

VII. Access to Drugs and Formularies

This section covers:

- *Pharmacy networks*
- *Formularies*
- *Cost-containment strategies*
- *Transition policies*

Each Part D plan has a network of pharmacies from which an enrollee can routinely access his or her Part D drugs. Additionally, each Part D plan covers the prescription drugs that it places on a formulary, or list of covered drugs. Formularies may vary greatly among the plans. Plans may also encourage enrollees to use certain drugs on their formularies in an effort to control costs. All of these factors may affect a beneficiary's access to prescription drugs, and thus are important to consider when selecting a plan.

A. Pharmacy Networks

The Part D plans vary in the extent of their “pharmacy networks.” A pharmacy network is a group of pharmacies under contract with a Part D plan to provide its enrollees access to prescription drugs. Some drug plans also designate “preferred pharmacies” that offer the lowest prices and out-of-pocket costs. The Medicare Plan Finder lists network pharmacies by name and location, and further notes those that are preferred pharmacies. It is important to learn if a beneficiary's pharmacy of choice is in the plan's network, and if it is not, to make sure that convenient alternatives exist. Because the drug plans renew their contracts annually, network pharmacies may change from year to year.

Counseling Tip:
Pharmacies in a Part D plan's network charge the lowest cost-sharing amount. For non-routine situations and emergencies, beneficiaries may be allowed to use non-network pharmacies.

A Medicare drug plan may not pay for prescriptions at a pharmacy that is not in its network. Exceptions apply, however, in emergencies and some other situations. CMS requires the drug plans to ensure that their enrollees have adequate access to covered drugs at out-of-network pharmacies when someone “cannot be reasonably expected to obtain covered drugs at a network pharmacy, or when such access is not routine.” Thus, CMS expects the drug plans to cover prescriptions filled at an out-of-network pharmacy when a plan enrollee loses his or her covered drugs or becomes ill and needs a covered drug, and cannot get to a network pharmacy. Similarly, a drug plan should cover prescriptions that a hospital or clinic-based pharmacy fills when someone is an emergency or outpatient surgery patient.

It is also important to know that the MMA allows pharmacies to waive or reduce the cost-sharing amount (i.e. co-pay, co-insurance) for beneficiaries who are otherwise unable to afford their prescription drugs. Pharmacies, however, cannot do this on a routine basis. The amount paid by the pharmacy counts toward the beneficiary's true out-of-pocket

costs (TrOOP). *For more information on TrOOP, please refer to Section V “Costs and Prices.”*

For Example: For the past 20 years, Charlie has been going to the ABC Pharmacy, which is exactly 2 miles from his house. He will be turning 65 in one month, and will consequently lose his retiree coverage. He takes three prescription drugs, and has decided to enroll in a Part D plan. He is currently deciding between two PDPs, *Plan Complete* and *Plan Revitalize*. Both plans cover all three of his prescriptions; however, only *Plan Complete* lists the ABC Pharmacy as a “preferred” pharmacy in its pharmacy network. Because Charlie does not want to change pharmacies, he decides to enroll in *Plan Complete*.

B. Formularies

Medicare drug plans use "formularies," comprehensive lists of the drugs they cover, to define their drug benefits. The MMA allows each drug plan to develop its own formulary within certain limits. CMS reviews the formularies to make sure that they comply with federal law. It evaluates the formularies to ensure adequate access to medically necessary drugs and to make sure that no formulary excludes drugs in such a way as to discourage particular groups from joining a plan. For example, CMS would not approve a formulary if it did not include insulin and oral anti-glycemic agents, as such a formulary would discriminate against people with diabetes.

The MMA requires all Part D drug plans to provide access to medically necessary medications including generic and brand-name drugs. Plans' formularies must include at least two drugs in each treatment category and class that a drug plan sponsor designates, although CMS may require plans to include more than two drugs for some categories and classes. Medicare rules require the plans to cover “all or substantially all” drugs in six categories:

- anti-cancer drugs,
- anti-convulsants,
- anti-depressants,
- anti-psychotics,
- immunosuppressants, and
- HIV/AIDS drugs.

