

# Navigating the Medicare Part D Prescription Drug Coverage Program

A Guide for People with Disabilities, Benefits Counselors, Disability Organizations and Others On Ensuring Adequate and Appropriate Access to Prescription Drugs



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## **Introduction**

Starting in 2006, Medicare beneficiaries have the right to purchase prescription drug coverage. Drug coverage was added to Medicare through the establishment of the Part D program in which individuals voluntarily enroll in a private plan offering stand-alone drug coverage (meaning that the plan only provides prescription drugs and is not responsible for physician, hospital or other Medicare benefits which individuals obtain through the traditional Medicare program)—or participate in a Medicare Advantage health plan (which is also called Medicare Part C or managed care) that offers drug coverage as a component of its benefits package. While technically voluntary, dual eligibles (low-income seniors and people with disabilities who receive both Medicare and Medicaid services) had their Medicaid drug coverage stop when the Part D program started, and these individuals have been transitioned into Medicare prescription drug plans. Even though dual eligibles retain their Medicaid coverage for other services, they cannot receive prescription drug coverage for most of their prescription drug needs.

This guide is for Medicare beneficiaries with disabilities, friends and family members, benefits counselors, physicians and services providers, disability organizations, and others who seek to assist individuals in accessing the prescription drugs that they need. The purpose of this guide is to identify action steps for being an empowered advocate for an individual’s own prescription drugs and other service needs by describing the rules and policies of the Part D prescription drug coverage program. We believe having access to this information is critical for individuals to take appropriate actions if they encounter difficulties accessing benefits under the Part D program.

This guide is a companion to a document published in late 2005 that is focused on helping people with disabilities understand and enroll in a prescription drug plan. That document, called, *Understanding Changes in Prescription Drug Coverage for People with Disabilities on Medicare: A Guide for People with Disabilities, Benefits Counselors, Disability Organizations and Others on Transitioning to the Medicare Part D Prescription Drug*

*Benefit*, is available in multiple accessible formats free-of-charge at <http://ihcrp.georgetown.edu/rxchanges.html>. One area covered by the transition guide that is not covered here relates to the costs associated with Part D drug coverage and the assistance that is available to dual eligibles and other low-income Medicare beneficiaries called *Extra Help*. If you have questions about the cost of prescription drug coverage and *Extra Help*, you are encouraged to consult the transition guide.

Before we get started discussing how to navigate the Part D program, we would like to give you some very basic information of how prescription drug coverage fits in with other parts of the Medicare program.

Medicare consists of several program components, or parts, and each provides different benefits:

<b>Part A</b>	Hospital insurance, including skilled nursing, some home health, and hospice services
<b>Part B</b>	Physician and outpatient services, some home health care, durable medical equipment, and ambulance services
<b>Part C</b>	Alternative to receiving traditional Medicare. Beneficiaries enroll in a Medicare Advantage health plan instead of participating in the other parts of Medicare
<b>Part D</b>	Prescription drug coverage program (beginning

All Medicare beneficiaries participate in the **Part A program**. Medicare Part A pays for hospital expenses, including hospitalizations in specialty psychiatric hospitals. Medicare Part A also pays for up to 100 days in a skilled nursing facility and for skilled home health services; for persons with a life expectancy of six months or less, it pays for hospice services.

The **Part B program** is voluntary. The Part B program provides medical insurance that pays for doctors' visits/services, skilled home health services, durable medical equipment, outpatient hospital services, ambulance services, and lab tests. The Part B program also covers certain preventive health care services.

**Parts A and B are sometimes referred to as "traditional Medicare."**

The **Part C program** is a voluntary program providing options to enroll in a Medicare managed care program. The Part C program operates Medicare Advantage health plans that provide an alternative to participating in Parts, A, B, and D. Medicare Advantage plans combine the benefits of the other parts of Medicare into a health plan that takes responsibility for providing all Medicare benefits.

The **Part D program** is a voluntary program affording individuals the opportunity to purchase Medicare prescription drug coverage. This new program began in January 2006 and is the focus of this guide.

### **Take Action to Advocate for Yourself**

In an ideal world, people with disabilities and others would always get their health and long-term services needs met without any problems arising. Unfortunately, in the real world, glitches happen and barriers need to be overcome.

It is important, therefore, for individuals to take a key responsibility for ensuring that they get the services they need. The Part D program will provide first time prescription drug coverage for many and replace existing coverage for others. Its creation comes at a time when prescription medications increasingly are becoming major tools people with disabilities and long term illness will use to enhance their health and independence. The Part D program can greatly enhance the access many have to medically necessary prescription drugs. But, Part D also may pose new barriers to individuals getting the drugs they need. This is why it is vital that individuals recognize that they still have important rights and opportunities to advocate for themselves. As a Medicare beneficiary, you need to understand how the Part D program works and the action steps you can take to make sure you receive high quality care—and appropriate access to prescription drugs. We strongly recommend that anyone on Medicare should take the following actions:

#### **1. Make sure you have a strong partnership with your doctor and other services providers.**

Developing a strong and open relationship with your doctor(s) could be the most important single step you can take to ensure that you get your needs met. This requires finding doctors with whom you can be honest and communicate openly. Trust is a two way street. You should be able to count on your doctor to listen to what you tell them about your health and well being and your doctor should be able to trust that the information you give them is as full and accurate as possible. This may be particularly true with regard to your prescription drug needs. If you have health problems that you don't feel comfortable discussing with your doctor, then this is a problem. If this applies

to you, ask yourself a couple of questions: Would you feel more comfortable talking with a different doctor? If so, maybe you need to look for a different doctor. If the answer is no, maybe you need to explore what is preventing you from communicating openly. Would you feel more comfortable if a spouse or other person accompanied you? Some people find it helpful to write down, before the doctor's appointment, all of the questions they wish to ask their doctor.

