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## The Medicare Drug Benefit: What Pharmacists Need to Know

*InetCE* 221-999-05-044-H03

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**PLEASE NOTE:** The content of this article was current at the time it was written. The exam for this article is not valid for CE credit after September 26, 2008.

### LEARNING OBJECTIVES

1. Explain the critical elements of the Medicare Drug Benefit that relate to pharmacists and pharmacies.
2. Compare the Medicare Drug Benefit enrollment options for people of varying income levels and eligibility, including limited income beneficiaries and dual eligibles.
3. Identify beneficiaries who may be subject to the late enrollment penalty.
4. Compute the out-of-pocket drug cost for patients under the standard Medicare Drug Benefit.
5. Define pharmacists' role in providing medication therapy management services under the Medicare Drug Benefit.

**ABSTRACT:** This review will provide pharmacists with a basic understanding of the Medicare Drug Benefit. The Medicare Modernization, Improvement, and Prescription Drug Act of 2003 (also known as MMA or the Medicare Drug Benefit), was enacted into law in 2003. The Medicare Drug Benefit represents the single largest change to Medicare since its inception in 1965. It provides

coverage for outpatient prescriptions to all Medicare beneficiaries on a voluntary basis. It will be administered by private entities, including prescription drug plans and Medicare Advantage prescription drug plans. Medicare beneficiaries with limited incomes will be entitled to extra help in paying for the benefit. Beneficiaries who are eligible for both Medicare and Medicaid will now receive coverage from Medicare for their prescription drugs. Medicare beneficiaries who sign up for the Medicare Drug Benefit will be required to select a prescription drug plan in their region to receive coverage for prescription drugs. The Medicare Drug Benefit will involve pharmacists and pharmacies at all levels. Pharmacists represent one of the first points of access to the health care system for Medicare beneficiaries. Pharmacists may perform various activities, including advising patients regarding signing up for the Medicare Drug Benefit and selecting a prescription drug plan, eligibility assessment, dispensing and processing prescriptions for the Medicare Drug Benefit, payment assessment, formulary management, appeals, and medication therapy management services. The Medicare Drug Benefit will take effect on January 1, 2006, when pharmacists will begin to accept prescriptions that are covered by the Medicare Drug Benefit.

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### **A Note to Readers**

This continuing education article provides fundamental information on the Medicare Drug Benefit specific to the final regulations that were released on January 28, 2005. This article is being released prior to the announcement of the programs offered by private prescription drug plans and Medicare Advantage plans. The reader should understand that private sponsors of the legislation and state pharmacy assistance programs have flexibility in terms of the programs they offer and coverage options. It is the author's intent to provide the reader with the basic fundamentals of the Medicare Drug Benefit as a benchmark for understanding the various program options that will be offered by prescription drug plans and Medicare Advantage plans. The reader is encouraged to enhance his or her knowledge gained in this continuing education article by reviewing the specific prescription drug programs offered in his or her region.

### **History and Background**

Medicare and Medicaid were enacted 40 years ago.<sup>1</sup> The year was 1965. During that year, the first United States (U.S.) combat troops were deployed to Vietnam, the Beatles released their new song *Help!*, the Sound of Music was voted best picture, and Walt Disney opened Epcot Center in Florida. On the health care front, President Lyndon Johnson signed legislation to enact Medicare (Title XVIII) and Medicaid (Title XIX) as amendments to the Social

Security Act, with former President Harry Truman at his side. Truman was Medicare's first beneficiary.

Medicare and Medicaid were revolutionary for their time, but their premise was based on the acute model of insurance and coverage for medical care. Reimbursement was made for acute episodes of illness and treatment, such as hospital encounters (Medicare Part A) and physician visits (Medicare Part B). At that time, reimbursement of outpatient prescriptions was not considered necessary through Medicare; the reimbursements were covered in Medicaid. Since 1965, health care transformed from an acute model to one in which chronic disease became more prevalent. The U.S. population is aging, with more people becoming dependent on Medicare. The number of people Medicare served doubled in the 30 years from 1970 to 2000 (to 40 million beneficiaries), and it will nearly double again in the next 30 years to almost 80 million beneficiaries.<sup>2</sup> In 1999, about three-quarters of Medicare beneficiaries had *some* prescription drug coverage, either through their former employer, labor union, Medicaid, or supplemental insurance. Nearly half of all seniors (46%) take 5 or more prescription medications.<sup>3</sup> Beneficiaries with prescription drug coverage fill more prescriptions than those without drug coverage, regardless of the number of chronic conditions they have.<sup>4</sup> People with insurance coverage for prescription medications get more prescriptions filled and have better health outcomes than people without insurance.<sup>5</sup> Since 1965, the lack of outpatient prescription drug coverage for Medicare beneficiaries became an increasingly severe problem as the population

continued to age, drug use increased, and drugs became more expensive relative to personal income. Many seniors had to choose between food and drugs. There were stories of seniors not getting prescriptions filled, splitting tablets, or taking reduced doses to stretch their prescription dollar.<sup>6</sup> There were attempts by politicians, including President Reagan, Congressman Dan Rostenkowski, and President Clinton, to introduce legislation that offered outpatient prescription drug coverage. In one failed attempt in 1988 by then U.S. Representative Dan Rostenkowski (D, Illinois) of Chicago, seniors were so unhappy with the drug benefit he crafted that they stormed his car on one of his visits to his home city.<sup>7</sup> The legislation was repealed one year later. Continued and persistent efforts finally led to the signing in December 2003 by President George W. Bush of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.<sup>8</sup> This represented the greatest change to Medicare since its enactment in 1965. The most significant part of this

legislation is the Medicare Drug Benefit that goes into effect on January 1, 2006. There are other provisions, such as new preventive benefits under Medicare, health care spending accounts, reimbursement changes for physicians, benefits to rural hospitals, and Average Wholesale Price (AWP) reform.

