



The New Medicare Drug Benefit

Frequently Asked Questions



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The Nation's Voice on Mental Illness

The New Medicare Drug Benefit: Frequently Asked Questions

On January 1, 2006, the new Medicare drug benefit will go into effect. The new benefit, part of the Medicare Modernization Act that Congress passed in 2003, will offer voluntary coverage of outpatient prescription medications that will be administered through private sector Prescription Drug Plans (PDPs) and Medicare Advantage (MA) plans. Individuals dually eligible for both Medicare and Medicaid will be required to enroll in the new program—known as Medicare Part D—starting on November 15, 2005. Those dual eligibles who do not enroll on their own will be randomly “auto-enrolled” in a drug plan.

Included below are a series of frequently asked questions designed to help Medicare beneficiaries with mental illness and their families better understand how the new program will affect them.

Who is eligible for the new Medicare drug benefit?

All individuals eligible for either Medicare Part A or Medicare Part B and “dual eligibles” who qualify for both Medicare and Medicaid will be eligible for the new benefit. People with severe mental illness are disproportionately represented in this dual-eligible category by virtue of eligibility for both Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) and Medicaid “spend-down” programs offered at the state level.

How will dual eligibles with mental illness be affected by the new Medicare drug benefit?

The most important change for dual eligibles is that starting January 1, 2006, they will begin receiving their prescription drug coverage through Medicare, rather than Medicaid. Starting in January, state Medicaid programs will no longer offer coverage for prescriptions for persons who are dual eligible. It is expected that some states will elect to cover certain drugs that are excluded from the new Medicare drug benefit (including benzodiazepines), for which federal Medicaid matching funds will be available. It is important to note that individuals eligible only for Medicaid (including non-elderly people with disabilities eligible for SSI) will continue to receive drug coverage from their state Medicaid program.

Once enrolled in a Medicare drug plan, dual eligibles will not have to pay a monthly premium, meet an annual deductible, or experience any gap in coverage (the “doughnut hole” gap between \$2,250 and \$3,600

of drug cost). Instead, dual eligibles will only have to make minimal co-payments of \$1 for a generic and \$3 for a brand-name prescription. Once co-payment costs rise above a catastrophic limit of \$5,100 (a limit expected to vary from state to state), these minimal co-payments will be waived.

More information on Medicare drug coverage for dual eligibles is available through the Kaiser Commission on Medicaid and the Uninsured at www.kff.org/medicaid/loader.cfm.

How will dual eligibles be enrolled in Medicare Part D?

Starting in October 2005, Medicare will begin notifying dual-eligible beneficiaries of the need to enroll in a Medicare drug plan. NAMI is currently pressing Medicare to send copies of these marketing and enrollment materials to family members, agency case managers, and representative payees. These initial enrollment materials will offer dual eligibles a menu of plan options to choose from. These plan options will describe which medications are covered under each available plan and indicate whether or not specific medications are subject to access restrictions, such as prior authorization or “fail-first” requirements.

If dual eligibles do not enroll in a Medicare drug plan by the start of the enrollment period on November 15, 2005, Medicare will randomly “auto-enroll” them in a plan. Dual eligibles will be able to switch plans at any time on or after January 1, 2006.

How does the new drug benefit affect individuals who are institutionalized?

Institutionalized dual-eligible individuals will pay *no* cost sharing for drugs covered under Part D. This means that dual eligibles residing in nursing homes will have no cost sharing and can retain their limited personal needs allowances, as long as the plans available to them cover their medications adequately. Non-dual eligible individuals residing in long-term care facilities and other institutions will receive cost-sharing subsidies based upon their level of income and resources. Part D institutionalized individuals who up to now have been using private sources to pay for their drugs will benefit from Part D drug benefits through the catastrophic coverage available for expenditures in excess of \$5,100.

How can dual-eligible beneficiaries know whether or not one of their medications that is currently covered by their state Medicaid program will be covered by the Medicare drug plan they are enrolling in?

The materials that will be available in advance of the initial enrollment period are expected to allow for an understandable comparison of each plan and which drugs are either on or off their formulary list or subject to

any restriction on access (such as prior authorization, “fail-first” requirements, etc.). If a drug is off a plan’s formulary, the plan will be required to cover at least an initial 30-day prescription for a dual eligible—during which the beneficiary can seek an exception to the exclusion of the drug from coverage.

In addition, Medicare has advised plans that for dual eligibles they will be expected to cover every drug within six so-called vulnerable therapeutic categories. Among these six categories are antipsychotics, anticonvulsants, and antidepressants.

How will non-dual eligibles sign up for Medicare drug coverage?

