

# Understanding the Medicare Donut Hole

How generic drug alternatives are no bargain for many patients during the mandated lapse in coverage.

BY JOHN A. HOVANESIAN, MD

The Patient Protection and Affordable Care Act of 2010 will eventually eliminate the Medicare “donut hole” in 2020, but until this gap in benefits is closed for good, it will continue to affect patients. The prospect of falling into a coverage lapse is a daunting reality for patients, especially in the current economic climate. In the interest of offering premium care to patients, it is important that cataract surgeons know and understand the ramifications of the donut hole, especially because many of their patients may not.

For the purpose of this article, the donut hole is defined as a gap in coverage where enrollees in Medicare Part D must pay out of pocket for all drug costs. This pause in coverage begins after the patient reaches a predefined expenditure for total retail drug costs in a calendar year. While in the donut hole, patients pay for all of their medications until they reach a predetermined total amount of out-of-pocket expenses. Once that total is reached, catastrophic coverage begins, and Medicare covers most of the patient’s prescription drug-related expenses (the portion not covered is coinsurance and copayment costs and any dispensing fees). For further information on the donut hole and other aspects of Medicare coverage, physicians should consult the Centers for Medicare & Medicaid Services’ Web site ([www.cms.gov](http://www.cms.gov)).

## DONUT HOLE PHASE OUT

For the 2012 calendar year, patients will enter the donut hole (lapse in coverage) once their total Medicare Part D expenditures total \$2,930. Once in the donut hole, patients will have to spend a total of \$2,600 out of pocket before their catastrophic coverage kicks in. The prescription drug expenditures of a given patient are calculated as the negotiated retail cost of that patient’s medications. The patient’s contributions (the initial \$320 deductible and the patient’s copayment of 25% of drug cost) are counted toward these expenditures, but plan premiums are not.

What this means is that the true out-of-pocket cost to

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a patient in 2012 will be \$972.50 before he or she reaches the donut hole; the patient’s plan will pick up the tab for the remaining \$1,957.50. In terms of total dollars, all patients reaching the donut hole will have spent the same amount, but how quickly patients reach the hole will invariably differ. It is important to note that different Part D plans may negotiate varying retail drug costs, so one patient may reach the donut hole faster than a second patient taking the same medications if that second patient has a different Part D coverage plan.

All told, for a patient to climb out of the donut hole requires \$4,700 of total out-of-pocket expenditures, which includes all dollars spent before falling into the coverage lapse, as well as all dollars spent in the hole. Lawmakers have instituted a number of steps to eventually close the donut hole. For instance, in 2010, Medicare Part D beneficiaries who entered the donut hole received a \$250 subsidy. Starting in 2013 and running through 2020, an escalating government subsidy coupled with a discount on brand-name drugs will mitigate out-of-pocket payments for Medicare Part D enrollees (Table). Although these steps will ultimately be beneficial, it will be another decade until the donut hole is done away with for good.

## IMPLICATIONS OF THE DONUT HOLE

Until the donut hole is eliminated, how physicians help their patients covered by Medicare Part D

plans manage their expenditures will be important. Obviously, patients want to save money, but once they fall into the coverage lapse, they will want to spend their way out of it as quickly as possible. The simple answer to how to help patients reduce their prescription drug costs appears to be generic equivalents, but this strategy might not be as simple as it appears.

On a deeper examination, the benefit a patient receives from lower-priced generic medications may not be as great as one thinks. Under the current rules, any money spent by a patient on generic medications is counted toward his or her total expenditures before catastrophic coverage begins. In contrast, the entire retail cost of a branded drug is counted toward this same amount. In real dollars, this means that patients get credit for the full price of a brand name—but only the discounted portion paid for generic medications. Given that they are already cheaper, use of generic medications may lead to patients' having a more difficult time spending their way out of the donut hole.

The Department of Health and Human Services and several pharmaceutical companies negotiated a 50% discount for brand-name drugs for Medicare beneficiaries.<sup>1</sup> In 2012, beneficiaries will receive a 14% discount on generic medications, meaning they are responsible for 86% of the cost. A patient may realize lower out-of-pocket costs with generics under this scenario, but how those dollars are counted toward the donut hole may negate the difference.

