



Perspective

Time to Fill the Doughnuts — Health Care Reform and Medicare Part D

William H. Shrank, M.D., M.S.H.S., and Niteesh K. Choudhry, M.D., Ph.D.

The passage of the Affordable Care Act (ACA) in March 2010 promised to put an end to the “doughnut hole,” the gap in prescription-drug coverage that is the most controversial component of

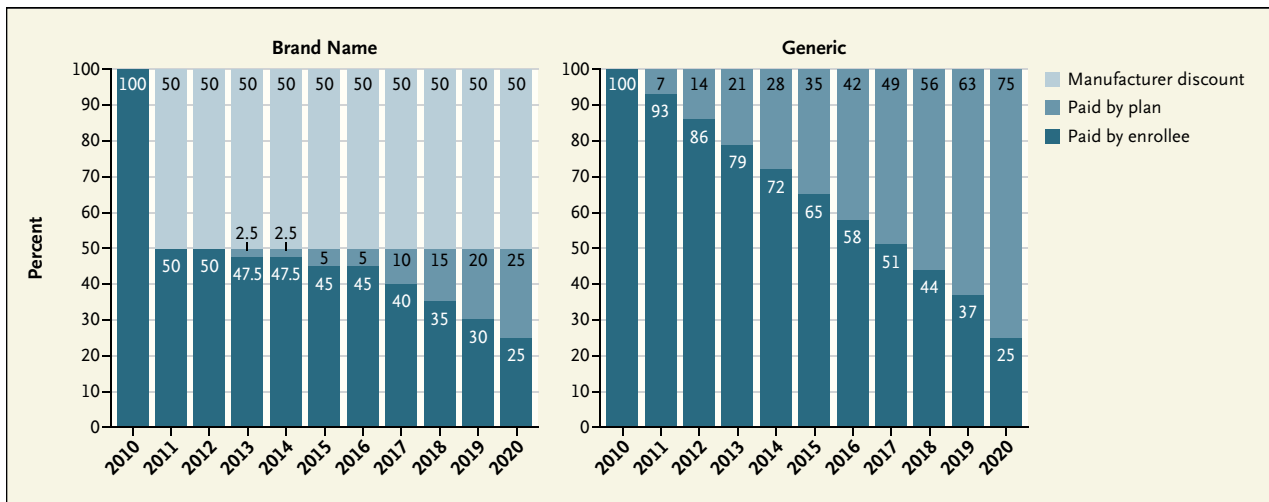
the Medicare Part D benefit.¹ Several months ago, seniors who had reached the spending threshold that marked the beginning of their doughnut hole began to receive their \$250 rebate checks. Incrementally between now and 2020, the coverage gap will be filled with subsidies from manufacturers of brand-name drugs and from the federal government. Thus, the ACA, like Part D itself, has expanded coverage for prescription medications — but it has done so in a complex manner that owes more to political wrangling than to any straightforward effort to promote health and cost-effective medication use. The plan for fill-

ing in the doughnut hole will most likely confuse many beneficiaries and, at least temporarily, work against cost consciousness, and providers and payers will need to assist patients in navigating the benefit and identifying affordable medications in the years leading up to 2020.

Medicare Part D was the largest expansion of Medicare benefits since the program’s inception and is widely considered to be successful. With the standard Part D benefit, patients are responsible for all their medication costs up to the dollar amount of an initial deductible. Having paid the deductible, they become responsible for only 25% of addi-

tional medication costs up to a preset spending limit. Then they enter a coverage gap, or doughnut hole, in which they must again pay the entire cost of their medications. Once their drug spending has passed the upper end of the doughnut hole, patients receive catastrophic coverage that pays for 95% of any further medication costs. Although few plans strictly follow the outlines of the defined benefit, the majority offer little or no gap coverage.

The implementation of Part D has meaningfully increased drug utilization overall, improved adherence to essential medications for chronic conditions, and reduced patients’ out-of-pocket costs.² Early reports evaluating the effect of Part D on health outcomes have also been encouraging.³ However, the inconsistent coverage patterns have proved



Affordable Care Act Provisions for Manufacturer and Federal Subsidies of Brand-Name and Generic Medications in Medicare Part D, 2011–2020.