Individuals who are not dual eligible will have to elect to participate in the new Medicare drug benefit. As with dual eligibles, they can begin signing up after November 15, 2005. Enrollment will be available through the mail, the Internet (at www.medicare.gov), by phone (at 1-800-MEDICARE), or at local Social Security offices. In addition, state health insurance programs (known as SHIPs) will be facilitating enrollment.

The initial open enrollment period will run through May 2006. After June 2006, those Medicare beneficiaries who are not dual eligible, or eligible for the low-income subsidies described below, will face a late enrollment penalty that will continue with them for the remainder of their eligibility.

Are subsidies available to low-income beneficiaries who are not dual eligibles?

Yes. For Medicare beneficiaries whose incomes are between 100% and 135% of poverty (up to \$12,920 for individuals and \$17,321 for couples in 2005) and whose resources are below \$6,000 (or below \$9,000 for a couple), subsidies will be available that will result in their having to pay no monthly premium and \$3 for a generic and \$5 for a brand-name prescription. Beneficiaries between 135% and 150% of poverty (up to \$14,355 for individuals and \$19,245 for couples in 2005) will face sliding-scale premiums and 15% co-insurance. In addition, they will have only limited cost sharing once drug spending surpasses the \$3,600 catastrophic limit of \$2 for a generic and \$5 for a brand-name drug.

Cost-sharing Requirements in the New Medicare Drug Benefit

	Optional Drug Coverage Above 150% Federal Poverty Level (FPL)	Between 135% and 150% FPL*	Under 135% FPL**	Dual-Eligible
Monthly Premium	\$35 per month (\$420 annually)	Sliding scale up to \$35	None	None
Annual Deductible (person pays in full)	\$250	\$50	None	None
Co-payment	25% up to initial coverage limit 100% up to \$3,600 out-of-pocket spending	5% of total costs up to \$5,100 catastrophic limit \$2 generic, \$5 brand-name thereafter	\$2 generic, \$5 brand name No co-pays after drug costs reach \$5,100	Under 100% FPL: \$1 generic, \$3 brand name No co-pays after drug costs reach \$5,100 Above 100% FPL: \$2 generic, \$5 brand name No co-pays for drug costs over \$5,100
Doughnut Hole	\$2,850 gap in coverage	N/A	N/A	N/A

A gap in drug benefits between the initial coverage limit of \$2,250, and a \$3,600 catastrophic threshold, in which there is no coverage for Medicare drug plan enrollees.

*135% to 150% of FPL – Up to \$14,355 for individuals and \$19,245 for couples, with under \$10,000 in assets for individuals, \$20,000 for couples.

**100% to 135% of FPL – Up to \$12,920 for individuals and \$17,300 for couples, with under \$6,000 in assets for individuals, \$9,000 for couples.

How can I apply for low-income assistance?

It is important to note that the process for applying for low-income subsidies is separate and distinct from the application for drug coverage under Medicare Part D. Applying for the low-income subsidy will *not* enroll an individual in a Medicare drug plan. It is merely a process of qualifying someone for the subsidy itself. This process of applying for and pre-qualifying for the subsidy is already open. Beneficiaries can apply on-line at www.medicare.gov or by calling 1-800-MEDICARE, or they may apply at a local Social Security office or through their state Medicaid agency. When applying, it is critically important that low-income beneficiaries (and their family members) inquire as to whether or not they are also eligible for other assistance programs such as the Medicare Savings Plan (MSP).

Once an individual qualifies for low-income subsidies, he or she can then sign up for drug coverage. Those eligible for low-income subsidies will not be subject to any late enrollment penalties.

What drugs will each Medicare drug plan be required to cover?

Medicare drug plans will be required to cover at least two medications within each therapeutic category. Plans will have discretion in deciding the breadth of the therapeutic classes they elect to cover. It is expected that most plans will be following model therapeutic categories recommended by the U.S. Pharmacopeia that Medicare will deem to be sufficient. At the same time, the law does provide for a strong anti-discrimination standard to prevent adverse selection. This standard allows the Secretary of Health and Human Services (HHS) the authority to demand that drug plans not use restrictive coverage policies for the purpose of discouraging beneficiaries with chronic illnesses or disabilities from enrolling.

As noted above, HHS is already insisting that drug plans offer coverage of every available drug within six distinct therapeutic classes commonly prescribed to the most vulnerable Medicare beneficiaries. These include antipsychotics, anticonvulsants, and antidepressants.

What are formularies, and who decides what medications are on a plan's formulary?

A formulary is a list of medications that are available to drug plan enrollees. Plan enrollees (and their doctors) are generally not able to access drugs excluded from a formulary unless they are able to successfully petition for an exception through a grievance or appeal. In addition, most drug plans “tier” medications within a formulary by requiring higher co-payments for some or by subjecting them to a prior authorization requirement. Under the Medicare drug program, plans using a formulary

will have to establish a Pharmacy and Therapeutics (P&T) Committee to develop and review the list. The law does not specify how often formularies have to be reviewed by P&T Committees.

