## **EDITORIAL AND COMMENT**

## Medicare Part D Prescription Drug Program: Benefits, Unintended Consequences and Impact on Health Disparities

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he Medicare Part D prescription drug program, administered by the Centers for Medicare and Medicaid Services, took effect on January 1, 2006 and covered all 43 million Medicare beneficiaries who were enrolled at that time, making it the largest policy change to Medicare since the inception of the program. Dual Medicare/Medicaid eligible individuals were switched from Medicaid to privately owned Part D drug plans when Part D began. Dual eligible individuals receive low income subsidies under Part D that cover deductibles and premiums and some cost-sharing from the government. According to the latest information from the Center for Medicare and Medicaid Services, no Medicare drug plan can have a deductible exceeding \$320. Once total (patient and Medicare) expenditures reach \$2,930, the individual enters the coverage gap ("donut hole") and remains in the coverage gap until total expenditures reach \$4,700. While in the gap, patients pay 50 % of brand-name covered drugs and 85 % of generic covered drugs. After exiting the gap, the individual is entitled to catastrophic coverage, paying only a small coinsurance or copayment for additional medications. Plans under part D include both Medicare Advantage and traditional plans. Medicare Advantage plans cover drugs and other medical care expenses. Part D was compulsory only for dual eligible individuals on January 1, 2006. Beneficiaries were permitted to switch plans on a monthly basis if not satisfied with their existing plan.

Medicare Part D has been shown to be associated with higher medication utilization, lower out-of-pocket costs for beneficiaries, lower cost-related medication non-adherence and lower non-persistence. Medicare Part D also appears to have paid for itself, with groups of beneficiaries that had no or minimal drug coverage before Part D implementation experiencing cost reductions in non-prescription medical services that approximately offset the increased pharmaceutical costs. However, few studies have assessed the

unintended consequences of Medicare Part D in low income and ethnic minority populations, especially during their time in the "donut hole". This is particularly important for chronic diseases like diabetes, a condition that is highly prevalent in low income and ethnic minority populations, and for which generic medications may not be available.

In this issue of the journal, Sacks et al.<sup>2</sup> examine the effects of cost sharing in the Medicare Part D standard (non-low income supplement) benefit on adherence to different oral anti-diabetic classes of medications. They find that non-low income supplement beneficiaries have higher odds of adherence to brand medications.<sup>2</sup> They also find that 82 % of all beneficiaries use oral anti-diabetics in primarily generic classes.<sup>2</sup> Among the generic oral anti-diabetic medications, they find small or no significant difference in adherence odds by low-income supplement status, though they do find that crude adherence rates are sub-optimal when cost-related non-adherence is not a factor.<sup>2</sup> They conclude that the Affordable Care Act policy of 2010 to close the Medicare gap by 2020<sup>1</sup> will not affect generic oral anti-diabetic medication adherence but should reduce costrelated non-adherence in branded oral anti-diabetic medications.<sup>2</sup> However, they also express concern that prior to gap closure, co-payments on the branded oral anti-diabetic medications may continue to lead to cost-related non-adherence.<sup>2</sup> The authors recommend modifications to the Part D benefit structure to remove cost-related adherence deterrents, as well as initiatives to address non-cost factors in adherence to the less expensive generic oral anti-diabetic medications.<sup>2</sup>

The study provides evidence that adherence to generic diabetes medications do not differ by low-income supplement status; however, it does not address what happens to low income patients who have to use branded medications as part of their treatment regimen. Given the strong association between poverty and race/ethnicity, it is important to understand the unintended consequences of the coverage gap in low income and minority populations with chronic diseases like diabetes. Prior studies have shown that after Part D implementation the share of seniors who lacked prescription coverage declined substantially and those who enrolled in Part D appeared better able to afford their medications with significantly higher use rates, lower out of

pocket costs, and reduced cost-related medication nonadherence.<sup>3</sup> However, evidence also showed that Medicare families with incomes up to 250 % of the federal poverty level were at elevated risk for incurring burdensome health care expenditures compared to wealthier families, especially those families that were ineligible for Part D low income supplement assistance.4 Other studies have determined that while total out of pocket expenditures and probability of having unmet drug needs have declined in ethnic minorities, the same groups have experienced greater difficulties in obtaining reliable information about coverage and obtaining needed Part D contracts compared to whites.<sup>5</sup> Thus, it appears that there have been some unintended consequences of the Part D coverage gap among individuals with chronic diseases like diabetes that need to be addressed. These include high rates of cost related non-adherence, especially among those with lower incomes, and higher out-of-pocket expenditures.<sup>6</sup> However, having generic-only coverage during the gap appears to be somewhat beneficial compared with having no coverage in the gap.<sup>7</sup>

The Affordable Care Act that was passed in 2010 has promise in terms of filling the coverage gap. However, beneficiaries will still be exposed to varying levels of out of pocket costs often not known until the prescriptions are filled. In addition, there are other potential problems that may not be solved by the Affordable Care Act, such as plans raising their premiums to avoid low-income beneficiaries, difficulty obtaining reliable information about available options and true cost of different plans, and challenges with navigating the maze of plan selection for low income and ethnic minority populations. For example, one study showed that between 2006 and 2009, 1.6 million beneficiaries were reassigned due to the decline in plans qualifying for low-income subsidy assignment.<sup>8</sup> The same study found that a fifth of beneficiaries spent at least \$500 more than they needed to on medications due to lack of knowledge about lowest cost plans.8 Hopefully, the inclusion of actual Part D data in risk adjustment models for payment in 2011 by Medicare will provide greater incentive for drug plans to compete for low-income enrollees.

In addition to the obvious benefits of the Affordable Care Plan, other potential interventions need to be considered for low-income beneficiaries. A reasonable approach is to provide patients detailed information about out of pocket costs for different medications and to encourage providers to prescribe generics when possible. Another approach is for the Center For Medicare and Medicaid Services to "drill down public reporting" of contract level scores by race/ethnicity as mandated by the Medicare Improvements for Patients and Providers act of 2008<sup>5</sup> and alert contracts with large disparities on their need to improve. A third strategy is for the Center for Medicare and Medicaid Services to routinely provide beneficiaries information on the three best (lowest cost, optimal benefit) plans. One study estimated

that both beneficiary and overall Medicare Part D program costs would be decreased if this approach was adopted. Finally, some have suggested that the Center for Medicare and Medicaid Services should adopt the formulary model that is used in the Department of Veterans Affairs. It is estimated that adoption of this approach would provide cost savings to the Medicare Part D program of about \$510 per non-low income supplement enrollee per year for total estimated savings of approximately \$14 billion per year.

In summary, we agree with Sacks et al.<sup>2</sup> that Medicare Part D has reduced health expenditures among beneficiaries and improved access to drugs for some Medicare beneficiaries via greater adoption of generic drugs. Recent improvements should help low-income beneficiaries even more. However, some of the unintended consequences of the current structure of Part D coverage need to be addressed in order to improve access to medications for beneficiaries with chronic diseases such as diabetes, especially those in lower income brackets and ethnic minorities. While the Affordable Care Act will provide further improvements, there are still potential challenges that will need to be addressed.

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