This article will deal exclusively with the Medicare Drug Benefit. The reader is referred to the original legislation or various review articles for information on other provisions of the law. This can be accessed at <http://www.cms.hhs.gov/medicarereform/pdbma/general.asp>.

The Centers for Medicare and Medicaid Services (CMS) is the federal agency that administers Medicare. Medicare consists of 4 primary programs (Table 1). Part A (Hospital Insurance) is provided to all Americans who meet basic criteria. Parts B, C, and D are voluntary and require additional payments by beneficiaries.

**Table 1. Medicare Parts**

	<b>What It Is</b>	<b>What It Covers</b>	<b>How It Is Paid For</b>
<b>Part A</b>	Hospital Insurance	Inpatient hospital services, skilled nursing facilities, home care.	Payroll taxes No premiums
<b>Part B</b>	Supplemental Medical Insurance	Physician and other health care provider office visits, outpatient services, drugs administered in an outpatient clinic.	Premiums \$78.20/month/person in 2005
<b>Part C</b>	Medicare Advantage (managed care) Formerly Medicare+Choice	Medicare Parts A, B, and D provided through a private health plan such as a managed care organization.	Combined payroll taxes and premiums.

<b>Part D</b>	Prescription Drug Insurance	Outpatient prescription drugs such as those purchased in a community pharmacy or from an outpatient hospital pharmacy.	Premiums around \$36/month/person
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**Overview of the Medicare Drug Benefit**

The Medicare Drug Benefit is a voluntary outpatient prescription drug benefit that is administered by private plans approved by CMS.<sup>9,10</sup> Private plans are stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage (managed care) programs that have integrated prescription drug plans (MA-PDPs). Through general guidelines, CMS will approve all the formularies and the private plans that provide the prescription drug benefit to beneficiaries. The United States Pharmacopeia was contracted by CMS to develop broad guidelines for plans to use when crafting their formularies (See: <http://www.usp.org/healthcareInfo/mmg/>). CMS established 34 PDP regions and 26 MA regions across the country (See: <http://www.cms.hhs.gov/medicarereform/mmregions/pdpmaosum.asp> and APPENDIX). Each region must have a minimum of 2 PDPs from which consumers may choose.<sup>11</sup>

The Medicare Drug Benefit provides insurance coverage for outpatient prescription drugs. As other forms of insurance, beneficiaries pay a premium and share in the cost of prescriptions. The cost of the benefit will depend on the drug plan chosen. Sponsors may offer various benefit levels from which to choose.

Enrolled individuals will have access to negotiated prices that the private plans

obtain for prescription drugs from pharmaceutical manufacturers. Private plans will negotiate price discounts directly with pharmaceutical manufacturers for prescription medications. These discounts will be passed on to beneficiaries in the form of lower prescription drug prices. Prescription drug prices may vary from private plan to private plan, based on the negotiations that each plan has with pharmaceutical companies. The enabling legislation for Medicare Part D forbids CMS from negotiating directly on prices with pharmaceutical manufacturers

The use of negotiated prices is a key concept of the Medicare Drug Benefit. Formerly, uninsured beneficiaries who paid usual and customary prices will now have a benefit based on negotiated prices if they enroll in the drug program. Pharmacists will be reimbursed based on these negotiated prices that will be applied to all prescriptions dispensed to all beneficiaries of the Medicare Drug Benefit.

Lower-income beneficiaries will be entitled to a low-income subsidy ('Extra Help'), which reduces the cost of the benefit to them. Beneficiaries with incomes less than \$14,355 per individual or \$19,245 per couple (150% of the Federal Poverty Level in 2005), and limited assets will receive a subsidized benefit that reduces the cost of the benefit to them. The amount of the

subsidy will depend on their income and assets level, with the most generous subsidy provided to individuals with the lowest income.

Overall, the Medicare Drug Benefit should increase access to outpatient prescription medications for beneficiaries—especially those with low incomes. Pharmacists should see increased use of prescription drugs among seniors who previously lacked insurance or lacked sufficient insurance, but their payment for these prescriptions will optimally decrease from usual and customary to a discounted payment from sponsors.

**Eligibility and Enrollment**

A person is eligible for the Medicare Drug Benefit if he or she is:

- Entitled to Medicare benefits under Part A (hospital insurance) or enrolled in Medicare Part B (supplemental medical insurance)
- **AND** lives in the service area of a Medicare Drug Benefit plan.

There are 3 levels of beneficiaries who are eligible for the Medicare Drug Benefit, which are based on income and assets (Table 2). These levels are referred to as Full-Benefit Dual Eligibles (Level 1), Low Income (Level 2), and Standard (Level 3). The Full-Benefit Dual Eligibles (Level 1) will be automatically enrolled in the Medicare Drug Benefit. Levels 2 and 3 will need to proactively enroll to receive the Medicare Drug Benefit.

