ABSTRACT

BACKGROUND: Upon signing the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) on December 8, 2003, President Bush set in motion the greatest change in the Medicare program since its inception in 1965. MMA was implemented on January 1, 2006, and established the Medicare prescription drug benefit, also known as Medicare Part D. Community and managed care pharmacists were essential to the success in 2006 of this new benefit program with 33 million beneficiaries. Pharmacists will continue to be an essential and integral part of the continued success of the Medicare prescription drug benefit in 2007, in part by being informed about the policies and regulations.

OBJECTIVE: To review policy statements released by the Centers for Medicare & Medicaid Services (CMS) for the Medicare prescription drug benefit in 2006 and to compile an abridged version of the highlights from the policy statements that may affect pharmacists and their interaction with Medicare beneficiaries.

METHODS: We reviewed all policy statements that were released publicly via the CMS Web site (www.cms.gov) policy guidance section between January 1, 2006, and September 30, 2006. We read through approximately 100 guidance statements and summarized approximately 50 that were determined to be relevant to beneficiaries and pharmacists in various practice settings.

RESULTS: Policy statements that may impact beneficiaries of the Medicare prescription drug benefit in 2007 include the timeline for the annual coordination election period, managed care open enrollment period, and distribution of annual notices of change to beneficiaries. Changes have also occurred in the standard benefit and cost sharing for low-income subsidy (LIS) or extra help that some beneficiaries are eligible to receive based on their current financial status. Discontinuation of coverage for erectile dysfunction drugs is a noteworthy coverage change. For all health care providers, the National Provider Identification (NPI) number will be used beginning May 23, 2007. Once the system using NPI numbers is required, no other provider identification number will be valid for billing Medicare and Medicaid.

CONCLUSION: Important policy updates to the Medicare prescription drug benefit in 2007 include the subject areas of: beneficiary enrollment, transition medication fills, standard benefit, cost sharing, particularly for those who qualify for low-income subsidy [LIS] or extra help that some beneficiaries are eligible to receive based on their current financial status. Discontinuation of coverage for erectile dysfunction drugs is a noteworthy coverage change. For all health care providers, the National Provider Identification (NPI) number will be used beginning May 23, 2007. Once the system using NPI numbers is required, no other provider identification number will be valid for billing Medicare and Medicaid.

KEYWORDS: Medicare Part D, Pharmacist intervention, Medicare policy

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When Can a Beneficiary Join or Change a Medicare Prescription Drug Plan (PDP)?

Medicare beneficiaries can join, switch, or drop coverage from a Medicare prescription drug plan (PDP) during the annual coordinated election period (AEP). For the contract year 2007, the AEP was from November 15 through December 31, 2006. This is an important date span to remember each year because, every year, the AEP for the following contract year will be from November 15 through December 31 of the previous year. The AEP is the only time when all individuals eligible for Medicare prescription drug coverage can join a Medicare PDP, add additional coverage, or leave a Medicare PDP or a portion of the coverage. A beneficiary may also switch PDPs during the same time period. For example, a beneficiary may decide to switch from one PDP to another PDP during the AEP. If an eligible beneficiary drops Medicare prescription drug coverage entirely or misses the enrollment deadline, that beneficiary may not be eligible to enroll in the Medicare prescription drug benefit until November 15 of the following year, which may cause the beneficiary to incur a penalty for late enrollment.

How Does the Open Enrollment Period (OEP) Differ From the Annual Coordinated Election Period (AEP)?

The open enrollment period (OEP) takes place between January 1, 2007, and March 31, 2007, and is scheduled to occur during the same time period in subsequent years. The OEP is the opportunity for beneficiaries to add or change enrollment in a Medicare Advantage (MA) plan. For example, a beneficiary already enrolled in a Medicare Advantage-Prescription Drug plan (MA-PD) may change enrollment to a different MA-PD plan or to the traditional Medicare plan with a PDP (Table 1). The beneficiary cannot use the OEP to add or drop Medicare prescription drug coverage—any new enrollment or disenrollment in prescription drug coverage must occur during the AEP.

