed.

Options Under Consideration

Democrats have proposed or say they are considering proposals that would:

- Remove the “non-interference” clause to allow or require the federal government to negotiate and purchase Medicare drugs “at VA prices.”

- Require Medicare negotiation of drug prices with specified discount parameters directed at drug manufacturers, e.g., a stipulated percentage discount relative to a benchmark price.

- Create a federal government-run Medicare Part D plan option that would compete with the private sector PDPs and for which the government would negotiate the prices.

Representative Henry Waxman (D-CA), incoming Chairman of the House Committee on Government Reform, along with some other Democratic proponents, has expressly stated that the savings derived from government-negotiated drug prices should be used to eliminate or substantially diminish the coverage gap (“donut hole”) in the Part D benefit. Other Democrats are more circumspect. According to The Washington Post (11/19/06, p. A6), incoming Senate Finance Committee Chairman Max Baucus (D-MT) has said that “We need to be very honest in getting the facts” about whether such a switch to federal negotiation of drug prices would be helpful.

Prices of Prescription Drugs

Drug manufacturers occupy a market where they are motivated and permitted to charge different prices to different buyers and market segments. In this market, the buyers of prescription drugs – wholesalers, PBMs (pharmacy benefit managers), health care systems, pharmacies, foreign health systems – basically negotiate the best prices they can for the quantities they wish to purchase.

The Non-Interference Clause

The MMA included a provision commonly referred to as the “non-interference” clause that prohibits the Secretary of HHS from interfering in negotiations between drug manufacturers, pharmacies and PDP (prescription drug plan) sponsors and also precludes HHS from requiring a particular formulary or instituting a price structure for Part D drugs.
Performance of the VA's Drug Purchasing Program

The VA administers multiple drug pricing schedules on behalf of the federal government: the Federal Supply Schedule (FSS) (and the Restricted FSS), the Big-4 pricing schedule, and the National Contract Prices schedule. VA facilities and providers may purchase from any of these VA price lists (including non-formulary drugs when necessary):

- **FSS**: The VA is responsible for managing and awarding FSS contracts related to medical products and services, including prescription drugs. FSS prices are based on pricing data the manufacturers provide to the VA. The VA negotiation objective is to obtain prices equal to or better than Most Favored Commercial Customer (MFC) prices, although some FSS prices may be higher than the MFC price. FSS prices are generally available to all federal government agencies and some state veterans’ homes. (The Restricted FSS is restricted to certain federal agencies.)

- **Big-4 Pricing Schedule**: Under this discount program established by the Veterans Act of 1992, the VA Secretary is authorized to negotiate drug prices on behalf of the VA, Department of Defense (DoD), the Public Health Service, including the Indian Health Service (IHS), and the Coast Guard. Under the Big 4 Pricing Schedule, a price cap is set on what manufacturers can charge the Big 4 purchasers at no more than 76% of the non-federal Average Manufacturer Price. (Some prices obtained are lower.) Only brand-name drugs are covered by this program. For prescription drug items that appear on both the FSS and the Big 4 Pricing Schedule, the Big 4 agencies may purchase from whichever has the lowest price.

- **National Contract Prices**: Under this program the VA negotiates prices specifically for its health programs and facilities that provide services to the approximately 5 million veterans and dependents it serves. National contracts are negotiated through competitive bidding and the drugs are then included on the VA formulary of preferred drugs to be used by VA health care providers. These prices tend to be lower than the other pricing schedules. They are available only to VA providers, and they apply to a very small percentage of the overall U.S. pharmaceutical drug market. The formulary is restricted, much more so than under employer plans.

Each of these various ways of determining federal government drug prices produce significant savings over the best price for drugs paid by private payers.

**Arguments and Data Advocating for Allowing Medicare to Negotiate Drug Prices**

- **Market clout of Medicare would lead to efficiencies and savings.** Proponents of authorizing negotiation of drug prices by the Medicare program maintain that it would result in lower prices for prescription drugs. Having the federal government act as the primary or exclusive negotiator would effectively eliminate the “middle men” – such as the PBMs and drug wholesalers – which impose intermediary mark-ups to prices in order to cover administrative costs and profits.

  — A June 2006 report by Families USA found that the lowest VA-negotiated price is lower than the lowest Medicare prescription drug plan price for all of the top 20...
drugs used by seniors (18 brand and two generic). Of the top 20 drugs surveyed, the median Part D lowest price was 46% more than the VA’s lowest price.

- The June 2006 Families USA study also found that for 19 of the top 20 drugs, increases in the median Part D plan prices were 3.7% during the first 6 months of the Part D program, “virtually identical” to changes in Average Wholesale Price (AWP) during the same time period. Families USA says that this finding suggests that Part D plans are not effectively restraining pharmaceutical industry price increases.

- The Government Accountability Office (GAO) in 2002 found that FSS prices obtained by the VA were about 42% to 50% of the AWP. (The AWP or “average wholesale price” is the publicly available, “suggested list price” for sales of a drug by a wholesaler to a pharmacy or other provider. Although the average manufacturer price is less than the AWP, the AWP is often used as a benchmark for analysis and for some prices.)

- The Congressional Budget Office (CBO) estimated that in 2003, prices available to the Big 4 agencies were about 49% of AWP, on average, for single–source, brand name drugs (includes drugs available under either a Big 4 price and a single FSS price available to all federal purchasers).