Other accessibility issues – e.g., the lack of transportation, barriers getting into the doctor's office, and other obstacles to effective communication – also can undermine the relationship between you and your doctor. If this is true for you, we encourage you to try to resolve such barriers by working with your physician and others.

Taking these types of proactive steps is crucial because having a good relationship with doctors and other health care providers is essential to good care. It is especially important to appropriate drug coverage under the Part D program because the doctors who treat Medicare beneficiaries have a critical role to play in advocating for their patients. In nearly all cases, your doctor can be your most influential advocate for why you need coverage of a specific drug. Also, some of the policies in the Part D program that are intended to protect Medicare beneficiaries will require the doctor who is treating you to assert that she/he believes that only a specific drug is appropriate for you.

#### **2. Keep your own records.**

Many times, plans may not approve coverage for a prescription because clinical standards established by the plan do not indicate that a particular drug is safe, effective, or cost-effective (if a cheaper, but effective drug is also available). Some times when a plan denies coverage for a prescription drug, the denial is in the best interest of the beneficiary. A plan also has an economic incentive to push individuals to take alternative drugs that cost less money. There are times when the cheaper drug is safe and equally effective for

the individual. Therefore, you should not automatically resist every decision by your plan that does not automatically result in your pharmacist filling a prescription. At the same time, decisions over when it is safe to substitute one drug for another should not be made solely by a Medicare beneficiary or their Part D plan—these decisions should be made in close consultation with the doctor who has prescribed the drug.

But, a plan's coverage policies may not meet your specific needs and that's where good record keeping are essential. In many cases, plans will deny coverage for a specific drug until you can provide evidence that the specific drug is needed. Again, the doctor who treats you will likely be the primary source of evidence that you need a specific drug. You can help your doctor and yourself, however, by supplementing this information by keeping good records. How long have you had the condition that the prescription is intended to treat? Has it gotten better (or worse) over time? Have you tried any other drugs to treat this condition? Do you have any allergies that prevent you from taking certain drugs? Have you ever experienced side-effects from taking any drugs? ...all of these types of questions could be helpful in establishing to your plan that you need a specific drug.

Many people who help people with disabilities advocate for themselves recommend that individuals keep a health care journal, as well as develop a system for keeping accurate records. One simple system that works for some people is to get a blank notebook and a large box. In the notebook, individuals could divide it into several sections that include:

- **Doctor Contacts:** This section allows you to write down the name, address and contact information of all of your doctors and health care providers. This could also include the names and addresses of your preferred hospital, as well as others, such as personal assistance providers, and people to be contacted in an emergency.
- **Prescription Drug Log:** This section could be used to keep a record of all drugs you are taking or have ever

taken. Include the date you start taking the drug (and the date when you stop). The name of the drug, the dosage, and the reason you take the drug, special instructions (i.e. take with food), and any other comments.

- **Diary of Health Concerns:** In this section, you could write down, all of your health concerns, as they arise. This means writing down the date, the problem you are experiencing (i.e. weakness in my right leg), what you do to correct the problem (i.e. went to see Dr. Smith) and what is the outcome (i.e. prescribed 10 sessions of physical therapy). In this way, you can look back over many years and see all of the health issues that you have had, and you have a record of all of the different steps you have taken to resolve the problem. You should also write down whenever you experience a problem, even if you do not take any specific action. For example, if you experience nausea on a regular basis, it could be helpful to have a record of how many times you have had this problem over a six month period.
- **Diary of Health Plan Issues:** In this section, you could write down all situations when a health plan has denied coverage for a drug or service, or taken any action with which you disagree. This means writing down the date, what the plan did (i.e. denied coverage for drug X because they said it was not medically necessary), and any steps that you took (i.e. asked pharmacist to assist with obtaining prior authorization). Other actions that you may need to take include contacting your doctor or calling your health plan. Whenever you make such a call—or send a letter—make sure that you write down the date, the number you called, the person you spoke to, what they told you, and what the next steps are, if any.
- **Other:** Different people have different organization styles. You can also add additional sections if this is helpful to you.

The box that goes with your notebook/journal is to store all paper records that you receive. Put in here every piece of paper you receive from your doctors, from any hospitals or clinics, and any letters or communications from your plan. Keep this information for many years. Given that many people use a lot of services and have multiple doctors or other providers, it is probably a good idea to divide this into separate sections, such as through the use of file folders, with one for each doctor, one for your health plan, etc. You

also could keep a file containing much the same information on your computer and print out a hard copy of it whenever you need it. Good records can be kept in a variety of ways. Choose the one that works best for you.

Be sure to let your physician(s), pharmacy, Part D plan and other providers know that you are keeping such records. This will let them know you are well informed about your own health and well being. It also will encourage them to ask for information they might not otherwise have.

### **3. Educate yourself about your health coverage and your personal needs.**

In the past, many people were raised to believe that they were supposed to defer to their doctors and not challenge their decisions. In recent years, public attitudes have changed—not to make doctors less important, but to elevate the role of individuals in making their own decisions about their health and services. Many people now find it is often more useful to think of themselves as the primary decision maker about their health care, with their doctors as their senior advisors. In order to assert this appropriate role as the primary decision maker, however, individuals have obligations to themselves to learn as much as they can about their own health.