**Table 2. Levels of Beneficiaries Eligible for the Medicare Drug Benefit**  
(<http://www.medicare.gov/Publications/Pubs/pdf/11105.pdf>)

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
	Full-Benefit Dual Eligible	Low Income	Standard
Medicare recipient & receiving the following:	Full Medicaid benefits & income ≤ \$9,570/ \$12,830 (single/couple) OR Medicaid with income > Level 1 <b>or</b> SSI without Medicaid <b>or</b> Medicare premiums paid by state	Income ≤ \$14,355/\$19,245	Income > \$14,355/ \$19,245
Value of assets	Not Applicable	≤ \$11,500/\$23,000	> \$11,500/\$23,000
Eligible?	Automatically enrolled	Must apply	Must apply

If a person in Level 2 or 3 already has prescription drug coverage through his or her former employer or union, then he or she may choose to keep his or her

current coverage. Some beneficiaries may be eligible for the Medicare Drug Benefit, but they may choose to stay with their current coverage. To

encourage employers and others to maintain these benefits, CMS will provide tax-free subsidies per retiree to employers providing drug benefits that are actuarially equivalent to (at least as good as) the standard Medicare Drug Benefit.

The sponsor of the current coverage (former employer or labor union, for example) was required to notify beneficiaries whether or not their coverage was actuarially equivalent, or at least as good as the Medicare Drug Benefit. If the current coverage was NOT actuarially equivalent, the

beneficiary was notified by the sponsor of the coverage. The beneficiary then has the option of enrolling in the Medicare Drug Benefit. If the beneficiary does not enroll in the Medicare Drug Benefit, then he or she is subject to the late enrollment penalty.

The type of benefit to be received will depend in part on a beneficiary's level of income and assets, with the most generous benefit being provided to those in Level 1 (Table 3). Each level of benefit will be described in detail in the following sections.

**Table 3. Type of Medicare Drug Benefit Based on Beneficiary Levels**

(<http://www.kff.org/medicare/7327.cfm>)

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
	Full-Benefit Dual Eligible	Low Income	Standard
Drug Coverage	Fully subsidized benefit	Extra Help	Standard Drug Benefit
Monthly premium	\$0	\$0 or reduced based on income	\$37 or more
Annual deductible	\$0	\$0 or \$50	\$250
Co-payment per prescription	\$1-\$2/generic, \$3-\$5/brand, or \$0 if in nursing home	\$2/generic, \$5/brand OR 15% of the cost of each prescription	25% of the cost of each prescription up to \$2,250
Co-payment under catastrophic coverage	\$0	\$0 OR \$2/generic, \$5/brand	5% of the cost of each prescription

Since the Medicare Drug Benefit is voluntary, a person must actively enroll to receive coverage for prescription drugs. If a person does NOT have actuarially equivalent prescription drug coverage and does NOT enroll in the Medicare Drug Benefit, there will be a late enrollment penalty. Although

enrollment in the Medicare Drug Benefit is voluntary, beneficiaries are expected to enroll in it because they may need it someday. A late enrollment penalty assessed as an additional cost to the basic premium will be charged to beneficiaries who enroll after their initial enrollment period. The penalty amounts

to a permanent premium increase of 1% a month for every month that enrollment is delayed. This penalty is designed to

serve as an incentive for timely enrollment.

### **Case Study: Joe**

Joe is a 70-year-old male who is retired from his job as a cook. He receives Social Security Income and has Medicare Part A and Part B. Joe does not have prescription drug coverage. He currently takes medication for high blood pressure that costs him \$45 per month.

#### ***Is Joe eligible for the Medicare Drug Benefit?***

*Yes, Joe is a Medicare beneficiary and is therefore eligible to enroll in the Medicare Drug Benefit.*

#### ***Does Joe already have coverage for prescription medications?***

*No, Joe does not currently have coverage for prescription medications.*

#### ***Does Joe want to enroll in the Medicare Drug Benefit?***

*Yes. Since Joe does not currently have coverage, he should enroll in the Medicare Drug Benefit during the enrollment period to avoid a late enrollment penalty.*

*The enrollment period for the Medicare Drug Benefit is November 15, 2005-May 15, 2006. Joe can stay with his regular (fee-for-service) Medicare providers and choose a stand-alone Medicare PDP. Or Joe can sign up for MA, a managed care plan with an integrated PDP (MA-PDP). A MA plan will cover all of his health care needs, including prescription medications, through one managed care organization. Joe will be offered a choice of PDPs and MA plans.*

### **The Standard Drug Benefit (Level 3)**

All PDPs or MA plans will offer a standard Medicare Drug Benefit or its actuarial equivalent (Table 4). A benefit is actuarially equivalent if it is at least as comprehensive for beneficiaries from an insurance standpoint. For example, a plan could eliminate the deductible or raise the deductible but lower the co-insurance. These options must not increase overall cost to the beneficiary above and beyond the standard benefit.

Each person will pay a monthly premium of around \$36 a month in 2006 for the Standard Medicare Drug Benefit. If the person is enrolled in a MA (managed care) plan, then the premium for the Drug Benefit will be combined with his or MA premium for other health care services. The Standard Drug Benefit requires the beneficiary to pay part of the cost of the benefit through various cost-sharing arrangements, as indicated in the Table 4. Cost sharing is the cost for health care services that the individual pays.