At year-end 2006, Congress passed the Tax Relief and Health Care Act of 2006, which President Bush signed on December 20, 2006. This legislation (a) relaxed the rigid lock-in/lock-out feature of the MA program and (b) allows eligible beneficiaries to enroll in a separate MA-only plan. Prior to the Tax Relief and Health Care Act of 2006, beneficiaries unhappy with the choice they made during the annual open enrollment had only 3 months, from January through March each calendar year, to move in or out of an MA plan. Beginning in 2007, the OEP for MA-only plans extends for the entire year in both 2007 and 2008. For example, if a beneficiary has original Medicare coverage, he/she may join an MA-only plan at any time during 2007 or 2008. These changes are indicated with an asterisk (*) in Table 1.

How Will Beneficiaries Know What Changes to Current Coverage Occur in 2007?

During October 2006, all beneficiaries received an annual notice of change (ANOC) from the plan in which they were enrolled, and ANOCs will be sent to beneficiaries each year. ANOCs include notice of the monthly premium amount and a summary of the benefits provided by the plan, including the drug formulary. In addition, those individuals who reside in an LTC setting are eligible for transition fills up to 90 days supply. The same appeals process for exceptions exists in 2007 as did in 2006.

What If a Beneficiary Changes Plans and a Drug Is Not Included in the Formulary?

A beneficiary who changed prescription drug plans in the AEP period may find, upon refilling usual prescriptions, that the drugs are not on the formulary of the new plan. A transition period applies in 2007, as it did in 2006, during which the nonformulary drug is covered for the first 30 days supply even if the prescription is for a drug that is not on the new plan’s drug list (or is a step-therapy drug). This gives the beneficiary and the physician time to find another drug on the plan’s drug list that would work as well or time for the physician to request an exception due to any special medical needs. In addition, those individuals who reside in an LTC setting are eligible for transition fills up to 90 days supply.
What If a Formulary Brand Drug Becomes Available as a Generic Drug?

If a plan changes the formulary status of a medication in the middle of a contract year, a beneficiary who had received the medication affected by the midyear formulary change can continue to receive the brand formulary medication for the same cost-share amount for the remainder of the contract year. For example, if a generic version of a single-source medication is released to the pharmaceutical market midyear and a plan adds the generic version to the formulary at tier-1 copayment and moves the original version of the drug, now a multiple-source brand drug, to tier-3 copayment from tier-2 copayment, the beneficiary who had received the brand medication in the contract year would be permitted to continue to receive the drug at the tier-2 cost-share amount for the remainder of the contract year.7

How Will the Change in the National Average Premium Affect the Penalty Payment?

The national average premium in 2006 was $32.20. The Part D base beneficiary premium for 2007 has been reduced to $27.35.8,9 Beneficiaries who have incurred the late-enrollment penalty are most affected by the decrease in the national average base premium because the penalty amount is based on the national average Part D base beneficiary premium. “The late-enrollment penalty amount is at least 1% of the “base beneficiary premium” (the national average premium) for each full uncovered month that someone was eligible to but did not join a Medicare prescription drug plan.”8 For example, if a beneficiary must pay a 7% penalty because the beneficiary missed the May deadline for enrollment in 2006, the beneficiary will pay a penalty of $27.35 X 0.07 = $1.91/month in addition to their normal monthly premium. Pharmacists need to be aware that the penalty is based on the national average premium, not the premium of the beneficiary, and affected beneficiaries will always pay the penalty but the penalty amount will change from year to year as the national average premium changes each year.8

Will the Standard Benefit Change in 2007?

Changes will occur in the standard benefit (defined as the standard deductible, initial coverage limit, no coverage [“donut hole”], catastrophic coverage threshold, and other related factors) which is required to be updated every year by CMS as directed in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.10 These changes are outlined in Table 2. In fact, most beneficiaries do not have the standard coverage because beneficiaries can enroll in a plan with enhanced coverage that may charge a higher premium. Many beneficiaries have plans that require no deductibles or include coverage for drugs that are not Part D-covered drugs, such as benzdiazepines or barbiturates. For 2007, beneficiaries may enroll in plans offering enhanced coverage that includes ED drugs. Individuals who qualify for certain levels of extra help will not be affected by the changes to the standard benefit because they qualify for premium assistance provided by the federal government.