Counseling Tip:

Many plans actually cover more than two drugs in each class, though most plans do not have open formularies that cover *all* Medicare Part D allowable drugs.

There are a few exceptions to the "all or substantially all" standard. Medicare drug plans are allowed to exclude the following drugs from their formularies:

- **Iressa** (a cancer drug that has not been shown to extend life but is sometimes used for patients with non-small cell lung cancer who have not done well on other medicines); and

- **Fosphenytoin** (an anticonvulsant medication that is usually injected to control seizures when other anti-seizure medications are ineffective or cannot be taken orally such as during brain surgery).

For further clarification on this "all or substantially all" rule, please refer to:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf>.

Drugs Excluded from Part D Coverage

Aside from requiring coverage for drugs in certain categories, the MMA specifically excludes some drugs from Part D coverage. Part D plans do not cover prescription drugs when they are covered by Medicare Part A or Part B, such as chemotherapy drugs. Other drugs that the law generally excludes from Part D coverage are:

- drugs prescribed for weight-loss or weight-gain,
- drugs prescribed for the symptomatic relief of coughs and colds,
- prescription vitamins, with the exception of prenatal vitamins and fluoride,
- over-the-counter drugs, with the exception of insulin,
- prescription drugs to promote hair growth,
- fertility drugs,
- cosmetic drugs,
- drugs that must be monitored by testing services that only the manufacturer provides, such as certain anti-psychotic medications,
- barbiturates (drugs used to control seizures or used for sedation or anesthesia such as Phenobarbital® or Nembutal®),
- benzodiazepines, often referred to as minor tranquilizers, used to treat anxiety or insomnia (such as Xanax®, Valium® and Ativan®), and
- erectile dysfunction (ED) drugs, when prescribed for the treatment of sexual or erectile dysfunction¹.

Counseling Tip: The state Medicaid program may cover some Part D excluded drugs for full-duals. See Section VI "Help for Low-Income Beneficiaries" for more information.

¹ For Contract Year (CY) 2006 Erectile Dysfunction (ED) drugs met the definition of a Part D drug and were available on Plan Sponsor formularies. On October 26, 2005, Section 1860D-2(e)(2)(A) of the Social Security Act was amended to exclude ED drugs when prescribed for the treatment of sexual or erectile dysfunction for CY 2007 and beyond. Please see the CMS Q&A on ED drugs for more information: http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/QAEDDrugs_07.06.06.pdf.

More information on specific drugs that are generally excluded from Part D coverage is available at: <http://www.hapnetwork.org/assets/pdfs/Part-D-drugs-Part-D-Excluded-drugs.pdf>. (Please refer to Section II “Types of Plans” for more information on plans that may cover drugs that are excluded from the standard Part D benefit.) After reviewing the formularies in light of the standards above, CMS approves complying formularies for use in the Part D program.

Formulary Changes

Part D plans can change their formularies within certain limits.

- Medicare drug plans may only change the therapeutic categories and classes in their formularies once each year. These changes must occur between plan years, that is, a 2007 plan can change the categories and classes on its formulary for the 2008 plan year, but not prior to January 1, 2008.
- Plans may add a drug, drop a drug, or move drugs from one cost-tier to another on a monthly basis. The plans must notify CMS as these changes occur. The plans also must provide a 60-day notice to affected beneficiaries, or those who are currently taking a drug that is removed from the formulary or whose costs are changing because of a shift in a drug's tier placement. If the plan does not provide prior notice, it must authorize a 60-day fill of the drug and provide notice at the point of sale.
- Plans may not remove drugs from the formulary during the Annual Election Period (November 15-December 31 each year), nor during the first 60 days of the plan year.

C. Cost-containment Strategies

Price Competition

The federal government does not regulate the drug prices charged by plan sponsors in the Medicare Part D program. Part D plan sponsors, however, individually negotiate prices with drug manufacturers. Thus, drug prices vary from plan to plan. The plans' negotiated drug costs affect the length of time it takes an individual takes to reach the initial coverage gap or doughnut hole, as well as the full prices one pays for drugs once in the doughnut hole.