**Table 4. 2006 Standard Drug Benefit**

<b>2006 STANDARD DRUG BENEFIT</b>	<b>Beneficiary Pays (in addition to the monthly premium)</b>	<b>Cumulative Beneficiary Payment (true out-of- pocket costs, also known as TrOOP)</b>	<b>Percentage of Beneficiaries Who Stop at Each Level</b>
<b>Annual Deductible</b>	<b>\$250</b>	<b>\$250</b>	<b>17%</b>
<b>Co-insurance</b>	<b>25% from \$251-\$2,250 in total drug costs</b>	<b>\$750</b>	<b>35%</b>
<b>Coverage Gap</b>	<b>\$2,251-\$5,100 total drug costs</b>	<b>\$3,600</b>	<b>28%</b>
<b>Catastrophic Insurance</b>	<b>5% over \$5,100 total drug costs</b>	<b>\$3,600 + 5% of costs above \$5,100</b>	<b>20%</b>

A deductible is the amount an individual must pay for health care services before the insurance such as Medicare begins to pay. Coinsurance is the percentage of the plan charge for services that an individual pays after any plan deductibles. In a typical plan, the coinsurance payment is a percentage of the cost of the service (e.g., 20%). The coverage gap is a period of no coverage in the plan benefit. This is also known as the 'doughnut hole.' The individual must pay the full cost of the service during the coverage gap. For the

Medicare Drug Benefit, a gap in coverage occurs when total drug expenditures are between \$2,250 and \$5,100, or when the individual's out-of-pocket costs are between \$750 and \$3,600. Catastrophic insurance is coverage for individuals who have very high expenditures. For the Medicare Drug Benefit, catastrophic insurance amounts to a 5% coinsurance for all drug costs over \$5,100 or more than \$3,600 in out-of-pocket costs. About 20% of Medicare Drug Plan participants are expected to need catastrophic insurance.

**Case Study: A.M. and P.M.**

A.M. (wife) is a Medicare beneficiary who has prescription drug expenditures of \$500 per month, or \$6,000 per year.

P.M. (husband) is a Medicare beneficiary who has prescription drug expenditures of \$61 per month, or \$730 per year.

***Are A.M. and P.M. eligible for the Medicare Drug Benefit?***

*Yes, they are both Medicare beneficiaries and are therefore eligible to enroll in the Medicare Drug Benefit.*

***Do A.M. and P.M. already have coverage for prescription medications?***

*No, they do not currently have coverage for prescription medications. They should sign up for the Medicare Drug Benefit during the enrollment period in order to avoid a late enrollment penalty.*

*A.M. (wife) has prescription drug expenditures of \$500 per month, or \$6,000 per year. Under the Standard Drug Benefit, A.M. will PAY \$3,645 for her medications. She will SAVE \$2,355, or 39%. In addition, A.M. will pay a premium of around \$36 per month in 2006.*

***Calculation:***

<i>Annual Deductible</i>	<i>\$250</i>
<i>Coinsurance</i> <i>(25% from \$251-\$2,260)</i>	<i>\$500</i>
<i>Coverage Gap</i> <i>(\$2,261-\$5,100)</i>	<i>\$2,850</i>
<i>Catastrophic Insurance</i> <i>(5% over \$5,100)</i>	<i><u>\$45</u></i>
<b><i>TOTAL</i></b>	<b><i>\$3,645</i></b>

*P.M. (husband) has prescription drug expenditures of \$61 per month, or \$730 per year. Under the Standard Drug Benefit, P.M. will PAY \$370 for his medications. He will SAVE \$360, or 49%. In addition, P.M. will pay a premium of around \$37 per month in 2006.*

***Calculation:***

<i>Annual Deductible</i>	<i>\$250</i>
<i>Coinsurance</i> <i>(25% from \$251-&amp;2,260)</i>	<i>\$120</i>
<i>Coverage Gap</i> <i>(\$2,261-\$5,100)</i>	<i>\$0</i>
<i>Catastrophic Insurance</i> <i>(5% over \$5,100)</i>	<i><u>\$0</u></i>
<b><i>TOTAL</i></b>	<b><i>\$370</i></b>

**Enhanced Coverage**

PDPs must always offer the Standard Drug Benefit or its actuarial equivalent to beneficiaries. Additionally, plans are free to offer more comprehensive coverage as a second plan offering. This is known as enhanced coverage or supplemental coverage. Some of the supplemental benefits may include reduced cost sharing or coverage of certain drugs that are not covered in the standard Medicare Drug Benefit. Individuals will pay a higher premium for enhanced coverage, if this is what they choose.

## Covered Medications

The standard Drug Benefit covers prescription drugs, biological products, insulin, vaccines, and certain medical supplies associated with the injection of insulin (syringes, needles, alcohol swabs, and gauze). Individual prescription drug plans will create formularies to determine which drugs are covered under their plan. Plans are required by CMS guidelines to include at least 2 drugs in every therapeutic category on their formularies. There are 146 unique therapeutic categories and pharmacologic classes, based on the USP classification system available at <http://www.usp.org/pdf/drugInformation/mmg/finalModelGuidelines2004-12-31.pdf>.

Two key requirements in the Medicare Drug Benefit are to ensure that drug plans provide access to medically necessary treatments for all and do not discriminate against any type of beneficiaries and to encourage and support the use of drug benefit management approaches that are proven and in widespread use in prescription drug plans today.<sup>12</sup> CMS must review and approve each plan's formulary. The CMS formulary review focuses on 3 areas: pharmacy and therapeutics committees, formulary lists, and benefit management tools.

Certain drugs or classes of drugs are not included in the Standard Drug Benefit because they are excluded by federal law. These drugs are listed below. PDPs or MA plans may choose to offer enhanced coverage that covers some or all of these drugs or classes of drugs.

### **Drugs or Classes of Drugs Excluded from Standard DrugBenefit**

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Drugs used for anorexia, weight loss, or weight gain

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Drugs when used to promote fertility

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Drugs when used for cosmetic purposes or hair growth.

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Drugs when used for the symptomatic relief of cough and colds.

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Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

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Nonprescription drugs

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Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer as a condition of sale.