If a beneficiary enrolls in a plan with the standard coverage, the deductible will increase to $265 and the initial coverage limit will increase to $2,400. The true out-of-pocket (TrOOP) threshold will increase to $3,850, thereby creating a coverage gap between $2,400 and $5,451 in CY 2007.11 TrOOP costs are defined by CMS as “the expenses that count toward the annual Medicare drug plan threshold for the year. These annual expenses determine the start of a beneficiary’s catastrophic coverage. The drug plan will keep track of each person’s TrOOP costs. For every month that a beneficiary buys covered prescriptions, an explanation of benefits will be mailed that shows the beneficiary’s TrOOP costs to date.”12

What Changes Apply to Those Who Are Qualified for “Extra Help”?

The income points for qualification for the LIS, or “extra help,” in 2007 are annual incomes below $14,700 if single or $19,800 if married and living with a spouse.13 The subsidy and copayments are based on a sliding scale according to income and assets. The prescription copayment for institutionalized beneficiaries will remain at $0 in 2007. The copayments for noninstitutionalized LIS beneficiaries will increase in 2007. For those beneficiaries whose copayments were $1 (generic)/$3 (brand) in 2006, the copayments in 2007 will increase to $1/$3.10. For those whose copayments were $2 (generic)/$5 (brand) in 2006, the copayments in 2007 will increase to $2.15/$5.35.14 Therefore, beneficiaries who are not institutionalized and who qualified for extra help in 2006 will experience this (small) increase in their copayments in 2007.

### Table 2 2007 Changes to the Standard Benefit ($)

<table>
<thead>
<tr>
<th>Benefit Parameters</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deductible</td>
<td>250</td>
<td>265</td>
</tr>
<tr>
<td>Initial coverage limit</td>
<td>2,250</td>
<td>2,400</td>
</tr>
<tr>
<td>Out-of-pocket threshold</td>
<td>3,600</td>
<td>3,850</td>
</tr>
<tr>
<td>Total covered drug expenses at out-of-pocket threshold (start of catastrophic coverage)</td>
<td>5,100</td>
<td>5,451</td>
</tr>
<tr>
<td>LIS Copayments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutionalized</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Up to or at 100% FPL</td>
<td>1/3</td>
<td>1/3.10</td>
</tr>
<tr>
<td>Other LIS</td>
<td>2/5</td>
<td>2.15/5.35</td>
</tr>
</tbody>
</table>

FPL=federal poverty level; LIS=low-income subsidy.
Where Can a Beneficiary Find Help

Choosing a Medicare Prescription Drug Plan?

The Medicare Prescription Drug Plan Finder (www.medicare.gov) is useful in finding options within the Medicare prescription drug benefit. Beneficiaries can enter into the Medicare Prescription Drug Plan Finder their maintenance medications, location of residence, and preferred pharmacy, and the finder will provide them with plan options that fit their individual needs. Changes have been made to the finder to enhance its use and understanding, allow for the results to be more specific to the beneficiary, view and compare plans, and allow the beneficiary to determine what each plan will cost monthly.

What If a Beneficiary Has a Complaint?

Assisting a beneficiary with a complaint can be a demanding but rewarding endeavor. The complaints process can be reviewed at: The Tip Sheet: Information Partners Can Use On: Handling Medicare Part D Prescription Drug Complaints, released in August 2006; it is located on the CMS Web site.

If the complaint refers to the drug formulary of a prescription drug plan, the appeals process is the first option. Once the plan renders a decision through the appeals process, the complaint process is the second step if the beneficiary believes that the plan has not acted in accordance with the policy of the Medicare Drug Benefit.

What Is the Coverage Policy for Erectile Dysfunction Drugs Under Medicare Part D in 2007?

One major change in the coverage provided by the Medicare prescription drug benefit beginning in 2007 is the exclusion of ED drugs when prescribed for the treatment of sexual dysfunction or ED; the coverage exclusion for ED drugs does not apply, however, when prescribed for a U.S. Food and Drug Administration-approved indication other than ED, such as pulmonary hypertension. Also a beneficiary may be enrolled in an enhanced coverage plan that extends coverage for certain drugs that are not mandated to be covered by law, such as ED drugs for ED. Additional information on Part D drug coverage was issued in February 2006. This important guidance can be located on the CMS Web site at Part D Drugs/Part D Excluded Drugs (Table 3).