You do not need to become a doctor—or try to claim expertise that you do not have. But, you should try to learn as much as possible about your disability or other health problems—and steps that you can take to protect and enhance your own health and independence. A common frustration of many doctors is that they prescribe a course of treatment that their patients do not follow. You should not be forced to undertake any treatment regimen with which you do not feel comfortable—and you can change your mind about whether or not a course of treatment is right for you. But, absent a reason to change a course of treatment, you do have a responsibility to adhere to any course of

treatment as closely as possible. Part of making sure you do as much as possible to protect your health—and minimize the impact of disability—is to ask yourself whether you are contributing as much as you can to your health—and your partnership with your health care providers.

### **4. Know and follow your plan's rules.**

Your prescription drug plan is also critical to ensuring that you get the drugs you need. While plans may appear unapproachable and it may be hard to understand why they act the way that they do, they are an important partner in working with you...and if they deny you drugs that your doctor has prescribed for you, then you need to follow their rules for trying to get them to change their mind—or to get to an outside appeals process. Later sections of this guide will explain why prescription drug plans operate the way that they do, and will explain your rights under the exceptions, grievance, and appeals processes.

### **5. Know how to solve problems.**

There is an old adage that says that the squeaky wheel gets the grease. The same principle is applicable to people with disabilities that need access to prescription drugs and other services. Many people are denied drugs or other services and they just go away. The squeaky wheels—the people who call their plans to complain or who ask for exceptions—are most likely the ones who get what they need. Sometimes, a plan will have legitimate reasons for declining to cover drugs for individual beneficiaries. Other times a plan's denial decision deserves to be challenged. In both instances, one of the ways that you can ensure that you get the drugs you need is to follow your plan's rules—and use information or your doctor's support to advocate for yourself.

## Overview of the Medicare Part D Drug Coverage Program

The Medicare Part D program is the new part of Medicare that provides prescription drug coverage. The law that created the Part D program was called the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This is sometimes abbreviated as the Medicare Modernization Act or the MMA. If people refer to MMA prescription drug coverage, they are talking about the Part D program.

*Extra Help* is a component of the Medicare Part D program that provides financial assistance to dual eligibles and other low-income Medicare beneficiaries (with countable income up to 150% of the federal poverty level, \$1,225 in monthly income for a single individual and \$1,650 for couples in 2006) to assist with the costs of obtaining prescription drug coverage. The benefits of the *Extra Help* program—and how to apply—are described in greater detail in the transition guide. Information about how to obtain this document is provided at the beginning of this guide. To apply for *Extra Help*, you can contact your local Social Security office or the Medicaid office. If you apply through the Medicaid office, you should also be screened for Medicaid eligibility and for the Medicare Savings Programs. To find our local Social Security office, go online to: <http://s3abaca.ssa.gov/pro/fo/fo-home.html>. Individuals can also call toll-free 1-800-772-1213. For people who are deaf or hard of hearing, the toll-free TTY line is 1-800-325-0778. Telephone, fax, and internet contact information for state Medicaid programs can be found at [www.cms.hhs.gov/medicaid/allStateContacts.asp](http://www.cms.hhs.gov/medicaid/allStateContacts.asp). Or, for the phone numbers for the Medicaid program in your state, call directory assistance.

### ***Who can purchase Part D prescription drug coverage?***

All Medicare beneficiaries are eligible to participate in the Part D program. This includes persons entitled to

Medicare Part A coverage and anyone enrolled in the Part B program.

### ***What benefits does the Part D program provide?***

Part D prescription drug coverage provides coverage for prescription drugs and biologicals (such as insulin). As a general rule, Part D drug coverage does not cover over-the-counter drugs (drugs that can be purchased without a prescription). Part D also does not cover drugs already covered by other parts of the Medicare program. There are a certain group of drugs, called “Medicaid excludable drugs” (described below), which Part D plans generally cannot cover, except for products used to help people quit smoking.

While the cost-sharing responsibilities of Medicare beneficiaries changes as their annual drug costs rise, there is no upper limit on the amount of drug coverage an individual has—no Medicare beneficiary can be told that they have exceeded the coverage limit for prescription drugs under the Part D program.

### ***What drugs are covered by other parts of the Medicare program?***

Part D prescription drug plans are prohibited from covering drugs covered by other parts of Medicare. As a general rule, drugs that are covered by other parts of Medicare include prescription medications provided during a stay in a hospital or skilled nursing facility which are paid for by the Part A program and limited circumstances when the Part B program covers prescription drugs. In general, the Part B program can pay for outpatient prescription drugs in the following circumstances:

1. Drugs billed by physicians and typically provided in physicians offices (such as chemotherapy drugs);
2. Drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer;
3. Drugs billed by pharmacy suppliers and self-administered by the patient (such as

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immunosuppressive drugs and some oral anti-cancer drugs);

4. Separately billable drugs provided in Hospital Outpatient Departments; and,
5. Separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO).