Adapted with permission from the Kaiser Family Foundation.⁵

confusing to most seniors.⁴ Beyond introducing complexity, the presence of the doughnut hole has led seniors to stop taking essential medications. Studies indicate that patients reduce their use of medications once they reach the gap, and the resulting drug-use patterns resemble those seen among uninsured seniors before the implementation of Part D.²

In recognition of these limitations, the ACA will eliminate the doughnut hole incrementally by 2020 (see graphs).^{4,5} Under health care reform, enrollees who had reached their annual coverage gap in 2010 were mailed checks for \$250. In 2011, patients in the doughnut hole will receive 50% discounts on brand-name drugs from manufacturers and 7% discounts on generic medications from the federal government. These discounts on generics will increase by 7% per year until 2019, and an additional 12% discount will bring coverage of generics up to 75% in 2020. The federal government will also begin subsidizing the purchase of brand-name medi-

cations — paying 2.5% of the cost of these drugs in 2013 and gradually increasing the amount to 25% by 2020. In addition, between 2014 and 2019, the initial coverage limit (i.e., the point at which patients enter the coverage gap) will gradually be raised to meet the coverage-gap threshold, and in 2020, it will revert to levels that were previously specified in the Medicare Modernization Act. By that year, the prescription-drug benefit will be generous: after the deductible phase, enrollees will receive 75% coverage of all prescription drugs until they reach the catastrophic-coverage threshold, when they will begin receiving 95% coverage.

At a time of constrained resources, we believe that the goal of coverage expansion must be to promote the use of the most cost-effective therapies — those that offer the greatest value per dollar spent, while limiting waste. Yet lawmakers must take advantage of a political window when they have one. Lawmakers designed the benefit expansion in partnership with pharmaceutical manufacturers to improve the

likelihood that the legislation would pass. Though there is no question that this expansion will promote greater use of prescription drugs, its design limits its ability to fully achieve its goals.

The \$250 check that seniors received this year can only be considered a political gesture. Whereas there is a rich evidence base demonstrating how small differences in copayments influence medication purchasing, there is little evidence to suggest that small subsidies or one-time checks will have any effect on prescription-drug utilization. In these tough economic times, it is unlikely that seniors will apply their rebate checks to purchases of prescription medications.

More important, discounting brand-name drugs by 50% at the outset while delaying the reduction of generic-drug prices was a step in the wrong direction. One potential silver lining of the coverage gap is that exposure to out-of-pocket costs may encourage seniors to consider the cost of their medications and to seek more cost-effective options. Doing so can reduce both their out-

of-pocket spending and federal spending on prescription medications once they emerge from the doughnut hole. By disproportionately reducing the cost of brand-name medications, the legislation creates incentives for patients to use more expensive drugs and will leave the federal government on the hook for increased medication costs during the catastrophic-coverage period. These increased costs may ultimately be passed on to patients as increased Part D premiums. Moreover, given the arbitrary pricing of brand-name prescription drugs and the absence of a mechanism whereby Medicare can regulate them, there are no safeguards to ensure that manufacturers will not raise prices to mitigate their losses.

In addition to posing such cost problems, the 10-year plan for eliminating the doughnut hole increases the complexity of a benefit design that already confuses many seniors. The incremental and imbalanced approach to medication subsidies will further limit seniors' ability to anticipate and objectively consider the cost burden of potential therapeutic options.

The perfect, however, must not be the enemy of the good. The new benefit does represent a route to a coverage system that could well enhance the health of se-

niors. Over the next 10 years, physicians, nurses, pharmacists, and payers must play a role in helping patients to understand their options and in promoting appropriate medication use.

First, providers and patients should be aware that the coverage gap still exists and that, consequently, patients will continue to be exposed to varying levels of cost sharing when they reach it. In many cases, these out-of-pocket costs cannot be anticipated before patients actually try to purchase their medications. Providers should therefore routinely ask patients about the costs of their medications and whether those costs may impair their adherence to therapy.

During the coverage gap, generic medications will continue to offer greater value than brand-name medications for most patients, since the generous subsidies that begin in 2011 will generally amount to far less than existing price differences between brand-name and generic medications. Encouraging cost-effective medication use, regardless of the level of subsidies applied, will reduce seniors' overall out-of-pocket costs as well as federal outlays for prescription medications, allowing health care resources to be used more efficiently.

Medicare and participating

Part D prescription-drug plans must also play an active role in educating patients about benefit changes and the prices of the therapeutic options available to them. With annual alterations in the coverage design and out-of-pocket costs for medications, efforts to assist seniors are needed to ensure that they maintain confidence in the benefit and that they can be objective consumers of their own health care.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston.

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