
Managing the Donut Hole

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While an estimated 4 million Medicare beneficiaries fell into the donut hole last year, more are likely to be affected this year unless their physicians act now. The donut hole represents a gap in coverage that leaves beneficiaries 100% responsible for the cost of their medications under the minimum-benefit design. This gap, which for 2006 was between \$2250 and \$5100, is actually larger for 2007. While last year the gap was \$2850, this year the amount is increased to just over \$3000. In addition, since innovative new oral medications for the treatment of osteoporosis, Parkinson's disease, and some cancers are increasingly available—but not covered—more Medicare beneficiaries will be affected.

Of course not all Medicare beneficiaries are affected by the donut hole. The dually eligible—those having Medicare and Medicaid—are fortunate enough to have complete coverage with nearly zero out-of-pocket expenditures, meaning they never pay more than small co-payments of \$1.00 to \$3.15 for their medications covered by Medicare Part D. Those who are dually eligible in long-term-care (LTC) facilities pay nothing for Part D-covered medications. But the non-dually eligible will be teetering on the edge of the donut hole.

Medication Adherence Inside the Donut Hole

Given the difficulty in maintaining patient adherence to medication regimens when patients are solely responsible for the cost of their medications, physicians must work harder to keep patients out of the donut hole and protected from preventable health-related problems. The Kaiser Family Foundation demonstrated that pa-

tient adherence to treatment falls significantly when out-of-pocket expenditures rise.¹

When residents of LTC facilities have inadequate resources to pay for medications, the facilities become responsible for ensuring availability of medications despite a resident's inability to pay. Facilities, most of which cannot handle these extra expenses, then struggle under these additional monetary burdens. So how can the donut hole be filled so that neither the Medicare beneficiary nor the LTC facility has to bear these expenses?

Choosing the Right Medications

The first step in providing coverage inside the donut hole is making sure that patients don't enter this gap in coverage unless they truly cannot avoid it. Ensuring that patients are prescribed the most effective and most efficient medications is one way to avoid the gap. *Most effective* refers to those medications that deliver the highest re-

sults with the least side effects, while *most efficient* refers to those medications that are lower in cost but most pharmacokinetically similar to the first-choice drug. These medications may include generic or combination drugs.

All prescription plans are required to offer Medication Therapy Management Services (MTMS), a program aimed at optimizing medication therapy, including efficient and effective use of medications. Unfortunately, MTMS is limited to those Medicare beneficiaries who are taking multiple medications, suffering from multiple chronic diseases, and likely to incur annual medication expenditures of more than \$4000. In the year 2007, the cutoff point of \$4000 remains the same.

By definition, Medicare beneficiaries who enter the donut hole will have met at least one of these requirements, but it is possible that many do not meet all three requirements. Because MTMS programs are directed by each prescription drug plan, each process varies. Since prescription plans are not financially affected by Medicare beneficiaries within the donut hole, many plans may not see the benefits of aggressively managing the expenditures of their members. As a result, this management responsibility is likely to fall on other providers, even though consultant pharmacists are best suited for the task.

Choosing the Right Plan

Once a patient's medication profile is optimized, there are still oth-

er options to help beneficiaries gain the most coverage. The first step is for beneficiaries to enroll in the “best” plan. A relatively short 6-week annual enrollment period runs from November 15th to December 31st. Residents of LTC facilities and those who are dually eligible do not have to wait until November 15th to enroll in a new prescription plan or wait until January 1st for that plan to become effective; instead those who have access to the Special Enrollment Period (SEP) can change plans as needed. The SEP can be used for moving to a plan that provides greater access to needed medications instead of paying greater out-of-pocket copayments or undergoing an appeals and exceptions process. Being in the optimum plan is critically important.²

Patient Assistance Programs Can Help

One of the most overlooked opportunities for delaying entry into the donut hole is taking advantage of the low-income subsidy. For Medicare beneficiaries with limited income and resources, a significant subsidy of both premiums and out-of-pocket expenses is available. Instead of falling into the major gap that exists for most Medicare beneficiaries, these individuals pay a \$50 deductible charge instead of \$250, and a 15% copayment instead of the 100% charged within the donut hole. Despite this significant benefit, many Medicare beneficiaries have failed to take advantage. It is as important for social workers and other healthcare providers to help identify eligible low-income subsidy individuals as to assist them through the enroll-

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ment process, since such assistance is already provided by either the Social Security or Medicaid programs.

Pharmaceutical patient assistance programs (PAPs) can also provide extra help in paying for medications. However, many of these programs have stopped providing coverage because of fear of landing in hot water with the Office of Inspector General (OIG). AstraZeneca announced in November 2006 a new PAP that is said to offer significant and convenient savings for Medicare Part D enrollees. Medicare patients who qualify and enroll are now able to go to their participating local pharmacies and immediately receive savings on AstraZeneca products. This unique program provides savings on AstraZeneca medications at the pharmacy counter. Under the AZ Medicine & Me™ program, enrollees pay no more than \$25 for a typical 30-day supply of covered medicines 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. Qualified patients are those who are enrolled in Medicare Part D, have incomes below \$30,000 (individual) or \$40,000 (couple), are taking AstraZeneca drugs, and spend more than 3% of annual household income on prescription drugs. Patients can sign up by calling the AZ Medicine & Me hotline at (1-800-957-6285) or visiting www.azmedicineandme.com (Table 1).

AstraZeneca has received a favorable advisory opinion from the OIG, affirming that the company's extension of coverage to Medicare Part D beneficiaries in its new program is consistent with OIG guidelines.