### ***What happens if there is confusion over whether Part D or another part of Medicare should pay?***

There may be some cases when there is confusion over whether Parts A or B will pay for a drug or whether Part D should provide coverage for the drug. Part D cannot pay for drugs when Part A or B should pay, even if an individual is unable to get Part A or B coverage for the drug. In cases where there is a dispute over which part of Medicare is responsible for coverage of a specific drug, see the following document from the Centers for Medicare and Medicaid Services (CMS) which provides guidance and scenarios for deciding which Part of Medicare is responsible for coverage:

[http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc\\_07.27.05.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf)

### ***What are the “Medicaid excludable drugs”?***

Part D prescription drug plans are prohibited from covering Medicaid excludable drugs under standard coverage plans, with the exception of smoking cessation products. Medicare plan sponsors that offer standard coverage plans, however, can offer enhanced coverage plans for a higher premium, and these plans are permitted to cover the Medicaid excludable drugs.

The following are Medicaid excludable drugs:

1. drugs when used for anorexia, weight loss, or weight gain;
2. drugs when used to promote fertility;
3. drugs when used for cosmetic purposes or hair growth;
4. drugs when used for the symptomatic relief of coughs and colds;

5. drugs when used to promote smoking cessation (can be covered by Part D plans);
6. prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;
7. nonprescription drugs;
8. covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;
9. barbiturates; and,
10. benzodiazepines.

These listed exclusions were enacted into law in the Omnibus Budget Reconciliation Act of 1990 and are sometimes referred to as “OBRA exclusions” or “OBRA-90” exclusions.

Although Medicaid generally cannot receive federal funding for prescription drugs for Medicare beneficiaries, this prohibition does not apply to excludable drugs. Indeed, if a state covers these excludable drugs for other Medicaid beneficiaries, then they must cover them for dual eligibles, when they are medically necessary. So, dual eligibles (i.e. seniors and people with disabilities who receive both Medicare and Medicaid) who need excludable drugs may be able to get coverage for them from their state Medicaid program.

### ***What types of plans will provide Part D prescription drug coverage?***

The Medicare Part D program does not provide a Medicare benefit directly. Rather, it creates a right for Medicare beneficiaries to purchase prescription drug coverage from a Medicare prescription drug plan. Prescription drug plans can be stand alone plans (called PDPs) or individuals can enroll in a Medicare Part C managed care plan (now called Medicare Advantage health plans or MA plans). For this guide, all references to prescription drug plans apply to both types of prescription drug coverage.

### ***What are prescription drug stand alone plans?***

Stand-alone plans are programs offered by insurers or other entities that provide coverage only for prescription drugs, and no other health care services. For Medicare beneficiaries wishing to participate in the traditional Medicare program, they should select a stand-alone plan to receive their prescription drug coverage.

### ***What are Medicare Advantage plans?***

Medicare Advantage plans combine the benefits of the other parts of Medicare into a single health plan that takes responsibility for providing all Medicare benefits. In some instances, this can improve coordination among providers and lead to a better quality of care.

But, there are important trade-offs to think about when considering enrolling in a Medicare Advantage plan. Some plans offer premiums and cost-sharing that is lower than in traditional Medicare. Some plans offer expanded benefits. Typically, plans are able to do this, in part, by tightly managing the benefits. This could mean that if an individual enrolls in a Medicare Advantage plan they may not be permitted to see all of the doctors they want. Before enrolling in a Medicare Advantage plan, it is important to check and make sure that all of your doctors are in the plan's network.

While deciding whether to enroll in a Medicare Advantage plan is a personal choice, the program's history serving people with disabilities and chronic conditions has produced mixed results. Individuals with disabilities considering enrolling in a Medicare Advantage plan should weigh this decision with care.

### ***Can I go to any pharmacy I choose to have my prescriptions filled?***

As a general rule, any pharmacy could decide to participate in a Part D plan's network, but plans can offer favorable terms for individuals to use a preferred pharmacy. It is also possible that an individual's regular

pharmacy is not in the network of a particular plan. For some individuals, this may be an important criterion in selecting a Part D plan. This may be especially true for people with mobility limitations, as well as those living in rural communities or other areas where pharmacies are few and far between. In some instances, even these types of difficulties can be lessened if a Part D plan allows for mail-order delivery of prescription drugs. If any of these issues are of particular concern to you, it is important that to the extent possible you: 1. weigh them as a critical factor when deciding which plan to enroll in; and/or 2. work with the plan you are currently enrolled in to resolve them in a mutually satisfactory way that ensures you are able to obtain the prescription drug you need in a timely and effective fashion.

### ***What is the benefit of using a "preferred pharmacy"?***

Your prescription drug plan may permit you to go to a large number of pharmacies in your community, but may also negotiate with a smaller number of pharmacies (or pharmacy chains) to become preferred pharmacies. This means that cost-sharing will often be lower at a preferred pharmacy than if you went to another pharmacy, even if the other pharmacy is part of your plan's pharmacy network. If you cannot get into a preferred pharmacy near you because it is not wheelchair accessible or there is no accessible transportation to it, you might consider requesting the plan to make an "exception" to its policy of offering lower cost sharing at preferred pharmacies only. The steps you take to request such an exception is described further below.

### Understanding How Plans Manage Access to Prescription Drugs

When you get a prescription from your doctor, you take it to your pharmacy, and you expect to get it filled. When a prescription drug plan denies coverage for the prescription or asks for medical justification before filling the prescription, this can be stressful. It can also make people angry or confused because they do not understand why the plan would not allow them to get their prescription filled. Some of this suspicion of plans can be justified. Sometimes, when a plan tries to operate its prescription drug business efficiently, it can lead to people being denied particular drugs they really need. Problems can also arise when prescription drug plans that are accustomed to providing insurance coverage to relatively healthy, working populations first encounters people with disabilities. Their inexperience with disability could lead them to deny coverage first and ask questions later. Therefore, if you seek to obtain prescription drugs that your doctor has prescribed for you, you should not stop seeking the drug if the plan initially denies you coverage for your prescription.