Utilization Management Systems

Along with price competition, the MMA allows drug plans to control costs through drug utilization management systems that may have an impact on a beneficiary's ability to access prescribed medications. The common elements in these utilization management systems are:

- cost-tiers,

- prior authorization,
- step therapy, and
- quantity limits.

Counseling Tip: It is important that a beneficiary choose to fill all of their medications at the same pharmacy to avoid drug interactions and better predict their drug spending.

As a SHIP counselor, keep in mind that even though a drug plan lists a client's medication as a covered drug on its formulary, a utilization management restriction may affect access to that drug. It may be necessary to ask the prescribing physician to make the case to the plan that your client's medical condition creates a medical need for the drug.

Cost-tiers

Many plan sponsors assign the covered drugs on a plan's formulary to different cost-sharing tiers. The MMA allows plan sponsors to design plans with as many as six tiers, though plans more commonly have three or four. Plans usually assign generic drugs to a low cost-sharing tier. A plan's co-payments for generic furosemide and brand-name Lasix®, for example, might be \$5 and \$40, respectively. The smaller co-payment in the lower tier works as an incentive for beneficiaries to select less costly drugs instead of the more expensive alternatives placed in higher tiers.

For Example: Bernard was enrolled in the "Lots of Drugs" plan, while his neighbor, Kyle was enrolled in the "Drugs R Us" plan. Both take diabetic medication and use the same local pharmacy. Bernard takes the brand-name drug Avandia, and Kyle takes the generic form metformin. Bernard's medication is on the fourth tier, and his co-payment is \$120 for a month's supply. Kyle's medication is a "tier two" generic drug, and costs only \$22 per month.

Prior authorization

Prior authorization requires an added step in filling a prescription. Plans typically use prior authorization requirements to control the use of higher cost medications. The MMA gives plan sponsors considerable latitude to design their prior authorization systems. The plans can use different forms, and may ask physicians to provide more or less documentation to establish the need for a drug. Thus, it may be easier for prescribing physicians to secure prior authorization in one plan as opposed to another. SHIP counselors may be in a position to help clients with information about the exceptions and appeals process following an unsuccessful request from the plan for prior authorization.

For Example: Bernard’s physician has prescribed a brand-name diabetic drug, Avandia. The plan covers the generic form of the drug, metformin, but requires prior authorization for Avandia. Bernard’s doctor contacted the plan and provided documentation, through notes in his medical record, that Bernard had tried the generic form in the past and that it caused him to retain fluid. He also provided information from clinical trials to tie Bernard’s reaction to a proven side effect. The drug plan approved the physician’s request for coverage. This approval by the plan applies only to Bernard; it does not change its policy about covering Avandia for other enrollees who cannot take the generic form.

Step therapy

Step therapy is a cost control method that requires beneficiaries to use a less expensive medication, long-established as effective in treating a condition, before moving on to the next “step” in the process, involving a higher cost, newer, brand-name drug. Drug plans that require step therapy for a particular drug will not pay for the more expensive drugs, in the second and third steps, until the beneficiary tries the less expensive first step, and it proves to be ineffective or harmful. When beneficiaries have already tried the less expensive drug unsuccessfully, the doctor should contact the drug plan to request an exception. *Please refer to Section VIII “Coverage Determinations and Appeals” for more information on how to file an exception.*

For Example: Carmen’s doctor prescribed Prevacid to treat symptoms of acid reflux disease. The cost for a 30-day supply of the 15mg tablets is \$135. Carmen’s drug plan required her to first try Omeprazol at \$25 per month. The pharmacist contacted her doctor to ask if she could take Omeprazol instead of Prevacid. Because Carmen had a history of negative reactions to the less expensive drug, her doctor contacted the plan to ask it to cover the brand-name drug. The plan would not pay for the Prevacid until the doctor described in writing the poor results Carmen had with Omeprazole.