What Is the Difference Between Part B and Part D for Vaccines?

The only vaccines currently covered under Medicare Part B are the “preventive vaccines” for influenza, pneumonia, and hepatitis B (for intermediate- to high-risk beneficiaries), along with “medically necessary” vaccines to treat illness or injury. When a Part B-covered vaccine is administered, the health care professional who administers the vaccine may bill an administration fee to Part B in addition to the vaccine fee. Newer vaccines, such as the herpes zoster vaccine, are covered by Part D. When a Part D-covered vaccine is administered, Part D will pay for the vaccine. According to the Tax Relief and Health Care Act of 2006, the health care professional who administers the vaccine may bill an administration fee to Part B in 2007 for the Part D-covered vaccine. In 2008, both the administration fee and the vaccine fee for a Part D-covered vaccine may be billed to Part D.

There are a small number of inexpensive vaccines, such as those for tetanus, that are not covered by Part B. Part D plans are required to provide access to vaccines not covered under Part B. During rule-making, CMS described use of standard out-of-network requirements to ensure adequate access to the small number of inexpensive vaccines covered under Part D, when the vaccines must be administered in a physician’s office. “The beneficiary would pay the physician and then submit a paper claim to their Part D plan for reimbursement up to the plan’s allowable charge, possibly leaving a differential amount for which the beneficiary is solely responsible for paying.”

When Are Syringes Covered Under Part D for Long-term Care?

CMS issued guidance for the coverage of syringes used to administer insulin in the LTC setting versus coverage of syringes used to administer other drugs covered by the Medicare prescription drug benefit. CMS went on to define insulin syringes equipped with a safe needle device as Part D drugs. “Syringes,
when used for the administration of insulin, meet the definition of Part D drugs. Preexisting 2006 regulations from the Occupational Safety & Health Administration require employers whose employees are exposed to self-injected needles, such as in nursing homes, to provide ‘safe needle devices.’ We view the sharps injury prevention feature involved with these specific types of syringes as ‘special packaging’ required for the administration of insulin in LTC facilities."

“Part D sponsors are required to contract with LTC pharmacies that provide safe needle devices (and who meet all other applicable minimum performance and service criteria), and we expect the availability of these safety-capable syringes to be incorporated into the Part D sponsor’s standard network contract. As a reminder, payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in the final regulations. These safe needle devices would be legitimate costs reflected in the dispensing fee. “This does not extend Part D reimbursement to any other types of syringes used in the administration of other Part D drugs in the LTC facility.”

“While we continue to maintain that the syringes, associated with the administration of insulin dispensed in the long-term care setting, must maintain a safety device, based upon comments from the public, we believe these are better described in accordance with 1860D-2(e) of the Act, which defines ‘medical supplies associated with the injection of insulin’ as covered Part D drugs. Therefore, we are correcting our previous Q&A to define insulin syringes equipped with a safe needle device, in their entirety (syringe and device), as Part D drugs and subsequently they should be managed like any other Part D drug the plan places on their formulary.” LTC pharmacies may continue to seek Part D coverage for the appropriate insulin syringes used in administering insulin to patients residing in LTC facilities. Pharmacies that supply services to nursing homes, hospices, and home health services must follow the appropriate guidance for the appropriate setting.

**Under What Circumstances Can Beneficiaries Return or DonateUnused Medications?**

CMS issued guidance for the handling of Part D-covered unused medications, which may commonly occur in the LTC setting. “If a beneficiary, typically residing in a nursing home, finds that they have an unused prescription medication, paid for by the Medicare prescription drug benefit, they can donate this medication, to the extent allowable under federal and state law and regulation, to state agencies and charitable organizations. Once the beneficiary has taken possession of, and insurance has paid for, the medication, the beneficiary is the owner of such medication and can dispose of the medication as they deem necessary. In certain circumstances, specially packaged unused drugs could be returned to long-term care pharmacies (LTCs) and resold, provided such returns and resales are consistent with provisions of federal and state law. However, LTC administrative costs to inspect, document, reverse claims, reimburse any beneficiary cost sharing, and reinventory of any such returned medications cannot be included in either the Part D ingredient cost or a corresponding dispensing fee. Consequently, these associated restocking fees cannot be billed as Part D drug costs. Further, while facilitating returns is discretionary, for those plans and pharmacies that process returns for resale, they must adjust the prescription drug expense and TrOOP accordingly. In order to adjust the prescription drug expense and TrOOP expenses, a plan must follow the current policies of the plan that are based on the guidance issued by CMS for that contract year.