At the same time, a plan is not at fault every time it denies individuals coverage for certain prescription drugs. There are many good reasons why a plan would deny you coverage. For example, some drugs are not safe for people with certain conditions to take. Some drugs cannot be safely taken with other drugs—and since many individuals receive prescriptions from more than one doctor, your prescription drug plan may have more complete information about all of the drugs you are taking than even your doctor. In other words, a plan's refusal to buy a specific drug can either promote or hinder your health and independence. The only way you will be able to tell which it is will be if you keep an open mind, ask a lot of questions, and challenge denial decisions through the exceptions and appeals methods described below.

Plans have a role to play in managing access to prescription drugs that extends beyond safety concerns. When the Congress created the Medicare Part D program, it recognized that Medicare beneficiaries—including people with disabilities—need access to

prescription drugs. But, it was also concerned about the cost of drug coverage and the potential for over use of drugs, in some cases even when they are not necessary. Many advocates for beneficiaries have expressed the belief that prescription drug plans have too many incentives simply to deny coverage of drugs to maximize their profit. It is important to remember and remind others as well, however, that the Congress intended for prescription drug plans to balance their goal of operating profitable businesses with their obligation to provide appropriate access to prescription drugs. When the system works as intended, plans may place reasonable limits on access to certain drugs when lower cost alternatives are available that have been shown to be as effective as the prescribed drug—as long as they allow for individuals to get quick and easy access to drugs that they need—even if they respond differently to some drugs.

If individuals are denied access to a prescription they have been prescribed—or have been charged a high level of cost-sharing that they believe is either unaffordable or unfair—it is hard for them to judge whether the plan's denial is appropriate and based on medical information or whether the plan is denying them drugs that they really need. If this happens to you, your doctor and your pharmacist are both critical sources of information. Often, they can provide helpful advice on whether to accept a substituted drug, for example, or whether to try to get the plan to dispense the prescribed drug. Shortly, we will describe some of the rights that individuals have and the steps they can take to try to get a prescription they have been denied. Here, we will describe some of the key tools that prescription drug plans use to decide when they will provide coverage for a particular prescription drug, and when they will deny coverage for it.

#### *What is a formulary?*

Part D prescription drug plans are permitted to operate formularies, which are lists of drugs that a plan chooses to cover. This means that plans can choose to cover

some, but not all FDA approved prescription drugs. Part D plans can also have tiered formularies where medications a plan has designated to be “preferred drugs” have a lower level of cost-sharing and drugs the plan considers non-preferred can have a higher level of cost-sharing. In some cases, plans can charge very high levels of cost sharing for non-preferred drugs.

Some beneficiaries, however, are not required to pay high cost sharing. Dual eligibles and other low-income people receiving *Extra Help* (i.e. financial assistance with cost-sharing for dual eligibles and people below 150% of the poverty level) are generally protected from this higher cost-sharing. In 2006, this includes individuals who have less than \$1,225 of monthly income or \$1,650 for couples and moderate assets (less than \$10,000 for single individuals or less than \$20,000 for couples) qualify for a “partial” subsidy.

### ***What must a Part D formulary cover?***

In developing a formulary, drugs are grouped into classes of drugs which work in the same way or which are used to treat the same condition. As a general rule, Part D plans are only required to cover two drugs in each class. For example, there are at least 14 drugs in the antihistamine class (i.e. drugs used to treat allergies), and plan formularies, at a minimum, must only cover two of these.

### ***Can I get a drug that is not on my plan’s formulary?***

A Part D plan may not have a drug prescribed by an individual’s physician on the formulary—or they may charge a high level of cost-sharing. In some cases, the drug on the formulary that is used to treat the same condition (or the preferred drug with a lower level of cost-sharing) is perfectly acceptable. In others, substituted drugs on the formulary may have interactions with other drugs an individual is taking, they may not work effectively, they may produce unacceptable side-effects, or they may pose safety risks. Therefore, individuals, alone, should not try to make

these determinations. If an individual is told that a drug prescribed by their physician is not on the formulary—of if they are told that the cost-sharing is at a high level, they should ask their pharmacist for options and recommendations, and they should check with their doctor.

If an individual needs a drug they are denied—or to request that a non-preferred drug be provided at the preferred level of cost-sharing, individuals can request an “exception” to the plan’s formulary or cost-sharing policy. To be successful at an exception, though, the physician or other provider who prescribed the drug must agree that the specific drug is necessary and that a substituted drug is not appropriate. Exceptions and appeals procedures will be described in more detail later in this guide.

### ***What is a quantity limit?***

A quantity limit is a policy of some prescription drug plans to limit how much of a drug they will dispense at one time. Some drugs are very costly and plans do not want to waste money on prescription drugs that an individual may not use. For example, if an individual fills a prescription for the first time, a plan does not want to pay for a quantity of drugs if the individual tries the drug and then discontinues taking it, either because the drug was not effective or because the individual could not tolerate the side-effects. While quantity limits can vary from plan to plan, it is a common practice for plans to limit the dispensing to a one month supply, and 90-100 days for so-called “maintenance drugs” which persons with chronic conditions are expected to take for an indefinite time.