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Barbiturates

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Benzodiazepines

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### **Extra Help (Level 2)**

About one-third of the Medicare population falls into Level 2 (Low Income). These individuals will be eligible for 'Extra Help,' or the Limited-Income Subsidy. This additional assistance will help to shield limited-income beneficiaries from premiums and

cost-sharing requirements of the Medicare Drug Benefit.

Determination of the Extra Help available to an individual is based on his or her income and assets. Income includes money earned from any of the following sources: wages, self employment net earnings, railroad

retirement, Veterans benefits, other pensions or annuities, alimony, net rental income, workers' compensation, or help from other people to pay for household expenses. Assets include money in bank accounts, stocks, bonds, savings bonds, mutual funds, individual retirement accounts (IRAs), cash, life insurance policies for the individual and spouse (if

married), and any real estate other than the individual's home.

The Medicare Drug Benefit has reduced premiums and reduced cost sharing for people who qualify for Extra Help. People receiving extra help will pay a small deductible or no deductible. They will not be subject to the coverage gap.

**Case Study: Joe (continued)**

Joe has an annual income from Social Security of \$13,000/year. He has a savings account that has \$9,000.

***Is Joe eligible for Extra Help?***

*Yes, Joe is eligible for Extra Help since his income is below \$14,355 and his assets are below \$10,000. Joe must sign up for the Extra Help through the Social Security Administration or the State Medical Assistance Office.*

***Joe signed up for Extra Help and was approved. Now What?***

*Joe MUST join a Medicare PDP for Medicare to pay for his drug costs. He can select a stand-alone PDP or one that is part of a MA plan. The enrollment period for Joe to join a Medicare PDP is from November 15, 2005 to May 15, 2006. If Joe signs up for a Medicare PDP before December 31, 2005, then his coverage will start on January 1, 2006. If Joe waits until AFTER January 1 to sign up, then his coverage will begin on the first day of the month after the month he joins.*

**Dual Eligibles (Level 1)**

A FULL-BENEFIT DUAL ELIGIBLE is a person over 65 or a person with a disability who is enrolled in both Medicare and Medicaid **AND** receives assistance from Medicaid for prescription drugs, nursing home care, other long-term-care services, and payment for Medicare premiums and cost sharing. Full-benefit dual eligibles account for 15% of Medicaid and 18% of Medicare recipients, totaling 7.5 million individuals. Some Medicare beneficiaries receive assistance from Medicaid for their premiums and cost sharing but not for prescription drugs. These people are NOT considered full-benefit dual eligibles and they will not

be part of the automatic enrollment in the Medicare Drug Benefit.

Full-benefit, dual-eligible individuals will have their prescription drug coverage automatically transferred from Medicaid to Medicare on January 1, 2006 and will receive their drug coverage through Medicare. State Medicaid programs will no longer provide coverage for prescription drugs for full-benefit, dual-eligible individuals.

Dual-eligible individuals can join a PDP starting on November 15, 2005. If they do not join a plan by December 31, 2005, then Medicare will automatically assign a PDP. The automatic

assignment will be random based on the plans available in the dual eligible's service area. Dual eligibles may switch plans at any time during the year. Full-benefit dual eligibles will pay a \$1 co-pay for generic medications and a \$3 co-pay for brand-name drugs.

### **Wraparound Coverage**

State Medicaid agencies or State Pharmaceutical Assistance Programs (SPAPs) may provide enhanced coverage for dual-eligible individuals or low-income individuals at no additional cost to them. This extra assistance from the states may cover drugs or classes of drugs that are not covered by the Standard Drug Benefit, such as over-the-counter drugs or benzodiazepines.

### **Case Study: Delores**

Delores is an 84-year-old female who receives Medicare and Medicaid and receives prescription drug coverage from Medicaid. Delores is a full-benefit dual eligible.

She is on 8 different chronic medications, including Prilosec over-the-counter.

### ***Is Delores a Full-Benefit Dual Eligible?***

*Yes, Delores receives Medicare and full Medicaid benefits, so she is a Full-Benefit Dual Eligible. Delores will be automatically enrolled in the Medicare Drug Benefit. Delores can join a PDP between November 15, 2005 and May 15, 2006. If Delores does not join a PDP, then one will be automatically assigned to her on January 1, 2006.*

## **Pharmacy Issues**

### Access to Pharmacies

To ensure access to a wide array of pharmacies for beneficiaries, the Medicare Drug Benefit specifies that a PDP must permit the participation of "any willing pharmacy," that is, any pharmacy that meets the terms and conditions of the plan. This means that any pharmacy that wants to be in a sponsor's network must be accepted into the network, as long as the pharmacy can meet the terms and conditions spelled out in the sponsor's contract. Sponsors will be able to modify contracting terms and conditions as might be necessary to ensure access to pharmacies, for example in rural or remote areas. Sponsors are required to meet the Department of Defense TRICARE pharmacy access standards, which are designated for military beneficiaries. In rural areas, 70% of covered beneficiaries must live within 15 miles of the nearest network pharmacy. Sponsors may also designate preferred pharmacies in their network. A sponsor may reduce co-insurance or co-payment for drugs dispensed through in-network, preferred pharmacies, effectively designating and distinguishing "preferred" and "non-preferred" pharmacies. Mail-order pharmacies most likely will be offered to beneficiaries that enroll in plans. To level the playing field, pharmacies will be allowed to dispense up to 90-day supplies for patients choosing to use their local pharmacy instead of the mail-order option, but the cost may be more for the 90-day supply obtained from a non-mail-order pharmacy. Out-of-network emergency dispensing will be allowed. Some PDPs may specifically contract with out-of-area pharmacies as a contingency for individuals with

multiple residences during a year (e.g., “snowbirds”).