A hypothetical example may demonstrate this concept: brand Drug X has a negotiated retail price under a given Medicare Part D plan of \$200, and its generic equivalent Drug Y costs \$100. In 2012, a patient will

pay \$100 for brand Drug X and \$86 for generic Drug Y. Although the patient will pay \$14 more for Drug X if he or she opts for the brand-name agent, \$200 will be credited toward that patient's total out-of-pocket expenditures before catastrophic coverage. If this same patient chooses generic Drug Y, however, only \$86 will be credited.

Interestingly, generic medications cost about 30% to 50% less than their branded equivalents, so this example is particularly generous to generic medicines.

### GENERIC SUBSTITUTIONS

In an ideal world, cataract surgeons would be making decisions about care based solely on the safety and efficacy of the drug they want their patients to use. The new reality, however, is that cost is a consideration. Yet, cataract surgeons will continue to be judged on their outcomes: a patient may save \$5 per month by using a generic medication, but if there is a complication, he or she is likely to blame the surgeon instead of the drug.

As a result, the prospect of generic substitutions engenders a discussion about the suitability of non-branded medications for patients after cataract surgery. Generic medications have their place in the aftercare of patients, but cataract surgeons would be wise to be cautious regarding their (ie, anti-inflammatory drops and steroids) long-term use. There is ample anecdotal evidence to suggest a different safety profile for generic medications, most likely due to differing incipient ingredients. This safety concern is greatest with nonsteroidal anti-inflammatory drugs, where generic substitutes have historically and recently been reported to cause persistent corneal epithelial defects and corneal melts.

**TABLE. COMPARISON OF PATIENTS' OUT-OF-POCKET RESPONSIBILITIES FOR BRAND-NAME AND GENERIC DRUGS WHILE IN THE MEDICARE DONUT HOLE**

Year	Brand			Generic	
	Negotiated Discount on Price	Subsidy to Beneficiaries	Beneficiary's Responsibility	Subsidy to Beneficiaries	Beneficiary's Responsibility
2012	-50%	0	50%	14%	86%
2013	-50%	2.5%	47.5%	21%	79%
2014	-50%	2.5%	47.5%	28%	72%
2015	-50%	5%	45%	35%	65%
2016	-50%	5%	45%	42%	58%
2017	-50%	10%	40%	49%	51%
2018	-50%	15%	35%	56%	44%
2019	-50%	20%	30%	63%	37%
2020	-50%	25%	25%	75%	25%

There is another danger in generic substitutions. Some states, like California, have laws dictating that pharmacies inform a physician before making a generic substitution. In other states, however, pharmacies are free to make that decision without informing the physician, and often to their own benefit. Pharmacists are heavily incentivized to make generic switches, because their pharmacies become more profitable if they do.<sup>2</sup>

The great danger is that a pharmacist making a switch may be well intentioned, but not well informed. This can sometimes result in an out-of-class switch, for example offering generic ketorolac instead of bromfenac sodium ophthalmic solution 0.09% (Bromday; Ista Pharmaceuticals).

### COMMUNICATING WITH PATIENTS

My practice is focused on delivering premium cataract care. I know I will be judged on results, so it is important to me that patients receive the medications I prescribe. This desire is communicated to the patient, and he or she is reminded that cataract surgery is a once-in-a-lifetime event. I do not want the patient to pay an excessive amount, so if costs are going to be more than \$200, I will work with the patient and offer samples when appropriate.

My practice also works closely with our local pharmacy. Our practice has two offices, and we partner with a pharmacy close to each office with the understanding that if they keep costs to patients reasonable, we will continue to recommend them to future patients. We also ask that they dispense two bottles of drops per patients' copayments, as is requested on the written prescription. One prescription for one drug should equal one copayment, even if two bottles are required to distribute that drug to two eyes.

The good news is that reforms will eventually eliminate the donut hole, which will certainly benefit patients. During the next decade, until these reforms take full effect, cataract surgeons can help their patients navigate through the confusing ramifications of the donut hole. ■

*John A. Hovanesian, MD, is in private practice at Harvard Eye Associates in Laguna Beach, California, and is a clinical instructor at the UCLA Jules Stein Institute. He is a consultant to and is on the scientific advisory boards of Abbott Medical Optics Inc. and Bausch + Lomb. Dr. Hovanesian may be reached at (949) 951-2020; drhovanesian@harvardeye.com.*



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