### ***When my plan tells me that my drug is on a tier (i.e. such as tier 1 or tier 2) what does that mean?***

Once a plan decides to include a drug on its formulary, it then must determine what level of cost-sharing to charge. As a general rule, the lowest cost drugs for the prescription drug plan—and the most cost-effective drugs are often on the lowest cost-sharing tier. This

means that individuals pay a lower level of cost-sharing than drugs placed on a higher tier. There are other drugs that a plan may realize are needed by some of its members, but the drugs are especially costly for the plan. Thus, they want to make the drugs available, but also limit their use to only rare cases. For these drugs, plans place them on a higher tier, in which the individual pays a higher co-payment or a higher percentage of the drug's cost (cost-sharing level). In certain instances, such as when the only drug found to be effective in treating a person is one that the plan has placed on a higher cost-sharing tier, individuals should consider requesting an exception and ask their plan to permit them to pay the lower level of cost-sharing.

### ***What is a generic drug?***

A generic drug is a drug which has been determined by the Food and Drug Administration (FDA) to be chemically equivalent to a brand name (or single source) drug. In many cases, prescription drug plans will either encourage doctors to prescribe generic drugs when they are available or to require pharmacists to fill a prescription with a generic drug, when it is available. While in most cases generic drugs work as effectively as brand name drugs, in rare cases, they may not be equally as effective, or they may cause problems with side-effects that an individual does not experience with the brand name drug. In some of these cases, doctors can write “dispense as written” prescription to require the pharmacist to give the patient only the brand name drug. If this is not an option, the individual can still work with their doctor to request an exception from the plan to obtain the brand name drug.

For many of the prescription drugs taken by people with disabilities, including many of the newer classes of drugs, generic drugs are not available.

### ***Which classes of drugs are given special treatment under the Part D program?***

As previously stated, the MMA generally requires prescription drug plans that operate formularies to cover

at least two drugs in each drug class. Federal officials have established a higher standard of coverage, however, for six specific classes. Plans are required to cover “all or substantially all” of the drugs in the following classes: anticonvulsants; antidepressants; anticancer drugs; antipsychotics; immunosuppressants; and HIV/AIDS drugs. For drugs other than HIV/AIDS drugs, Part D plans are permitted to use utilization management tools such as prior authorization (requiring a patient to provide medical justification before a specific drug is covered) and use a fail first policy (also known as step therapy) by requiring a patient to try certain drugs or therapies in a particular order) with new users, but not with patients who already are using the drugs.

### ***What should I do if my plan will not fill a prescription from my doctor, but wants to give me a different drug?***

It is a common practice for plans and pharmacists to substitute a generic drug—or require a higher level of cost-sharing if an individual demands a brand name drug. In most cases, this should not cause a problem. A more serious issue arises, however, if a plan want to make what is called a therapeutic substitution. This is where a plan will only cover a chemically different drug, often in the same class of drug as the one the doctor prescribed. In this case, it is a good idea to check with your doctor—unless the pharmacist is able to provide you clear assurances that this substitution is safe and equally effective.

### ***What is a fail-first policy?***

In some cases, a plan will include a drug on its formulary, but it will only agree to dispense the drug after an individual has tried another drug which has not worked for them, or for which they cannot tolerate the side-effects. This is called a fail-first policy. For some conditions and drug classes, fail-first policies may be appropriate. In other cases, an individual's ability to benefit from the drug prescribed by their doctor could be compromised by being forced to try and fail on another drug. If you are told that you must try another

drug before your plan will provide coverage for a drug that has been prescribed by your doctor, check with your doctor before agreeing to take the substituted drug.

Under the rules of the Part D program, individuals who were stabilized on a treatment regimen before they enrolled in their Part D plan should not have to fail on another drug before they can access the drugs they were previously taking.

### ***What is meant by step therapy?***

This is another term for a fail-first policy.

### ***What is prior authorization (PA)?***

For some drugs, your prescription drug plan will place the drug on the formulary, but it will not agree to provide coverage for the drug unless it grants prior authorization (PA). This involves a process where the plan will require clinical justification before dispensing a drug. In some cases, the plan wants most of its members to use a specific drug within a class, so it will only give access to other drugs in the class if the prescribing doctor can show that the specific drug is needed. In other cases, PA is used to enforce other policies, such as fail-first policies. In this circumstance, the plan will ask the pharmacist if there is a record of the patient trying and failing on a specific drug. In still other cases, PA can be used to make sure that only safe drugs are provided—or in safe doses. For example, some people with disabilities require high doses of narcotics, a class of drugs used to treat chronic pain. Some people may require a significantly higher dose of the drug than is commonly prescribed. The PA process is used to ensure that individuals receive unusual doses of a drug when it is needed, and not through an error—or even due to a lack of information on the case of the doctor.

From the perspective of a person trying to get a prescription filled, PA is not automatically problematic. In most cases, pharmacists interact with the

prescription drug plan, and if necessary the doctor, to meet the plan's PA requirements. You may have drugs that require PA, but since the process works smoothly, you do not even realize it. In other cases, the PA process can create problems for physicians and pharmacists because the PA requirements are not clear, or because they take up too much time for both the doctor and the pharmacist. As a general rule, prescription drug plans require PA on only a small percentage of the drugs on their formularies.

### ***If I am prescribed a drug that requires prior authorization, do I need to do anything to get the drug approved?***

As a general rule, the pharmacist will take responsibility for obtaining PA. As discussed, this may require her/him to consult with your doctor. Your doctor may learn that the plan would prefer you to take a different drug in the same class as the drug that has been prescribed. In other cases, your doctor may need to provide clinical information that will justify why you need a particular drug—or dose of a drug. This is an example where, as stated earlier in the guide, your ability to keep clear, up-to-date records also can help your doctor document your need to obtain a particular drug.