Quantity limits

Plans may limit the amount of medication that they pay for over a certain period of time. Some plans may only pay for a 30-day supply of tablets, even though a physician may prescribe more.

For Example: Ethel takes Toprol XL, a maintenance medication for chronic heart failure. She has done well on this drug. Her doctor plans to keep her on the same regimen indefinitely, but her drug plan will only cover a 30-day supply even though her doctor wrote her a 60-day prescription. To avoid health complications, Ethel will need to request an exception to the 30-day quantity limit. *Please refer to Section VIII “Coverage Determinations and Appeals” for more information on how to file an exception.*

The MMA allows Part D drug plans to use all four of these cost containment strategies. SHIP counselors should expect that their clients will encounter one or more of them as a potential road-block in access to prescribed drugs. Thus, it is important for clients to understand their rights, and know how to exercise them, when a drug plan's cost control requirements impede needed care.

Counseling Tip: Plans are generally not allowed to limit the use of antiretroviral drugs through utilization management systems. There is, however, one exception—Fuzeon, a brand-name drug for enfurvitide, which is used to control HIV. Fuzeon (which may also be called T-20 or Pentafuside) must be on all formularies, but prior authorization may be required for first-time users.

Counseling Tip: Our health is unpredictable; therefore, it is impossible to predict “the best plan” for the unforeseeable future. When enrolling in a plan, it's usually best to encourage beneficiaries to choose a plan that meets their needs at that point in time.

Counseling Questions:

When selecting a plan, a beneficiary should keep in mind the plan's pharmacy network, the formulary, and its use of utilization management controls.

- Is the beneficiary's pharmacy of choice in the plan's network, and if so, is it one of the plan's “preferred” pharmacies? If not, does the plan offer convenient alternatives, such as mail-order?
- Are all of the beneficiary's drugs on the plan's formulary? If not, which plans covers most of his or her drugs?
- What cost-tiers do the beneficiary's drugs fall into? How many of his drugs are on the lowest tier? the highest tier?
- Does the plan place any utilization management requirements, such as prior authorization and quantity limits, on the beneficiary's prescribed drugs?

D. Transition Policies

All Part D drug plans have “transition policies” through which enrollees sometimes can obtain a temporary fill of their prescription drugs, even if the drugs are not on a plan’s formulary. CMS requires these “transition fills” in some situations, and suggests them in others. While CMS has set forth minimum transition policy requirements to address the needs of new and current drug plan enrollees, the agency allows plans to craft their own transition policies. Because the policies may vary from plan to plan, with some exceeding the minimum requirements, it is important for your clients to check with their drug plans to learn how the transition policies might affect them.

New Enrollees

Under the MMA, Part D plans must offer a transition process for beneficiaries who are either enrolling in a Part D plan for the first time (i.e., new Medicare beneficiaries, beneficiaries who recently lost creditable coverage) or are enrolling in a different plan. This includes beneficiaries who are joining a Part D plan through a Special Enrollment Period (SEP). Under the transition process, plans must provide new enrollees with a temporary, 30-day supply of a non-formulary drug, including a drug dispensed under a utilization management restriction (e.g., prior approval) that he was taking before enrolling in the Part D plan. Plans may choose to extend the 30-day supply for these new enrollees, but at a minimum they must provide a 30-day supply. Plans must cover this temporary supply, or transition fill, when a beneficiary goes to the pharmacy to fill a prescribed medication within 90 days of his drug coverage becoming effective. If a beneficiary goes to the pharmacy 100 days after his plan became effective, the plan may not provide a transition fill as it is not required by CMS.

Counseling Tip:
Clients may want to check the plan’s transition policy before deciding to enroll in or switch to a plan.

