Insight

President's Request to Give HHS Secretary Authority to Negotiate is Non-negotiable

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Included in the President's fiscal year (FY) 2016 budget proposal are a myriad of provisions to reform the Medicare program, many of which impact the cost and availability of drugs under both Medicare Part B (outpatient services) and Part D (prescription drug coverage). Some of these changes include: implementing Medicaid-style rebates in Part D, increasing premiums for Parts B and D, reducing the period of exclusivity for biologics, increasing the manufacturer discounts for brand name drugs in order to speed up the closure of the Part D coverage gap by three years, and changing the formula for reimbursement of biological products and biosimilars under Part B. Individually, some of these proposals could potentially be agreeable, or at least provide a fair starting point for negotiations. However, when coupled together, the negative impact on beneficiaries, drug manufacturers, and plan sponsors is exacerbated to a point of potential disaster for the Part D drug benefit program, which has been the most successful part of the Medicare program.

Some of the provisions are simply non-starters for the Republican Congress. One such provision is the president's proposal to give the Secretary of Health and Human Services (HHS) authority to negotiate prices with manufacturers of biologics and other high-cost specialty drugs under Medicare Part D. The proposal would require drug manufacturers to participate in such negotiations, or forfeit participation in the Part D drug program entirely, and "to supply HHS with all data and information necessary to come to an agreement on price."

When the Part D drug benefit was created through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress explicitly prohibited the Centers for Medicare and Medicaid Services (CMS) from interfering in the negotiations of drug prices between manufacturers, plan sponsors, and pharmacies. Instead, Congress believed the private insurance companies that chose to offer Part D plans would have enough incentive themselves to negotiate for low drug prices. The competitive structure of Part D would force plan sponsors to find ways to offer low-cost, high-quality plans in order to achieve high enrollment among beneficiaries. And in fact, that is exactly what has happened. As of 2012, the cost of Part D was only 45 percent of the original projections[1], and plan beneficiaries give the program a 92 percent satisfaction rating[2].

Despite Part D's success, this administration has repeatedly sought to undermine the program. Twice in 2014, the Obama Administration proposed similar rules relating to Part D, both of which would have overstepped executive authority. Therefore, it is interesting that the president is now recognizing the need for Congressional authority to allow the Secretary to get involved in negotiations, despite having not sought approval for either proposal made last year.

The president's newest proposal aims to address concerns about the rising cost of some specialty and biologic drugs. Notably, while some drugs may be getting more expensive, the average stand-alone Part D plan premium has not increased since 2010[3]. Meanwhile, the expense of bringing *average* drugs to market has reached more than $2 billion and takes about 14 years[4]. The cost of developing biologics and other specialty drugs is even higher.

The president's proposal threatens to undermine the leverage that plan sponsors currently have, and undo the positive results that the program has experienced thus far. Given the strength of the negotiating power of the federal government—the largest health insurer in the country, forcing drug manufacturers to negotiate directly with HHS would be equivalent to setting price controls. The result will either be to limit seniors' access to revolutionary and potentially life-saving drugs should manufacturers decide they cannot agree to HHS' price demands, and/or to severely undermine the ability of plan sponsors to negotiate lower prices for other drugs. When plans' expected costs go up, plan bids will increase for the next program year. This would mean increased costs for both seniors and the federal government, which pays 74.5 percent of the program's average premium cost.

Even if drug manufacturers were forced into negotiations with HHS, the lower prices that manufacturers would be forced to accept, combined with the new reporting requirements that will increase costs, may well stifle innovation and the discovery of new drugs by limiting revenue available to be reinvested in research and development. At a time when medical research could be on the brink of potentially major breakthroughs- as the president acknowledged with the "Precision Medicine Initiative"- price negotiation with HHS could be particularly problematic.

Finally, the budgetary impact of this proposal is estimated to be less than $500 million over 10 years. It begs the question, is the government really concerned about controlling costs, or controlling the market?

[1] http://americanactionforum.org/research/competition-and-the-medicare-part-d-program