It is possible, however, that individual patients need to get involved in obtaining PA. You will know if you need to do something when your pharmacist tells you that he/she cannot fill a prescription because the plan refused to authorize payment. In this case, you may need to call the customer service number of your prescription drug plan and ask them why the drug was denied. You should also ask them what are the criteria for approving coverage of the drug. Write down all information you learn, including the date that you made the call, with whom you spoke, the number you called, and what the plan told you. With this information, you should contact your doctor and ask for assistance in obtaining PA—or, if your doctor agrees that it is appropriate, to get a prescription for a different drug.

### **Exceptions, Grievances, and Appeals**

In any insurance program, problems will arise. It is inevitable, therefore, that there will be cases when a prescription drug plan denies coverage for a specific drug, does not include a drug on the formulary, or charges an unusually high level of cost-sharing for a drug that some individuals must take. For this reason, public programs such as Medicare have very detailed rules and policies that are intended to protect the interests of beneficiaries. A key consumer protection is the right to complain if your plan does something with which you do not agree.

The Medicare Part D program adapted many of the existing rules for grievance and appeals that apply to Medicare Advantage plans to prescription drug coverage. In some cases, grievances and appeals can take a long time to get resolution of a problem—and the process is so complex it is either overwhelming for beneficiaries or legal counsel may be necessary. The law that created the Part D program envisioned a new part of the consumer complaint process, called an exceptions request, that is both easier for beneficiaries to understand, and which will lead to a more rapid resolution of complaints than the formal grievance and appeals process.

This section describes, in general terms, various actions that beneficiaries can take to complain about actions taken by their prescription drug plan—or to overturn a plan's denial of coverage for a prescription drug. This information should not be considered legal advice. If you are experiencing problems getting drugs that you believe you need, and you do not believe that you can get your plan to change its mind on your own, you should seek outside assistance. Your doctor is an important advocate for you. Additionally, consumer advocacy organizations may be able to either provide you with more information, or in some cases, assist you with the exceptions and appeals processes. In rare cases, you may need to seek out legal assistance—*i.e. a lawyer who can represent you*—to get a fair evaluation of your case.

#### ***What is a coverage determination?***

A coverage determination is when your prescription drug plan makes a formal decision whether or not to provide coverage for a prescribed drug. Making sure you get a coverage determination is an essential first step in getting a prescription filled if you are told that your plan will not fill your prescription.

If you are told by your pharmacist that your plan has denied coverage for a drug that you need, this is not considered a coverage determination. You, as the individual, must contact your prescription drug plan directly and ask them for a coverage determination. Getting this determination is necessary for you to advocate for your plan to cover the drug by requesting an exception.

#### ***What is an exception?***

A new feature of the Medicare Part D program is the exceptions process. This is a process where an individual can request that a plan cover a drug at the lowest level of cost-sharing, even if the plan normally charges a higher level of cost-sharing for the drug. This process also creates an opportunity for an individual to obtain coverage for drugs that their plan has kept off the formulary. Similarly, Part D plans are permitted to change the drugs on the formulary at any time. Except for emergency circumstances, they must give their enrollees notice 60 days before removing a drug. For enrollees taking a drug, the notice must be in writing and these changes can also be the subject of a request for an exception.

In general, the exceptions process is intended to be an easier process than a formal appeal for requesting coverage for drugs. If an individual has gone through the exceptions process and has still been denied a prescribed drug that they need, they have a right to access the appeals process.

### ***How do I request an exception?***

To request an exception, you should contact your prescription drug plan and tell them specifically that you would like to request an exception. You should also try to give the plan as much information as possible that they can use to approve your request. For example, you should describe the problem you are experiencing, how the plan's actions (whether it is to deny coverage for a drug or push you to take another) will be harmful to you. As well as clearly state what steps you would like the plan to take (*i.e. such as giving you a temporary supply until your doctor can give them clinical justification for dispensing the drug*).

### ***Who is permitted to request an exception?***

Medicare beneficiaries, their appointed representatives, or their prescribing physicians may request an exception. For this purpose, the appointed representative may include someone authorized by the individual to act on their behalf in the appeals process, as well as persons who are authorized under state law to act on behalf of the individual.

### ***What is required of my doctor for me to get an exception?***

A key part of the exception request is the medical opinion of the treating physician, who must be able to state that the requested treatment is needed by the individual and less costly alternatives have not worked for the individual or are unsafe or inappropriate for the individual.

### ***If an exception is granted, how long is it effective?***

If an exception is granted, it remains effective until the end of the year as long as the doctor prescribes the drug and the drug remains effective. Assuming that an individual remains enrolled in the same plan for the next year, the prescription drug plan can continue to honor the exception—or it can require the individual to request another exception each year.

### ***Is my plan required to approve exceptions requests?***

Federal rules for prescription drug plans require them to operate a process for considering exceptions and requires them to grant exceptions when the plan determines that a drug is medically necessary, consistent with the statement of the treating physician. Each plan develops its own process for operating an exceptions process and its own standards for making decisions about whether or not to grant exceptions. This means that prescription drug plans have a great deal of leeway in making exceptions decisions.

### ***What do I do if I am denied an exception?***

Persons who are denied an exception are automatically eligible to file an appeal.