**What Is the NPI and Why Do I Need One?**

“The NPI is the first opportunity for pharmacists to have an individual provider number with which to bill third parties. This includes billing PDPs for medication therapy management services (MTMS) under the Medicare Part D drug benefit. Pharmacists are encouraged to obtain an individual NPI. This is a new opportunity for pharmacists. Use of an NPI number is a
There are 3 ways to obtain an NPI: (1) complete the application online, which can be found at https://NPPES.cms.hhs.gov/NPPES/Welcome.do; (2) download the paper application at www.cms.hhs.gov/NationalProvIdentStand/ and mail the application to the address on the form; or (3) after asking the provider’s permission, an employer or other trusted organization may obtain an NPI for the provider by bulk enumeration, or electronic file interchange (EFI).

Did You Know That Medicare Covers All of the Preventive Services Listed Below?

Pharmacists are the health care providers most accessible to Medicare beneficiaries and are in a key position to inform beneficiaries about the new preventive services that are covered by Medicare. For example, a beneficiary is eligible for a “Welcome to Medicare” medical office visit that includes a comprehensive physical examination during the first 6 months that a beneficiary first becomes eligible for Medicare Part B. The entry physical examination is the gateway to the Medicare health system and an opportunity for an individual to be diagnosed and receive care before the disease state has advanced and requires more care. The early diagnosis is beneficial to the individual because the beneficiary receives earlier care, resulting in better outcomes.

When beneficiaries see their physician for the “Welcome to Medicare” physical examination, they should receive any needed referrals for other preventive services or treatment to be covered by Medicare. Beneficiaries need to utilize this benefit within the first 6 months of enrollment in Medicare Part B if their Medicare coverage begins on or after January 1, 2005.

A beneficiary may also receive other preventive services such as:
- influenza, pneumococcal or hepatitis B vaccination;
- mammography screening and Pap test and pelvic examination;
- screening for colorectal cancer, prostate cancer, cardiovascular disease, diabetes, glaucoma;
- bone-mass measurement;
- diabetes self-management, supplies, and services;
- medical nutrition therapy; and
- smoking cessation.

Many health care professionals may not be aware of these benefits available to Medicare beneficiaries, and CMS has been working to promote awareness of the available preventive services. “CMS recognizes the crucial role that health care professionals play in promoting, providing, and educating Medicare patients about these potentially life-saving preventive services and screenings. Because of this understanding, we are taking significant steps to reach out and educate the provider community as well as Medicare beneficiaries about the array of preventive services and screenings covered by Medicare. However, we need your help to get the word out to your Medicare patients and their caregivers about the many preventive services and screenings covered by Medicare.”

Health care providers can find additional information and links to materials for educating patients at: http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp#TopOfPage on the CMS Web site.

Important Dates

• October 1, 2006: Plans begin marketing for 2007 plan year
• Mid-October 2006: 2007 plan data and enhanced plan finder available
• October 31, 2006: Annual notice of change and Medicare & You 2007 handbook must be in the mail to beneficiaries
• November 15, 2006: Annual enrollment begins for 2007 plan year
• December 8, 2006: Optimum date for early enrollment to ensure timely processing
• December 31, 2006: Annual enrollment ends for 2007 plan year
• January 1, 2007: Open enrollment for managed care plans begins
• March 31, 2007: Open enrollment for managed care plans ends

A Pharmacist Can Find More Assistance At:
• Call 1-800-MEDICARE: 1 (800) 633-4227
• TTY users should call 1 (877) 486-2048
• Visit www.medicare.gov and select “Frequently Asked Questions”
• Visit www.medicare.gov/contacts/static/allStateContacts.asp for a list of local senior health insurance program (SHIP) organizations
• Web sites provided in Tables 3 and 4.

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REFERENCES