- In an analysis using 2003 CBO data, the Center for Economic and Policy Research (CEPR) —a liberal study group—projected Medicare savings over eight years (2006-2013) ranging from $370-$735 billion on drug purchases as a result of direct negotiation of drug prices. The CEPR, in a July 2006 report, states that: “If Medicare had been allowed to bargain directly with pharmaceutical companies -- as is done by the Veterans Administration and many countries -- 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.”


- **Prices might be more consistent and less variable for all Medicare beneficiaries.** Currently, under the Part D program, Medicare beneficiaries pay different prices for the same drugs.

**Counter Arguments to Allowing Medicare Negotiation of Drug Prices**

- **Availability of deeper discounting questionable.** Some analysts doubt whether discounts that the federal government could obtain for the Medicare program would be substantially greater than those that the private sector is able to accomplish.

  - When asked about the effect of striking the “non-interference” provision of the MMA, in a 1/23/04 letter to Senator Bill Frist (R-TN), the CBO estimated it would have a negligible effect on federal spending. However, in a subsequent 3/3/04 letter to Senator Ron Wyden (D-OR), the CBO stated that there could be
potential for some savings if HHS were to have the authority to negotiate prices specifically in the area of “single-source drugs that do not face competition from therapeutic alternatives.”

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Large prescription drug benefit managers (PBMs) already have significant market share and tens of millions of covered lives. According to the Congressional Research Service, the Chief Actuary at CMS concluded that giving HHS the ability to directly negotiate might not produce additional savings over what private plans could obtain.

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The Centers for Medicare and Medicaid Services (CMS) counters some of the Families USA’s June 2006 study by indicating that Part D prices for drugs used to treat common chronic conditions have experienced a lower increase than the AWPs (3.6% for the chronic drugs under Part D PDPs versus a 4.1% increase in AWPs).

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According to CMS, a 20% savings to Medicare beneficiaries in the Part D program – significantly greater savings than that originally predicted in the 2005 Medicare Trustees report – is due to stable, large price discounts combined with therapeutic and generic substitution of less expensive drugs.

- **Indirect consequences of cost-shifting unknown.** Overall drug prices could increase, both for the private sector – specifically for the under-65 population – and for other federal programs (such as those administered by the VA). The price sensitivity of demand in other segments of the market is an important determinant of the success of a federal negotiation strategy.

- **Research and development of pharmaceuticals suffers.** Drug manufacturers have stated that R&D for pharmaceuticals would suffer if retail prices are pushed down and their returns on investment are negatively impacted. There have been some analyses on whether this could happen but the possible impact is difficult to quantify.

**Impact on Employers**

Depending on the specifics and the scope of the legislative proposal, direct Medicare negotiation for prescription drugs could have a major impact on the purchasing of prescription drugs for all buyers, and the direct and indirect consequences need to be better understood. Furthermore, the impacts would likely be different for different groups of employers. Here are some of the preliminary issues to consider.

- The actual extent of potential federal Medicare savings remains uncertain at this point, with conflicting vantage points, projections and assumptions.

- Using the federal savings to fill in the “donut hole” would potentially reduce retiree health costs for employers that wrap around Medicare Part D, contract with a Part D plan, or contract with CMS as a Medicare PDP (and provide gap coverage).
• Regarding employers taking the retiree drug subsidy (RDS), for savings to be realized, there would have to be an increase in the limits on drug costs that may be submitted to CMS for payment. During the MMA debate, CBO argued, and Ways and Means believed, that the alternative options of taking the subsidy or going through Part D should result in approximately the same level of savings. Subsidy employers would want to argue on that basis, that the limits on gross drug costs per retiree ought to be raised; otherwise, there will be a disincentive for employers to continue their current retiree health coverage.

• For retiree drug costs not paid by Medicare, employers would need to determine whether they could only reimburse for the Medicare-approved price, similar to what employers do now with the Medicare Part B fee schedule. If they can’t, Medicare negotiation of drug prices may result in cost shifting to retiree health plans, and the “value” of the policy change to employers would be the value of the retiree drug subsidy minus the cost shift. If the value of RDS diminishes in the face of higher prices, it would make less sense to continue to accept RDS in such an environment.

• How the pharmaceutical industry would react is a critical factor. It may not have much effect on the pharmaceutical market if the manufacturers were able to dig in and say that current discounts are the best they can give. But if the law mandates VA-level prices for Medicare drugs, it seems that there would almost have to be a cost shift to other purchasers which probably translates into their commercial business. The effect on the industry may be lessened if the federal government just focuses on a small group of drugs that seniors use in high volume, rather than on concessions for all drugs across the board.

• Would a cost shift increasing the prices of drugs for active employees be acceptable, and if so, to whom? For some employers that offer retiree health benefits, the cost shift to actives is perhaps tolerable provided it does not erode completely the financial gains made in 2006 with RDS. The cost shift to active employee drug costs could be offset by increases in employee copayments and coinsurance for drugs, which might neutralize some of the financial impact of cost shifting on the employers. Employers not offering retiree health benefits are unlikely to tolerate cost shifting that may result from Medicare direct negotiations, leading them to oppose the legislation. Cost shifting, if significant, could also increase the number of uninsured individuals, and cause more employers to consider dropping health coverage.

• Would employers support federally-regulated drug prices for Medicare if this could be viewed as a philosophical precedent with potential application of similar policies to other industries?

Sources:


Congressional Budget Office, *Prices for Brand-Name Drugs under Selected Federal Programs*, June 2005


Families USA, *Big Dollars, Little Sense: Rising Medicare Prescription Drug Prices*, June 20, 2006,

GAO, *VA and DoD Health Care: Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges*, July 22, 2002 [GAO-02-969T]