### ***What is a grievance?***

A grievance is a complaint or dispute about any issue with a prescription drug plan other than one that involves a coverage determination. For example, if an individual has problems getting in contact with their prescription drug plan because there are unable to get through on the plan's telephone line, they could complain about this through a grievance.

### ***What is an appeal?***

An appeal is a request to have a further review of a coverage determination. This means that if an individual is denied coverage for a drug that they have been prescribed, an appeal is the process that requires the prescription drug plan to reconsider their decision—and if the beneficiary fails to get the plan to reverse their initial decision to obtain an independent review of the plan's decision by parties who are not affiliated with the plan.

Individuals can appeal coverage determinations related to formulary drugs and non-formulary drugs. They cannot appeal denial of coverage for excludable drugs.

### ***Who is permitted to file an appeal?***

The individual or their appointed representative, but not their doctor, may request a redetermination or higher level appeal.

### ***How do I file an appeal?***

Individuals have a right to request a redetermination of a coverage determination. This is the first step of the appeals process. To request this redetermination, individuals should write a letter to their plan asking for a redetermination of the decision not to cover a drug (or charge a higher level of cost-sharing). In this letter you should clearly state the drug that has been denied coverage, the reason for the denial, and why you believe the drug should be covered. Plans are permitted, but not required, to accept oral appeals...but, it is in the beneficiary's interest to communicate through written requests—and keep copies of all communications for your own records.

As a general rule, individuals must request a redetermination within 60 days of the date that they were first denied coverage for a drug. If there are special circumstances that prevented you from appealing within 60 days, it may be possible to request a redetermination after more than 60 days...but you should always request a redetermination as soon as coverage is denied.

### ***How quickly must my plan make a coverage determination and respond to exceptions, grievances and appeals?***

Plans must make coverage determinations within 72 hours, and for expedited determinations (in emergencies or cases where delay could harm the health of the patient) within 24 hours. In all cases, plans must act more quickly if it is needed to protect the life and health of the patient. Exceptions requests are treated as a form of a coverage determination, so plans must meet these same time standards.

Plans must respond to a standard appeal within 7 days and they must respond to an expedited appeal within 24 hours; again, plans must respond more quickly if the enrollee's health requires it.

If an initial appeal is denied, there are several additional levels of review that can be pursued. This includes a right to have their request for a drug reviewed by an Administrative Law Judge (ALJ), who is independent of the Part D plan. Once an individual has exhausted their appeals rights, they also can access the federal courts—although this process can take months or years and is not likely an option for resolving routine disputes over the coverage of drugs.

### ***Is there a dollar amount I must meet to be able to appeal a plan decision?***

Yes. For an individual to receive a review by an Administrative Law Judge (ALJ), the amount in controversy in 2006 must be \$110. In order for the individual to have access to federal court, the amount in controversy must be \$1,090. These amounts are both adjusted annually. To satisfy these amounts, individuals can pull together the cost of drugs over several months. Further, if several beneficiaries are denied coverage for the same drug, they can pool together their complaints for an ALJ

## Key Contacts and Other Resources

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### Federal Government Resources

Centers for Medicare and Medicaid Services (CMS) (FOR CONSUMERS):  
<http://www.medicare.gov/medicarerreform/default.asp>

Centers for Medicare and Medicaid Services (CMS) (FOR ORGANIZATIONS): <http://www.cms.hhs.gov/medicarerreform/>

Social Security Administration (SSA) (FOR CONSUMERS):  
<http://www.ssa.gov/prescriptionhelp/>

Social Security Administration (SSA) (FOR ORGANIZATIONS):  
<http://www.ssa.gov/organizations/medicareoutreach2/>

State Health Insurance Counseling and Assistance Programs (SHIPs): To find the SHIP program in your state,  
<http://www.medicare.gov/contacts/Static/SHIPs.asp?dest=NAV>

SHIPs are federally funded programs operating in every state to assist Medicare beneficiaries. If you do not have internet access, you can make a toll-free call to Medicare to ask how to contact the SHIP in your state: 1-800-MEDICARE (1-800-633-4227). For people who are deaf or hard of hearing, the toll-free TTY line is 1-877-486-2048.

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### National Organizations and Research Organizations

Access to Benefits Coalition: <http://www.accesstobenefits.org/>

Center for Medicare Advocacy: <http://www.medicareadvocacy.org/>

Henry J. Kaiser Family Foundation:  
<http://www.kff.org/medicare/rxdrugdebate.cfm>

Medicare Rights Center: <http://www.medicarerights.org/>

## Key Contacts

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## Prescription Drug Log

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*Stop date:* \_\_\_\_\_

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## Diary of Health Concerns

Make multiple copies  
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Date: / /

Nature of problem:

Steps taken to resolve the problem:

Did you visit or call your doctor? If so, whom? What did they do?

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Date: / /

Nature of problem:

Steps taken to resolve the problem:

Did you visit or call your doctor? If so, whom? What did they do?

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## Diary of Health Concerns

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Nature of problem:

Steps taken to resolve the problem:

Did you visit or call your doctor? If so, whom? What did they do?

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## Diary of Health Plan Issues

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Date: / /

Nature of problem with your prescription drug plan:

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Steps taken to resolve the problem:

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Who did you contact?

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Phone Number:

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What did they do?

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Date: / /

Nature of problem with your prescription drug plan:

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Steps taken to resolve the problem:

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Who did you contact?

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## Diary of Health Plan Issues

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