Medicare Update: Into the Doughnut Hole

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The so-called “doughnut hole” in Medicare’s Part D prescription drug benefit is a difficult concept for many people to understand. The term raises such questions as these: What are the exact out-of-pocket requirements? When and where does this doughnut hole begin and end?

If you think you had the answer, it just changed for the new benefit year 2007 (Tables 1 and 2). Because the out-of-pocket expenses are adjusted annually according to an inflation factor, these expenses increase for each phase of the Part D benefit.

Given the heightened focus from the Democratic Party’s new leadership to “fill in” the doughnut hole, it is also likely that more changes lie ahead. These changes will probably take the course of one of three approaches:

• In the middle of the political spectrum—and most likely to be passed—is a plan whereby the Secretary of the Department of Health and Human Services (DHHS) would negotiate prices as a ceiling. These prices would be passed on to the prescription plans. Of course, the question remains: What will these prices be based on?

• At one end of the spectrum is a plan to simply remove the “non-interference” clause. This clause currently specifies that the DHHS Secretary may not interfere in negotiations between drug manufacturers, pharmacies, and prescription-drug plan sponsors; may not require a particular formulary; and may not institute a price structure for Part D drugs. Simply removing this requirement with the current Secretary is unlikely to result in any changes.

• At the other end of the spectrum is a plan whereby the federal government would create a national formulary.

Of course, health care providers can take actions to help reduce the impact of the doughnut hole. The first step in providing coverage is to ensure that Medicare beneficiaries don’t enter this gap in coverage unless they truly cannot avoid doing so. Patients may be able to avoid the doughnut hole if the most effective medications—as well as the most efficient ones—are prescribed. The most effective drugs deliver the best results with the fewest side effects. The most efficient drugs are similar enough in their pharmacokinetics but are available at a lower cost (including generic and available combination medications).

All prescription plans are required to offer Medication Therapy Management (MTM) services. Although MTM is aimed at optimizing therapy, including the efficient and effective use of medications, this service, unfortunately, is limited to the following Medicare beneficiaries:

• those who are taking multiple medications.
• those who have multiple chronic diseases.
• those who are likely to incur expenditures of more than $4,000 per year in medication costs. (This sum of $4,000 remains the same for 2007.)

Even though Medicare beneficiaries entering the doughnut hole, by definition, will have met at least one of these require-

### Table 1 Medicare Part D Beneficiary Coverage for 2006

<table>
<thead>
<tr>
<th>Beneficiary Percentage</th>
<th>Total Prescriptions Received (Range)</th>
<th>Out-of-Pocket Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual deductible</td>
<td>100%</td>
<td>$0–$250</td>
</tr>
<tr>
<td>Initial benefit</td>
<td>25%</td>
<td>$251–$2,250</td>
</tr>
<tr>
<td>Coverage gap</td>
<td>100%</td>
<td>$2,251–$5,100</td>
</tr>
<tr>
<td>Catastrophic coverage</td>
<td>5%</td>
<td>&gt; $5,100</td>
</tr>
</tbody>
</table>

Medicare beneficiary out-of-pocket expenses needed to reach catastrophic coverage in 2006 = $3,600.

### Table 2 Medicare Part D Beneficiary Coverage for 2007

<table>
<thead>
<tr>
<th>Beneficiary Percentage</th>
<th>Total Prescriptions Received (Range)</th>
<th>Out-of-Pocket Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual deductible</td>
<td>100%</td>
<td>$0–$265</td>
</tr>
<tr>
<td>Initial benefit</td>
<td>25%</td>
<td>$266–$2,400</td>
</tr>
<tr>
<td>Coverage gap</td>
<td>100%</td>
<td>$2,401–$5,451.25</td>
</tr>
<tr>
<td>Catastrophic coverage</td>
<td>5%</td>
<td>&gt; $5,451</td>
</tr>
</tbody>
</table>

Medicare beneficiary out-of-pocket expenses needed to reach catastrophic coverage in 2007 = $3,850.

Dr. Stefanacci is the founding executive director of the Health Policy Institute at the University of the Sciences in Philadelphia.
ments, many of them might not meet all three requirements. In addition, MTM programs are directed by each prescription drug plan, so the process varies by program.

Because prescription plans are not affected financially by Medicare beneficiaries within the doughnut hole, many plans may not find it worthwhile to aggressively manage the expenditures of these members. As a result, this responsibility is likely to fall upon other providers, such as physicians and pharmacists, although consultant pharmacists are best suited for this task.

One of the most overlooked opportunities for patients to delay entry into the doughnut hole is to take advantage of the low-income subsidy. For Medicare beneficiaries with limited income and resources, a significant subsidy of their premiums and out-of-pocket expenses is available. Instead of the major gap that exists for most Medicare beneficiaries, low-income individuals pay only a $50 deductible instead of $250 and a 15% copayment instead of the 100% copayment if they have fallen into the doughnut hole.

Even with this significant benefit, a large number of Medicare beneficiaries have not taken advantage of the subsidy. Social workers and others may be able to identify eligible individuals and assist them through the enrollment process. Enrollment is provided through either Social Security or Medicaid programs.

Pharmaceutical assistance programs can provide extra help in paying for medications; however, many of these programs have stopped providing coverage because of concerns about fraud and abuse raised by the DHHS’s Office of the Inspector General (OIG). These concerns stem from the possibility that branded products could be promoted over the use of less expensive generic medications, which could save Medicare resources.

In November 2006, AstraZeneca announced a new program that may offer convenient savings for Medicare Part D enrollees. Medicare patients who qualify and enroll will be able to go to their participating local pharmacy and receive savings on AstraZeneca products immediately. Enrollees in the current AstraZeneca program pay no more than $25 for a typical 30-day supply of covered medications that are available through Medicare Part D. A typical 60-day retail supply costs no more than $37.50, and a typical 90-day retail supply costs no more than $50. Patients can sign up for the program by calling AstraZeneca’s hotline (1-800-957-6285) or by visiting its Web site (www.azmedicineandme.com).

Qualifications for participating in the AstraZeneca program are as follows:

• Patients must be enrolled in Medicare Part D.
• An individual’s annual income must be at or below $30,000, and a couple’s annual income must be at or below $40,000.
• Patients must be taking AstraZeneca drugs.
• Patients must spend at least 3% of their annual household income on prescription drugs during the calendar year. (An income of $50,000 would mean medication expenses of $1,500.)

The DHHS’s OIG has issued a favorable advisory opinion concerning AstraZeneca’s program and affirms that the company’s extension of coverage to Medicare Part D beneficiaries is consistent with OIG guidelines. Other pharmaceutical companies may extend similar coverage to “at-need” Medicare beneficiaries.

In the end, the doughnut hole is a dangerous place to be for patients, providers, and pharmaceutical companies. It is possible to avoid falling into it with the help of astute clinical and health policy expertise, something that has been limited until now in the debate and management of Medicare Part D.