The transition process is also an opportunity for enrollees to work with the prescribing physician to find an alternative drug that is on the plan’s formulary or to file an exception to request coverage for the drug. Medicare rules require plans to give new enrollees a written notice that states that they must either switch to a therapeutically equivalent drug that is on formulary or request an exception from the plan to continue taking the drug for the remainder of the calendar year. Plans work with pharmacies to distribute the notice to enrollees when they receive a transition fill. In the event that a prescription is not filled and such a notice is not distributed, it is best to contact the plan for further information on the plan’s reasons for denying coverage and the appropriate next steps. For 2008, CMS has provided plans with a model transition letter ([http://www.hapnetwork.org/medicare-drug-coverage/aep-toolkit.html#Formulary and Transition](http://www.hapnetwork.org/medicare-drug-coverage/aep-toolkit.html#Formulary_and_Transition)). Please see Section VIII “Coverage Determinations and Appeals” for more information on how to file an exception.

For Example: Charlie recently enrolled in an MA-PD, *PlanChoice*, after losing creditable coverage through his former employer. For the past five years he has been taking a brand-name drug to help control his asthma. Although the other seven drugs that he is currently taking are on *PlanChoice*'s formulary, his asthma drug is not. Charlie was planning to rely on his son and daughter-in-law to help him cover the out-of-pocket costs for this drug. After his enrollment in *PlanChoice* became effective, he went to the pharmacy to fill his asthma prescription and to his surprise, found that the plan covered his prescription. He said nothing to the pharmacist, but he later called the plan to see if the formulary had changed. The plan told him that he had in fact received a transition fill, and that he should talk with his doctor about prescribing an alternative drug that is on the plan's formulary or consider filing an exception.

Counseling Questions:

It may be difficult to help a client understand why a prescribed medication cannot be filled and what the "next steps" are. Below are some questions to consider:

- Did the pharmacy fill a prescription for the client? Did the client pay the full cost out-of-pocket?
- If not, did the pharmacist explain why the plan did not cover a prescribed drug? Did the pharmacist give the client a notice saying that he must either switch to a therapeutically equivalent drug that is on formulary or request an exception from the plan to continue taking the drug for the remainder of the calendar year?
- Has the client spoken with his or her prescribing physician about taking a therapeutically equivalent drug that is on the plan's formulary? If there is no alternative, has the client asked the doctor to help file an exception with the plan?

Current Enrollees

For 2008, CMS *expects* Part D plans to have a transition process for enrollees in plans in 2007 who chose to stay with the same plan for 2008 but who may be negatively affected by a change in the plan's formulary. Such changes include the removal of a drug from the formulary or a change in the cost-sharing amount, both of which may result in a coverage lapse or higher out-of-pocket payments. CMS *expects* plans to implement one of two options.

1. Plans can provide a transition process for current enrollees that is consistent with the process for new enrollees in 2008. Under this option, CMS rules require plans to provide enrollees with a written notice that states how they must either switch to a therapeutically equivalent drug that is on formulary or request an exception from the plan to continue taking the drug for the remainder of the calendar year. Plans must distribute the notice to enrollees at the pharmacy when the transition fill is provided. In the event that a prescription is not filled and such a notice is not distributed, it is

best to contact the plan for further information on the plan's reasons for denying coverage and the appropriate next steps to prevent future problems. CMS has provided plans with a model transition letter

[http://www.hapnetwork.org/medicare-drug-coverage/aep-toolkit.html#Formulary and Transition](http://www.hapnetwork.org/medicare-drug-coverage/aep-toolkit.html#Formulary_and_Transition)).

2. Alternatively, plans could establish and implement a transition process for current enrollees prior to January 1, 2008. This option requires plans to prospectively transition current enrollees to a therapeutically equivalent drug on the formulary or complete requests for formulary and cost-sharing exceptions prior to January 1, 2008. If a plan does not do either, it must provide a temporary fill until the beneficiary has transitioned to a new drug on the formulary or until it has granted an exception.