Will drug plans be required to notify enrollees regarding formulary and coverage changes?

The MMA does allow plans to change a formulary (i.e., discontinue coverage of a medication, place it in a higher tier, etc.) in the middle of a plan year. However, when doing so, they must provide at least 60 days notice to doctors and pharmacists. During this period, plan enrollees will be able to seek either an exception for access to the excluded drug or the ability to continue coverage at a lower co-payment (an exception from a higher tier co-payment).

Is supplemental coverage available?

Yes. Enrollees with limited incomes are eligible for comprehensive coverage with no gap (i.e., no “doughnut hole”) in coverage. For most enrollees at 150% of poverty and below (up to \$14,355 for individuals and \$19,245 for couples in 2005), there are a number of options available:

- state pharmacy assistance programs;
- charitable assistance;
- supplemental coverage with Part D;
- certain programs offered by pharmaceutical manufacturers (most existing programs offered by drug makers are expected to continue, so long as they are deemed charitable organizations); and
- employer and union programs

What are true out-of-pocket costs (TrOOP)?

The new Medicare drug benefit creates a distinction between all enrollee out-of-pocket expenses and those that will be counted towards the annual Part D out-of-pocket threshold—the latter being known as “true” out-of-pocket (TrOOP) costs. These are costs actually paid by the beneficiary, by another person on behalf of the enrollee, or by a qualified State Pharmacy Assistance Program (SPAP) and not reimbursed by a third party (e.g., a supplemental insurance plan sponsored through a retirement plan) that will count toward the TrOOP threshold. Meeting this TrOOP threshold is critically important as it determines the start of catastrophic coverage and moves an individual through the “doughnut-hole” gap in coverage. Most third-party assistance, such as that from employers and unions, is not going to count toward the TrOOP threshold. Likewise, most out-of-pocket payments from drugs excluded from Part D coverage will not count towards TrOOP.

What exception, grievance, and appeals procedures are available for the Medicare drug plan?

The MMA requires all drug plans to put in place extensive procedures to allow plan enrollees to see exceptions from denials of coverage and appeal adverse decisions. These procedures are somewhat complicated, and concerns are already being raised that they will be difficult for vulnerable beneficiaries to navigate. Below is a detailed description of the exception, grievance, and appeal procedures in the Medicare drug benefit regulations that were issued in early 2005. For more information on these procedures, see the Center for Medicare Advocacy's fact sheet, Medicare Part D Appeals: A Mixed Bag for Beneficiaries, at http://www.medicareadvocacy.org/Reform_PartDAppeals.htm.

What exceptions processes will Medicare drug plans be required to have in place?

Prescription drug plans (PDPs) and Medicare Advantage (MA) plans will be required to have an exceptions process for enrollees to request that a formulary drug be provided at a lower tier for cost-sharing (thereby reducing the co-pay), or that a non-formulary drug be covered by the plan. Because exception requests are coverage determinations and are governed by the rules for coverage determinations, plans will be required to act within the time frame for standard coverage determinations (72 hours) or expedited coverage determinations (24 hours).

Plans will be able to grant exception requests to change the cost-sharing tier if it is determined that the non-preferred drug is medically necessary and that the preferred drug would not be as effective, or would have adverse consequences. In addition, the exceptions process must be able to address situations in which a formulary's tiered co-pay structure changes during the year and an enrollee is using a drug affected by the change. However, a plan does not have to cover non-preferred drugs at the lower, generic drug co-pay level if the plan maintains a separate tier dedicated to generic drugs.

Further, if the plan maintains a formulary co-pay tier in which it places very high-cost and unique items (e.g., certain biologics), it may exclude these very high-cost or unique drugs from its exceptions process. Participants may not use a plan's cost-sharing exceptions process to lower the co-payment for non-formulary drugs for which they have received coverage through the non-formulary drug exceptions process.

Plans must also grant an exception if they determine that a prescribed drug is medically necessary, consistent with the physician's statement, and that the drug would be covered but for the fact that it is an off-formulary

drug. For this purpose, “formulary” includes the application of cost-saving tools, such as dose restrictions, step therapy, and therapeutic substitution requirements—all of which would result in non-coverage of an otherwise coverable Part D drug.

Although the Medicare regulations include some criteria for plans to consider when evaluating an exception request, each PDP will have substantial flexibility to establish its own criteria and develop its own exceptions process. At the same time, Medicare will require plans to consider whether the requested drug is therapeutically equivalent to a drug on the plan’s formulary, as well as the number of drugs on the formulary within the same class and category as the requested drug. Additionally, the regulations leave it up to a plan’s discretion as to whether it will continue coverage after an exception has been granted into subsequent plan years.

