

Price Strategy Bulletin

Countdown to Change: Implications of Medicare Part D Reform

Introduction

The management of US drug prices is undergoing increased scrutiny. Two events have brought this into sharp focus. First, with the implementation of Medicare Part D in 2006, the Medicare program is indirectly paying an increasing portion of total prescription drug costs (projected to be ~32% by 2015). Second, Democratic leaders gained majorities in both houses of Congress in part through promises appealing to the influential elderly US voting population. This includes a proposal to increase the federal government's role in negotiating and/or managing drug prices under Medicare Part D. This would represent a substantial departure from current *laissez-faire* pricing policy and thus have strong implications for pharmaceutical manufacturers.

Medicare pays the Drug Costs for many Americans

Medicare, the US health insurance program for elderly and disabled individuals, provides medical coverage to 42 million Americans.¹ The program, administered by the Center for Medicare and Medicaid Services (CMS), accounts for a significant portion of all healthcare expenditures in the US. Last year, Medicare paid 15% of total US outpatient prescription drug costs.² Medicare is composed of four parts:

- Part A - inpatient hospital services
- Part B - outpatient services
- Part C - Medicare Advantage (alternative to Parts A and B)
- Part D - Medicare Prescription Drug Benefit (MPDB)

Medicare Part D currently subsidizes prescription drug costs for 8% of all Americans. With increasing enrollment, CMS projects that Medicare Part D will cost \$112 billion and may account for 32% of the US prescription drug market in 2015.³ Under the 'non-interference' provision of Medicare Part D, the US government is not allowed to negotiate prices directly with manufacturers.

Instead numerous private drug plans and pharmacy benefit managers (PBMs) currently negotiate drug prices on behalf of Medicare Part D beneficiaries who are enrolled in their competitive drug-coverage plans.

¹ CMS. "Medicare Enrollment Reports-All, 2005." [2006]

² US Dept. HHS. [Jan. 2006] and CMS. "Prescription Drug Expenditures: All Sources." [Apr. 2006]

³ CMS Office <http://www.cms.hhs.gov/>. [Jan. 2007] and Congressional Budget Office. <http://www.cbo.gov/>. [Jan 2007].

Medicare may leverage Significant Buying Power

Due in part to the program's significant and growing budgetary impact, Medicare Part D is now under close examination from leaders in the Democratic Party. They have vowed to help control costs by allowing government-led negotiation of drug prices within Part D. They argue that the US Government's massive buying power will lead to lower net prices. Democrats cite a report released by the House Committee on Government Oversight and Reform indicating that "over a ten-year period, the total savings for Medicare beneficiaries [as a result of lowered prices] would be an estimated \$61 billion."⁴

Medicare Prescription Drug Price Negotiation Act of 2007

The Medicare Prescription Drug Price Negotiation Act (H.R.4), submitted on January 5, 2007, stipulates that the Secretary of Health and Human Services (HHS) "shall negotiate with pharmaceutical manufacturers the prices...for covered part D drugs." Means of negotiation would include "discounts, rebates, and other price concessions." The act further states, however, that "nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary."⁵

H.R.4 mandates government price negotiations, but it is possible that there will be compromises by the parties in Congress that leads to a final bill differing substantially from the original. In this bulletin, we outline the range of potential outcomes relevant to manufacturers regarding the coming debate on H.R.4 and draw parallels to precedent in both the US and key European markets.

Key Considerations

When discussing the full spectrum of possible government price controls, there are many considerations that will ultimately inform the impact of any proposed measure:

- Scope of mandate: H.R.4 (if left in its current form) would mandate the Secretary of the HHS to undertake price negotiations with manufacturers. Alternatively, the Secretary could simply be authorized (and not *mandated*) to negotiate price, in which case the