### **Generic Drugs**

According to the Medicare Drug Benefit, pharmacists must inform beneficiaries if a lower-cost generic alternative is available. A pharmacy that dispenses a covered drug is required to inform the beneficiary of any differential between the price of the dispensed drug and the price of the lowest priced generic version of that drug available at the pharmacy. This notice shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery. If there is an opportunity for generic substitution, it will be the choice of the beneficiary whether the substitution is made.

### **Coordination of Benefits and True Out-Of-Pocket Expenditures**

When a Medicare Drug Benefit enrollee has other prescription drug coverage, coordination of benefits allows the sponsors that provide coverage for this same beneficiary to determine each of their payment responsibilities. This process is necessary to avoid duplication of payment and to ensure that payment occurs in the proper order. Coordination of benefits will also provide the mechanism for support of the tracking and calculating of beneficiaries’ “true out-of-pocket” (TrOOP) expenditures, or “incurred costs.” Costs are treated as “incurred” only if they were paid by the individual (or by another person, such as a family member, on behalf of the individual), paid by CMS on behalf of a low-income subsidy-eligible individual, or paid under a qualified state pharmaceutical assistance program. In

2006, under the defined standard benefit, catastrophic coverage is triggered only

after \$3,600 of TrOOP expenditures (or \$5,100 in total drug expenditures).

Pharmacy organizations worked in collaboration with the National Council of Prescription Drug Plans (NCPDP) to develop a TrOOP facilitation system that allows the majority of pharmacy claims processing to take place “real time” at the pharmacy Point of Sale (POS). The calculation and reporting of TrOOP is a new feature for pharmacy. The Medicare Drug Benefit is unique in that the level of benefit depends upon the beneficiary’s TrOOP. Pharmacy will depend on real-time claims processing to provide accurate and up-to-the-minute reporting of TrOOP.

### **Electronic Prescription Program (ePrescribing)**

The Medicare Drug Benefit allows prescriptions for covered drugs and required information to be transmitted electronically. Uniform standards that meet requirements for an electronic prescription drug program will be established by CMS. The electronic prescription program will encompass the ability to include eligibility information, formulary and cost-sharing structure for drugs, prior authorization requirements, information on drug interactions, warnings or cautions, dose adjustments when indicated, and availability of lower cost therapeutically appropriate alternative drugs. One year after the final standards are promulgated (required by the Medicare Drug Benefit to be adopted by April 2009), all prescriptions transmitted electronically will need to comply with those standards. After the standards are

established, sponsors must provide for the electronic transmittal of medical history information related to a covered drug being prescribed or dispensed when requested by the prescriber or pharmacist involved.

### **Medication Therapy Management Programs**

The Medicare Drug Benefit defines a medication therapy management program (MTMP) as the following:

A “program of drug therapy management that may be furnished by a pharmacist and that is designed to ensure, with respect to targeted beneficiaries, that covered drugs are used appropriately to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions.”<sup>13</sup>

The MTMPs will be for targeted beneficiaries with multiple chronic diseases (e.g., diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure), taking multiple covered drugs, and identified as likely to incur annual costs above roughly \$4,000 per year. Of note, the Medicare Drug Benefit provides no specifics to minimum eligibility standards for MTMPs. Sponsors will be able to establish their own minimum eligibility requirements potentially leading to an inconsistency of care available to beneficiaries.

The Medicare Drug Benefit states the MTMP for a sponsor shall be developed in cooperation with licensed and practicing pharmacists and physicians,

and that in establishing fees for pharmacists and others providing services under the sponsors, resources used and time required to implement the MTMP shall be taken into account. The Lewin Group assessed the potential cost of MTMP and provided useful guidelines.<sup>14</sup> In developing regulations related to MTMPs, specific services to be provided are viewed as being distinct from those required for dispensing medication and paid separately by sponsors. MTMPs, however, are considered part of the administrative activities of the PDPs. They are similar to quality assurance; drug utilization review; or measures to control fraud, abuse, and waste; and would not involve direct beneficiary cost sharing nor separate beneficiary fees for the services (although the cost could be reflected in the premium rate). The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and, therefore, not an additional benefit (even though it is limited to targeted beneficiaries). The Medicare Drug Benefit does *not* require sponsors to provide MTMP at the point of care by pharmacists. It remains to be seen whether MTMPs will be centrally controlled by PDPs or be provided at the point of care in pharmacies.

### **New CPT Codes for Medication Therapy Management**

On July 1, 2005, the American Medical Association (AMA) released new Current Procedural Technology (CPT) III codes for Medication Therapy Management.<sup>15</sup> CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures. CPT III codes are temporary tracking codes for emerging technology, services, and procedures. These codes

are intended to facilitate data collection on and assessment of new services and procedures. Medication Therapy Management services were assigned Category III CPT codes. Payment for the MTMS CPT III codes is at the discretion of the local Medicare carriers and payers. The AMA describes medication therapy management as follows:

Medication Therapy Management Service(s) (MTMS) describe face-to-face patient assessment, and intervention as appropriate, by a pharmacist. MTMS is provided to optimize the response to medications or to manage treatment-related medication interactions or complications.

MTMS includes the following documented elements: review of the pertinent patient history, medication profile (prescription and nonprescription), and recommendations for improving health outcomes and treatment compliance. These codes are not to be used to describe the provision of product-specific information at the point of dispensing or any other routine dispensing-related activities.