What should a beneficiary do if a pharmacist or provider says the drug is not on the drug plan’s formulary?

Enrollees should first contact their plan to request an exception when they find out that their drug is not on the formulary or is not in the “preferred” cost-sharing tier level.

If the plan denies an exception, then the enrollee can appeal the plan’s decision. In general, the appeals system follows the Medicare Advantage process, which includes access to independent reviews of plan decisions. Enrollees, prescribing physicians, or enrollees’ appointed representatives can begin the appeals process.

Who can request an exception?

The consumer/plan enrollee, or his or her prescribing physician, may file a request for an exception. If the prescribing physician files the request, it must be filed with an oral or written supporting statement that the preferred drug on the formulary is not as effective for the consumer as the requested drug, or that the preferred drug has adverse effects, or both.

Can a drug plan accept a prior authorization request over the phone, or can a plan require a written copy?

The regulations do not specify requirements for a PDP’s drug utilization management activities, such as prior authorization, so long as they are reasonable and appropriate. If a PDP chooses to accept oral requests, the final rule does provide that the PDP may require submission of subsequent written supporting statements.

What are the levels and processes for coverage determinations and appeals?

1. The appeals process begins when the PDP or Medicare Advantage Prescription Drug Plan (MA-PD) issues a coverage determination.
2. Next, the plan enrollee may request a redetermination of an unfavorable coverage determination, and then the redetermination will be performed by the PDP.
3. Individuals who remain dissatisfied after the redetermination can request a further review, known as a reconsideration; the reconsideration will then be performed by an “independent review entity” (IRE).
4. The enrollee may appeal to an administrative law judge (ALJ) following an IRE review, and then to the Medicare Appeals Council, and finally to federal court.

An expedited review is available if the standards set out in Medicare Part C (Medicare Advantage Program) are met. Plans must notify enrollees of initial coverage determinations as quickly as the enrollee’s health condition merits, and must notify the enrollee no later than 72 hours after receipt of the request. Plans then have seven days in which to notify enrollees of a redetermination decision. Plans must act on requests for expedited coverage determinations no later than 24 hours after receiving the request, and must act on expedited redeterminations within 72 hours. An enrollee must file a request for a reconsideration with the PDP or MA-PD. The plan then forwards the enrollee’s request to the IRE within 24 hours if it does not act in a timely manner on the redetermination request. The Part D regulations require the IRE to issue its reconsideration decision within the same time frames noted above for issuing a redetermination.

What triggers a right to appeal?

Coverage determinations that trigger appeal rights include a PDP’s decision not to pay for a medication because the drug is:

- not on the plan’s formulary;
- not considered medically necessary;
- furnished by an out-of-network pharmacy; or
- not a drug for which Medicare will pay under Part D.

Likewise, an appeal is allowed when a coverage determination is not provided in a timely manner; when that delay would adversely impact the health of the enrollee; when a request for an exception is rejected; and if the individual is dissatisfied with a decision regarding the co-payment required for a drug.

Can the prescribing doctor or another person assist me with an appeal?

Yes, assistance can come from a provider, a family member, or another person able to assist with an appeal.

Will a dual eligible have the same due process rights under Medicare Part D as Medicaid?

Unfortunately, the regulations appear to exclude the current Medicaid protection that in most states allows for continued coverage of a prescription pending an appeal. Many dual-eligible enrollees will likely lose this important protection when they move into Part D coverage. Although some plans may choose to give their enrollees a 60-day supply of a prescription when there is a formulary change, instead of sending notice 60 days in advance, it is not required. Since the pharmacy will only be required to post notice or give a general notice to call the plan for further information, it appears that enrollees who want the 60-day supply will have to first contact the plan and then return to the pharmacy to get their medicine.



**Links to Detailed Information
on the New Medicare Drug Benefit**

The official Health and Human Services Web site on the Medicare drug benefit:

<http://www.cms.hhs.gov/medicarereform/pdbma/>

General information on the MMA and the new drug benefit is available at:

NAMI: *www.nami.org/medicare/mma*

The Alliance to Improve Medicare:

www.aimcoalition.org

The Kaiser Family Foundation:

www.kff.org/medicare/rxdrugdebate.cfm

More information about prescription drug savings for Medicare beneficiaries is available at:

Access to Benefits Coalition: *www.accesstobenefits.org*

Partnership for Prescription Assistance: *www.pparx.org*

More information on the transition of dual-eligible beneficiaries into the Medicare drug benefit is available at:

www.kff.org/medicare/duals.cfm



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