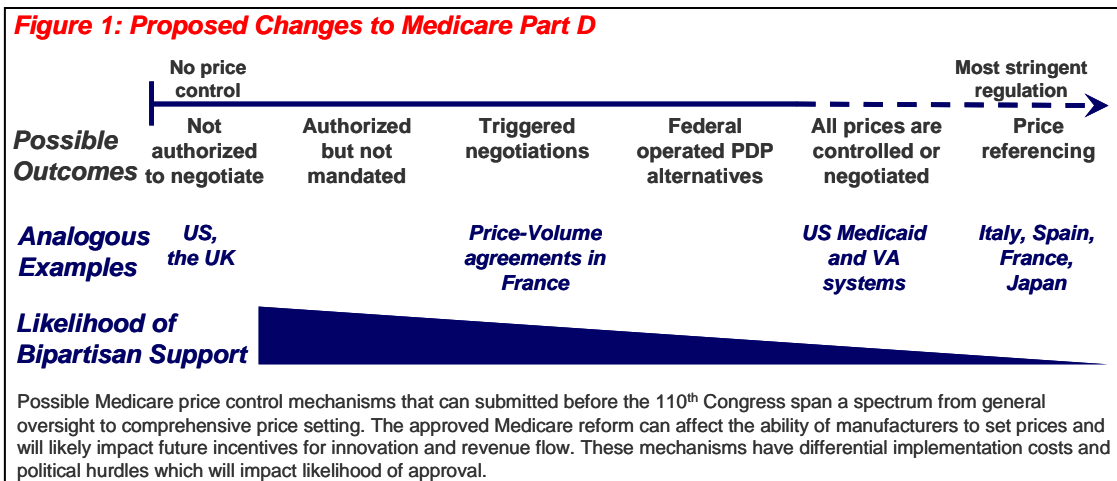
⁴ US House Committee on Government Reform. www.democrats.reform.house.gov/. [Jan. 2007]

⁵ US House of Representatives. "H.R.4 - Medicare Prescription Drug Price Negotiation Act of 2007." [Jan. 2007]

Secretary could choose not to exercise negotiating authority.

- **Formulary control:** H.R.4 does not authorize the government to create its own formulary. Without a formulary, the government loses a key bargaining tool. Dr. Alan M. Garber, director of the Center for Health Policy at Stanford University, said “If you cannot walk away from a deal, there’s no way you can be sure of obtaining a low price. That’s true whether you are buying a car, a house or medications.”⁶
- **The number of drugs affected:** The federal government could be mandated to negotiate prices of only some products, i.e. products within specific therapeutic areas, or all drugs prior to inclusion on all Medicare formularies. Attention might fall on the higher-cost drugs, such as biologic therapies that target chronic, age-associated conditions (i.e., cancer, rheumatoid arthritis, etc.).
- **Type of bargaining mechanism:** Though still a matter of speculation, the most commonly mentioned measures include negotiated rebates or discounts, use of mandated discounts and/or fixed maximum price limits. External or geographic price referencing, used in other global markets, is still a possibility but far less likely.

There are many possible outcomes to the current reform debate (Figure 1). The possibilities range from relatively less-stringent changes (e.g., HHS authorization to negotiate price) to far more restrictive measures (e.g., price referencing). As the measures become more draconian, the likelihood that a proposal will receive bipartisan approval decreases and the chance of overriding a likely presidential veto falls.



In the following analysis, we use five discrete scenarios to examine a range of potential legislative outcomes. This analysis may help inform strategic planning by manufacturers in response to various changes to the US pricing and reimbursement environment.

⁶ Pear, Robert. “Democrats’ Drug Plan Has Pitfalls, Critics Say.” New York Times. [Jan. 7, 2007]

Possible Outcomes of the Medicare Part D Debate

1. *The Secretary of Health and Human Services (HHS) is mandated to negotiate all drug prices.*
A mandate for the Secretary of the HHS forms the core of the existing proposal before Congress (H.R.4). Negotiations could take the form of mandated discounts or maximum price limits. These would be analogous to systems currently used by Medicaid (mandated discounts and preferred drug lists) and the Department of Veterans Affairs (VA - uses mandated discounts), but would require a more flexible government role. Given these established US precedents, this proposal could gain support from Congress. These precedents derive some of their bargaining power by limiting formulary access, which is currently prohibited by H.R.4, however. If Medicare was to be given formulary control, price bargaining with the US government would be similar to national price negotiations in some European markets.
2. *HHS could be authorized but not mandated to negotiate drug prices.*
Compromises with Republican minorities could result in a lack of a requirement for the HHS to engage in negotiations with manufacturers. Without a specific mandate, the exercise of bargaining power would be at the discretion of the HHS Secretary. The current Secretary, Michael O. Leavitt, has stated “I don’t believe I can do a better job than an efficient market” to justify his lack of desire for bargaining authority.

Such a proposal would likely gain bipartisan support, and although currently limited in scope, future changes might expand government interference. Under such a regime of authorized but not mandated intervention, manufacturers should be wary of eliciting unwanted interference. In this instance, the pharmaceutical industry has an opportunity to proactively address any budgetary concerns through the use of innovative pricing mechanisms (i.e. patient cost caps).