Another available pharmaceutical PAP is Pfizer's Connection to Care. Patients with prescription coverage, including those enrolled in Medicare Part D, who are experiencing financial or medical hardship may apply for “hardship exception” in this program. Patients must first apply to Connection to Care. If they meet the income requirement for Connection to Care (income at or below \$19,600 per year if single or \$26,400 per year if married), but have insurance coverage for prescription medicines, they will be sent a Hardship Exception Request form, which must be completed by patients and their physicians. Each hardship exception request is reviewed on a case-by-case basis by the Pfizer program. If the request is approved, patients receive their 90-day supply of Pfizer medicines at no charge. The medicines are shipped to physician offices for pickup by patients. Additional in-

formation on this program is available at 1-800-707-8990 or at www.pfizerhelpfulanswers.com (see Table 1).

A Novartis PAP is also available to patients who are enrolled in Medicare Part D and are taking Novartis Transplant or Oncology products. These patients must be ineligible for Medicare Part D low-income subsidy, but must show financial hardship in affording their medications despite their Part D coverage. Additional information is available directly from the Novartis program at 1-800-277-2254 or www.pharma.us.novartis.com/novartis/medicare.jsp (see Table 1).

Medicare also has developed a Web resource for accessing the availability of pharmaceutical PAPs,

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which can be reviewed from the point of each specific medication at www.medicare.gov/pap/index.asp. Medicare offers this site so that beneficiaries and their caregivers can determine if any programs are available for the drugs they are tak-

ing. If a drug is on the indexed list, patients can click the “details” link to obtain information about the program. CMS also provides detailed information regarding additional ways to lower costs during the coverage gap at: www.medicare.gov/bridging-the-gap.asp.

Will the Donut Hole Continue?

The progression in magnitude and effect of the gap in Medicare Part D coverage is directly related to the political will of the federal government. Several pieces of legislation currently exist that would provide coverage to fill the donut hole. These legislative fixes have gained significant political momentum since House and Senate leadership

Table 1.

PAP Programs

Company	PAP Program Contact Information	Inclusion Criteria	Benefits for Approved Patients
AstraZeneca	AZ Medicine & Me www.azmedicineandme.com 1-800-957-6285	<ul style="list-style-type: none"> • Medicare Part D • Income: ≤\$30,000 (individual); ≤\$40,000 (couple) • 3% of annual household income spent on prescription drugs during calendar year • Taking any AZ drugs 	<ul style="list-style-type: none"> • \$25 or less for a typical 30-day supply of AstraZeneca-covered medicines available through Medicare Part D
Pfizer	Connection to Care www.pfizerhelpfulanswers.com 1-800-707-8990	<ul style="list-style-type: none"> • Medicare Part D or other prescription drug insurance coverage • Income: ≤\$19,600 (individual); ≤\$26,400 (couple) 	<ul style="list-style-type: none"> • Free 90-day supply of Pfizer medications shipped to physician office
Novartis	Novartis Patient Assistant Program www.pharma.us.novartis.com/novartis/medicare.jsp 1-800-277-2254	<ul style="list-style-type: none"> • Medicare Part D • Taking Novartis transplant or oncology medications • Ineligible for Medicare Part D low-income subsidy but showing financial hardship despite Part D coverage 	<ul style="list-style-type: none"> • Individually evaluated

recently changed. Proposals being considered include elimination of the noninterference clause of the Medicare Modernization Act, which prohibits the federal government from interfering in price negotiations with pharmaceutical companies. It is likely that reimportation will be permitted by the Secretary of Health and Human Services although it is still unclear how this will work within a Medicare Part D plan.

Besides governmental intervention, economic forces will play a key role in 2007 and beyond. As Medicare beneficiaries become more knowledgeable about their medication needs, the drive toward prescription plans offering comprehensive benefit coverage—

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including coverage within the donut hole and MTMS—will increase. Given that Medicare beneficiaries have been drawn to plans that provide additional coverage beyond the legislative minimum, it is probable that more plans will opt to provide this additional cov-

erage. These plans will likely cover the donut hole and allow set monthly payments rather than variable adjustments that result from the donut hole. These plans could create escrow funds so that monthly out-of-pocket expenses remain equal. Through MTMS determinations of a patient's annual medication profile and expenditures, the plans can then average the annual payments over 12 months, thereby eliminating the donut hole.

Managing the donut hole requires Medicare providers to play a critical role not only in navigating these waters for their patients but also, and on a larger level, in providing direction to plan leaders and policy makers to ensure access to critical medications that may otherwise be limited because of a patient's inability to pay. In the end, we all pay for a patient's failure to take their medications when they then end up hospitalized at a much greater cost to the health-care system. **MPM**

PROVIDER ACTION

Impact to You

As physicians become more accountable for patient outcomes, they will also need to help patients adhere to medication regimens. Given the association between medication adherence and out-of-pocket (OOP) drug coverage, physician involvement in reducing patient OOP costs will be vital to achieving improved health outcomes.

What You Need to Know

Physicians need to first be aware of the Medicare Part D coverage gap and ways to lower OOP costs so patients adhere to medication regimens. This starts with educating patients about which prescription plan is most appropriate for them. Secondary steps include optimizing each patients' medication regimen and then directing them to programs that can provide additional assistance—such as patient assistance programs (PAPs) from pharmaceutical companies and state governments.

What You Need to Do

Review patients' medication regimens and work to optimize their drug profiles. Once optimized, direct patients in need to organizations that are able to assist in lowering patient OOP expenses for those who are eligible. These organizations include the Social Security Administration and Medicaid for low-income subsidies, pharmaceutical PAPs, community-based charitable programs, and state government programs. These steps are outlined at Medicare's website at: www.Medicare.gov/bridging-the-gap.asp

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