The CPT III codes for MTMS take effect on January 1, 2006. They include:

- 0115T Medication therapy management service(s) provided by a pharmacist; individual, face-to-face with patient; initial 15 minutes, with assessment and intervention if provided; initial encounter.
- 0116T Subsequent encounter
- 0117T Each additional 15 minutes

Eventually, the CPT III codes for MTMS will be changed to CPT I codes that represent distinct services provided by many practitioners across the U.S. Pharmacists look forward to this level of recognition.

#### Timeline

The Medicare Drug Benefit will go into effect on January 1, 2006, for those who are enrolled at that time. The initial enrollment period is 6 months to allow as many people as possible to enroll. Enrollment will begin on November 15, 2005 and will continue through May 15, 2006. After that, there will be only one open enrollment period each year, from November 15 through December 31. People can switch plans only during the open enrollment period. A more detailed timeline appears in Table 5.

**Table 5. Medicare Drug Benefit Timeline**

July 1, 2005	Applications for low-income subsidies can begin to be accepted.
September 14, 2005	CMS approves bids for Medicare Drug Benefit plans.
October 1, 2005	Approved Medicare Drug Benefit plans begin marketing.
October 13, 2005	CMS begins disseminating information comparing available Medicare Drug Benefit plans with beneficiaries.
October 27-November 10, 2005	CMS mails auto-enrollment information to dual eligibles.

November 15, 2005-May 15, 2006	<b>Coordinated enrollment period for 2006 Medicare Drug Benefit for all beneficiaries.</b>
December 31, 2005	Medicaid drug coverage ends for full-benefit dual eligibles.
December 31, 2005	Medicare drug discount card program ends.
<b>JANUARY 1, 2006</b>	<ul style="list-style-type: none"> <li>• <b>Medicare Drug Benefit coverage begins for all beneficiaries enrolled in a plan.</b></li> <li>• <b>Dual eligibles auto-enrollment takes effect.</b></li> <li>• <b>Low-income subsidies for Medicare Drug Benefit begin.</b></li> </ul>
May 16, 2006	Late enrollment penalty begins.
November 15-December 31, 2006	Annual coordinated enrollment period for 2007 Medicare Drug Benefit for all beneficiaries.

### **Implications for Pharmacists**

*Prescription volume will most likely increase, but reimbursement will decrease because of the impact of negotiated prices and contracts.*

Two trends will impact pharmacies. Formerly uninsured individuals will fill a greater number of prescriptions owing to the availability of insurance. This will increase prescription volume in pharmacies. This increased volume, however, will be offset by a lower payment from sponsors that is based on negotiated rates. CMS predicts that the net effect on pharmacies will be an increase in dollar revenue of about 1%.

This does not take into account other positive spillover effects on pharmacy, which may result from the Medicare Drug Benefit. Beneficiaries will be visiting the pharmacy more often and will purchase other items in the store. Pharmacists who provide Medication Therapy Management Services will be able to realize a new revenue stream from this clinical function.

*Pharmacists will spend more time answering questions about the Medicare Drug Benefit and assisting beneficiaries.*

By now, pharmacists have most likely received questions from beneficiaries such as whether they should sign up, which plan to choose, enrollment periods, who is eligible, and how consumers' spending will change if they enroll. It will be useful to have a basic knowledge of general coverage provisions and specifics of plans that pharmacists may participate in or know of that will operate in their locality. Other questions may arise about pharmacy access and regions, in network and out-of-network pharmacies, mail-order pharmacy, formulary coverage, and emergency access. Knowledge of coverage regions and emergency access procedures may be particularly important for those beneficiaries having residence in multiple regions.

Claims processing will include real-time information on TrOOP. Pharmacists will need to communicate TrOOP to their beneficiaries, since the level of the benefit depends on TrOOP. Catastrophic insurance is triggered by a TrOOP of \$3,600. Once the benefit has started, beneficiaries likely will need to know where they stand in regard to their deductible and/or the initial coverage limit, and potential cost saving opportunities to prevent reaching the

initial coverage limit and falling into the “doughnut hole.”

*Medication Therapy Management will open new clinical doors for pharmacists and can possibly lead to formalized, large-scale payment for pharmacy services.*

Pharmacists will need to establish themselves as a likely source for providing these services and will need to demonstrate benefit from specific components to the PDPs. This is an important advocacy role for pharmacists. Other health care professionals will also be able to provide these services. Pharmacists should use the new CPT III codes for MTMS (0115T, 0116T, and 0117T) for reporting MTM services.

*Electronic prescribing will provide a longer-term opportunity for pharmacists to be more completely linked with physician offices.*

Through electronic prescribing, pharmacists may have more complete access to certain patient records. This new technology will enhance the continuity of care that will be provided by pharmacists and will enhance the opportunity for pharmacists have access to all necessary information to provide more comprehensive clinical pharmacy services.

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## Conclusion

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 represents the greatest change to Medicare since its enactment in 1965. The most significant part of this legislation is the Medicare Drug Benefit that goes into effect on January 1, 2006. The Medicare Drug Benefit provides voluntary insurance for outpatient prescription drugs and is administered by private plans. Beneficiaries qualify for different levels of the Medicare Drug Benefit, which is based on their income and assets. Pharmacists will also have an opportunity to provide Medication Therapy Management Services to qualifying beneficiaries. The Medicare Drug Benefit will surely change the face of pharmacy practice in the coming years.