For example: Mary joined a Part D plan in February of 2007, and decided to remain in the same PDP, *Plan Supreme*, for 2008. In 2007, she paid \$25.00 for a brand-name drug for her arthritis. In November 2007, she learned that her share of the cost would increase to \$50.00 in 2008. Because Mary lives on a fixed income and takes six other prescription drugs, she cannot pay the additional \$25.00 per month. She checked with her prescribing physician about switching to another drug, but he advised against it. Mary filed an exception to the cost-sharing amount on December 30, but as of January 2 she had not heard from the plan. When she went to fill her prescription on January 2, the pharmacist provided a transition fill. On January 3, she heard from the plan that she had been granted an exception to the higher cost-sharing amount. As a result, she will continue to pay \$25.00 for her drug in 2008.

For more information about the transition process, please see “*Summary of CMS Transition Process Requirements and Expectations.*”

Summary of CMS Transition Process Requirements and Expectations

Transition Process	CMS Requirements and Expectations
New Enrollees	
New enrollees into prescription drug plans on January 1 following the Annual Election Period (non-long-term care beneficiaries)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to enrollment (including Part D drugs that are on a plan's formulary but required prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan.
Newly eligible Medicare beneficiaries from other coverage into a Part D plan (non-long-term care beneficiaries)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to enrollment (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan.
Current Enrollees	
Individuals who switch from one Part D plan to another after January 1; (non-long-term care beneficiaries, including re-assignees and any individual moving to a new plan)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to switching plans (including Part D drugs that are on a plan's formulary but required prior authorization or step therapy under a plan utilization management rules) within the first 90 days of their coverage under the new plan.
Enrollees who remain in same plan they were enrolled in for 2007 but experience negative formulary changes in 2008 (e.g., taking a drug that was on-formulary in 2007, but is not on-formulary in 2008 or had an exception granted in 2007 that will not be honored in 2008)	<p>Negative formulary changes:</p> <ol style="list-style-type: none"> 1. <u>Provide a transition process for current enrollees consistent with the transition process required for new enrollees beginning January 1, 2008.</u> In order to prevent coverage gaps, plans choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated), consistent with the 2007 Formulary Transition Guidance (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/TransitionGuidance_Final.pdf), and provide enrollees with notice that they must either switch to a therapeutically appropriate drug on the plan's formulary or get an exception to continue taking the requested drug; or 2. <u>Effectuate a transition for current enrollees prior to January 1, 2008.</u> In effectuating this transition, plans must aggressively work to (1) prospectively transition current enrollees to a therapeutically appropriate formulary alternative; and (2) complete requests for formulary and tiering exceptions to new formulary prior to January 1, 2008.

<p>Enrollees who remain in same plan they were enrolled for 2007 and are on a drug as a result of an exception that was granted 2007</p>	<p>Plans have the option of “honoring” exceptions that were granted in 2007 beyond the end of the plan year (i.e. a plan may choose to continue to grant an exception for as long as the beneficiary remains in the plan). If a plan is NOT going to honor an exception beyond the end of the plan year, it must notify the enrollee in writing at least 60 days before the end of the 2007 plan year and wither (1) offer to process a prospective exception requests for the 2008 plan year or (2) provide the enrollee with a temporary supply of the requested prescription drug (where not medically contraindicated) at the beginning of 2008 and provide the enrollee with notice that they must either switch to a therapeutically appropriate drug on the plan’s formulary or get an exception to continue taking the requested drug.</p>
<p>Enrollees who remain in same plan they were enrolled for 2007 and are on a drug that has a PA requirement that is expiring</p>	<p>Prior to the beginning of the new plan year, enrollees may either attempt to satisfy the PA requirements by requesting a coverage determination, or requesting a formulary exception if they cannot satisfy the PA requirement.</p>
<p>Enrollees who request an exception, but the plan fails to issue a timely decision on the request by the end of the transition period</p>	<p>Per the March 30, 2006 memo “Critical Steps as Transition Period Ends,” (http://www.hapnetwork.org/assets/pdfs/transition-appeals-03-30-FINAL.pdf) CMS expects plans to make arrangements to continue providing requested drugs via a case-by-case extension of the transition period to the extent that the individual’s exception request or appeal has not been processed by the end of the minimum transition period.</p>