3. *Negotiations could be mandated under special circumstances (i.e., triggered negotiation).*
Likely triggers include those covering particularly high-cost items (such as biologic drugs), budget shortfalls (total or indication-specific drug expenses), or instances where private plans cannot achieve adequate cost savings. Since triggered negotiations are limited to unique situations, bipartisan support is

possible. The pharmaceutical industry once again has an opportunity to proactively address concerns, thereby reducing the extent of potential government price interference.

4. *CMS may regulate formulary inclusion via one or more government-run drug plans.*

The government would compete with PBMs that currently negotiate on behalf of beneficiaries. There are two important implications of this proposal. First, the buying power of a government-led plan is directly tied to the number of its enrollees. With larger numbers of beneficiaries, a Medicare plan would wield greater buying clout vis-à-vis manufacturers. Second, the Federal Government would become more involved in the direct administration of healthcare. Logistical and budgetary concerns in implementing and running a plan would be a significant hurdle and partially offset potential cost savings. As such, bipartisan support may be difficult to garner for this proposal. Though not included in H.R.4, this option has been discussed among policy leaders in Washington.

5. *Benchmark prices could be set for all drugs for all Medicare beneficiaries via a price referencing system.*

Across the globe, there are various forms of price referencing used. Benchmark systems can take the form of internal referencing (limited to common therapeutic compounds or classes, as in Germany) or external referencing (incorporating a basket of international markets, as in many European markets and Japan). The implementation of an external benchmark suggests an implicit approval of other countries' policies for domestic use. Reference systems are also inflexible with regard to manufacturers' product value arguments because price negotiation is often precluded. Referencing is thus seen as highly restrictive and therefore unlikely to gain wide support if considered in Congress.

A Call to Action

The industry should recognize that as government budgets become increasingly exposed to the impact of prescription drug prices, the risk of future price intervention increases. The changes we have touched upon will have far-reaching implications for pharmaceutical pricing. The ability of manufacturers to freely set value-based prices and thereby recoup investments in the next generation of products is at stake.

The pharmaceutical industry can choose to respond to the current political pressure in the US in a number of ways. The industry could muster its collective strength and lobby hard to keep the status quo, but this may feed further political impetus for even greater government restrictions in the future.

Manufacturers may also choose inaction at this time, which may result in missed opportunities to participate in legislation that will strongly impact the future of the US prescription drug market.

There may, of course, be a more proactive approach that could be taken by the pharmaceutical industry to address looming Medicare budgetary concerns. Targeted initiatives could be set in motion prior to any further government involvement. For example, the industry could more aggressively promote and expand on programs that guarantee patient access to much-needed medications while limiting overall budgetary impact to payers (i.e. innovative pricing via patient cost caps). The industry could also further support rational prescribing as a way to ethically promote appropriate use and ease government budgetary impact. Further, sustainable pricing could be considered for new products that will reflect both intrinsic product value and thoughtful regard to the realistic limits to government reimbursement. Some drug prices could be voluntarily frozen.

The ability to set value-based prices has been a hallmark of the US prescription drug market. A comprehensive assessment and understanding of the risks associated with potential pricing reforms will help to shape decisive planning around the issues and suggestions discussed in this bulletin. As recommended, coordinated, proactive strategies will be necessary to ensure the best possible outcome for all pharmaceutical manufacturers. After all, the stakes in the US market are high, and this is one area in which the industry cannot afford a significant setback.

PriceSpective is an international firm of pricing strategy experts focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. Our team has specific expertise on a wide range of policy matters and detailed knowledge of the US environment and markets worldwide. If your firm has questions/comments regarding this bulletin or would like to simply leverage our focused capabilities to address a pressing business need, feel free to contact us.

In the US:

Steve Slovick, PriceSpective LLC, U.S.A.
+1 310 869 1440
sslovick@pricespective.com

Ted Sweeney, PriceSpective LLC, U.S.A.
+1 917 446 2473
tsweeney@pricespective.com

Nigel Gregson, PriceSpective LLC, U.S.A.,
+1 610 828 6780
ngregson@pricespective.com

In Europe:

Keiron Sparrowhawk, PriceSpective Ltd, U.K.
+44 1763 273949
ksparrowhawk@pricespective.com

Corporate Homepage:

www.pricespective.com