For more information, pharmacists are referred to the following web sites:

American Pharmacists Association: [www.aphanet.org](http://www.aphanet.org)  
Centers for Medicare and Medicaid Services: [www.cms.gov](http://www.cms.gov)  
Federal Register Main Page: [www.goaccess.gov/fr/](http://www.goaccess.gov/fr/)  
Kaiser Family Foundation: [www.kff.org](http://www.kff.org)  
Medicare Page for Consumers: [www.medicare.gov](http://www.medicare.gov)  
Medicare Drug Benefit (complete legislation): <http://www.cms.hhs.gov/medicarerreform/pdbma/general.asp>.

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## APPENDIX

### MA & PDP Regions: State-by-State Summary Table

<http://www.cms.hhs.gov/medicarereform/mmregions/pdpmaosum.asp>

State	PDP Region	Total Beneficiaries in PDP Region	MA PPO Region	Total Beneficiaries in MA PPO Region	Medicare Beneficiaries in State
Alabama	<u>12</u>	1,663,097	<u>10</u>	1,663,097	750,732
Alaska	<u>34</u>	51,198	<u>26</u>	51,198	51,198
Arizona	<u>28</u>	769,443	<u>21</u>	769,443	769,443
Arkansas	<u>19</u>	471,368	<u>15</u>	1,389,193	471,368
California	<u>32</u>	4,257,579	<u>24</u>	4,257,579	4,257,579
Colorado	<u>27</u>	516,005	<u>20</u>	778,442	516,005
Connecticut	<u>2</u>	1,805,085	<u>2</u>	1,805,085	536,258
Delaware	<u>5</u>	901,259	<u>5</u>	901,259	125,231
District Of Columbia	<u>5</u>	901,259	<u>5</u>	901,259	77,195
Florida	<u>11</u>	3,041,852	<u>9</u>	3,041,852	3,041,852
Georgia	<u>10</u>	1,019,216	<u>8</u>	1,655,581	1,019,216
Hawaii	<u>33</u>	182,651	<u>25</u>	182,651	182,651
Idaho	<u>31</u>	417,788	<u>23</u>	1,764,310	186,976
Illinois	<u>17</u>	1,720,335	<u>14</u>	2,555,008	1,720,335
Indiana	<u>15</u>	1,588,640	<u>13</u>	1,588,640	910,980
Iowa	<u>25</u>	1,913,827	<u>19</u>	1,913,827	496,059
Kansas	<u>24</u>	405,801	<u>18</u>	947,170	405,801
Kentucky	<u>15</u>	1,588,640	<u>13</u>	1,588,640	677,660
Louisiana	<u>21</u>	650,510	<u>16</u>	1,107,824	650,510
Maine	<u>1</u>	422,515	<u>1</u>	422,515	235,804
Maryland	<u>5</u>	901,259	<u>5</u>	901,259	698,833
Massachusetts	<u>2</u>	1,805,085	<u>2</u>	1,805,085	995,597
Michigan	<u>13</u>	1,501,197	<u>11</u>	1,501,197	1,501,197
Minnesota	<u>25</u>	1,913,827	<u>19</u>	1,913,827	702,052
Mississippi	<u>20</u>	457,314	<u>16</u>	1,107,824	457,314
Missouri	<u>18</u>	917,825	<u>15</u>	1,389,193	917,825
Montana	<u>25</u>	1,913,827	<u>19</u>	1,913,827	148,409
Nebraska	<u>25</u>	1,913,827	<u>19</u>	1,913,827	264,491
Nevada	<u>29</u>	291,959	<u>22</u>	291,959	291,959
New Hampshire	<u>1</u>	422,515	<u>1</u>	422,515	186,711
New Jersey	<u>4</u>	1,255,829	<u>4</u>	1,255,829	1,255,829
New Mexico	<u>26</u>	262,437	<u>20</u>	778,442	262,437
New York	<u>3</u>	2,845,450	<u>3</u>	2,845,450	2,845,450
North Carolina	<u>8</u>	1,258,190	<u>7</u>	2,239,963	1,258,190
North Dakota	<u>25</u>	1,913,827	<u>19</u>	1,913,827	105,887
Ohio	<u>14</u>	1,784,284	<u>12</u>	1,784,284	1,784,284

Oklahoma	<u>23</u>	541,369	<u>18</u>	947,170	541,369
Oregon	<u>30</u>	1,346,522	<u>23</u>	1,764,310	535,276
Pennsylvania	<u>6</u>	2,527,088	<u>6</u>	2,527,088	2,167,299
Rhode Island	<u>2</u>	1,805,085	<u>2</u>	1,805,085	176,688
South Carolina	<u>9</u>	636,365	<u>8</u>	1,655,581	636,365
South Dakota	<u>25</u>	1,913,827	<u>19</u>	1,913,827	125,645
Tennessee	<u>12</u>	1,663,097	<u>10</u>	1,663,097	912,365
Texas	<u>22</u>	2,504,912	<u>17</u>	2,504,912	2,504,912
Utah	<u>31</u>	417,788	<u>23</u>	1,764,310	230,812
Vermont	<u>2</u>	1,805,085	<u>2</u>	1,805,085	96,542
Virginia	<u>7</u>	981,773	<u>7</u>	2,239,963	981,773
Washington	<u>30</u>	1,346,522	<u>23</u>	1,764,310	811,246
West Virginia	<u>6</u>	2,527,088	<u>6</u>	2,527,088	359,789
Wisconsin	<u>16</u>	834,673	<u>14</u>	2,555,008	834,673
Wyoming	<u>25</u>	1,913,827	<u>19</u>	1,913,827	71,284

**Note: each territory is its own PDP region.**