

# National Senior Citizens Law Center

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## Medicare Part D Materials for Advocates

# MEDICARE PART D FOR LOW-INCOME ADVOCATES: THE BASICS

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## 1. MEDICARE PART D BASICS

### 1.A What is Medicare Part D?

Medicare Part D is the name for the Medicare prescription drug program. Under Medicare Part D, Medicare beneficiaries can get health insurance coverage for prescription drugs by enrolling in plans offered by private insurance companies. The government and the beneficiaries share the cost of the coverage.

The program began on January 1, 2006. Before the program began, Medicare provided only limited prescription drug coverage to Medicare beneficiaries. The program is run by the Centers for Medicare and Medicaid Services (CMS). CMS is a part of the federal Department of Health and Human Services (HHS).

### 1.B Who is eligible for Part D?

Any individual who is entitled to Medicare Part A or enrolled in Medicare Part B is eligible to enroll in a Medicare prescription drug plan. For most beneficiaries, enrollment in a Part D plan is voluntary.

Dual eligibles, beneficiaries who receive both Medicare and Medicaid, are in a very different position. Once a Medicaid beneficiary becomes eligible for Medicare, her Medicaid prescription drug coverage stops and she must rely on Part D (or some other source like employer coverage or Veterans' Administration benefits, etc.) for her prescription drug coverage.

Federal law provides for an auto-assignment process for full-benefit dual eligibles. Medicaid beneficiaries who do not voluntarily pick a plan are supposed to be put automatically into one by CMS so that they never lose access to their prescription drugs. See 3.C below for more details on the auto-enrollment of dual eligibles.

**Statutes, Regulations and Guidance:** The Part D program was created by the Medicare Modernization Act of 2003 (the MMA), 42 USC §1395w-101 et seq. CMS regulations are at 42 CFR §§423.1-423.910; SSA regulations regarding the Low Income Subsidy (see below) are at 20 CFR §§418.3001-418.3680. Most of the operating procedures for the program are laid out in subregulatory guidance issued by CMS to Part D plans. Guidance to the plans is available on the CMS website:

[www.cms.hhs.gov/PrescriptionDrugCovContra/12\\_PartDManuals.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage)

## **2. PART D COSTS AND THE LOW INCOME SUBSIDY**

### **2.A How much do beneficiaries pay for medications under Part D?**

How much beneficiaries without a low-income subsidy will have to pay for Part D coverage differs from plan to plan. Most plans charge beneficiaries a monthly premium, an annual deductible and co-payments for each medication. Premium, deductible and co-payment amounts vary widely by plan.

Nearly all plans also include a coverage gap which amounts to a second deductible for beneficiaries. This coverage gap is commonly referred to as the “donut hole.” After the beneficiary’s total drug costs for the year reach a certain amount,<sup>1</sup> the beneficiary is in the “donut hole” and is responsible for all of her drug costs. Once the total drug costs hit another, higher amount (known as the “catastrophic limit”), the beneficiary is out of the donut hole and her “catastrophic coverage” kicks in. At this point, the plan begins to help pay for medications again and the beneficiary is responsible for reduced co-payments. Some plans provide limited coverage (e.g. generics only) in the “donut hole.”

### **2.B What help is available for low-income beneficiaries, including dual eligibles?**

Taken together, the costs described above can be substantial. Low-income Medicare beneficiaries can get coverage for most of their Part D out-of-pocket costs through a program called the “Low-Income Subsidy” or “Extra Help.” Four groups of individuals qualify for the Low Income Subsidy (LIS). Each group qualifies for a different amount of subsidy.

- 1. Full Benefit Dual Eligibles.** Full benefit dual eligibles are individuals who qualify for full Medicaid benefits and Medicare (including medically needy beneficiaries who have qualified for full Medicaid by meeting a spenddown or share of cost). These LIS recipients qualify for a full subsidy.
- 2. Partial Dual Eligibles (Medicare Savings Program Recipients) and SSI recipients** who do not receive Medicaid. Medicare-eligible persons on SSI who are not receiving Medicaid (SSI-only) and individuals enrolled in Medicare Savings Programs and not on full Medicaid (referred to as partial dual eligibles) are eligible for a full subsidy. This group includes Qualified Medicare Beneficiaries Only (QMB-only), Specified Low-Income Beneficiaries Only (SLMB-only) and Qualified Individuals (QI-1).

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<sup>1</sup> This amount changes annually. In 2009, the initial coverage limit is \$2,700 and the catastrophic limit is \$6,153.75. Amounts counting toward the initial coverage limit and the catastrophic limit include all payments by the Part D beneficiary (including payments by her family or designee, a charity, or a state pharmacy assistance program) and by the plan for covered Part D drugs.

3. Non-Medicaid or non-SSI eligible individuals with countable **income below 135 percent** of the FPL and countable resources below \$8000 for an individual or \$12,910 for a couple. These LIS recipients qualify for a full subsidy.
4. Non-Medicaid or non-SSI eligible individuals with countable **income below 150 percent** of the FPL and countable resources below \$12,510 for an individual and \$25,010 for a couple. They qualify for a partial subsidy on a sliding scale.

Payments for each group are set out below:

	Premium for benchmark plan <sup>2</sup>	Deductible	Co-Payments
Full Benefit Dual Eligibles	\$0	\$0	\$1.10/\$3.20 if income ≤ FPL \$2.40/\$6.00 if income ≤ 125% FPL \$0 if in nursing home \$0 for all above the catastrophic level
Partial Dual Eligibles and SSI recipients	\$0	\$0	\$2.40/\$6.00 \$0 above the catastrophic level
Income ≤ 135 % FPL	\$0	\$0	\$2.40/\$6.00 \$0 above the catastrophic level
Income ≤ 140 % FPL	25% of benchmark premium	\$20	15% of full drug price or plan's co-payment amount, whichever is lower. \$2.40/\$6.00 above the catastrophic level
Income ≤ 145 % FPL	50% of benchmark premium	\$40	15% or plan's co-payment amount, whichever is lower. \$2.40/\$6.00 above the catastrophic level
Income ≤ 150 % FPL	75% of benchmark premium	\$60	15% or plan's co-payment amount, whichever is lower. \$2.40/\$6.00 above the catastrophic level

## 2.C How does a beneficiary get the Low Income Subsidy?

Medicare beneficiaries can be either “deemed” eligible for the subsidy or “determined” eligible for the subsidy.

Full benefit dual eligibles, partial dual eligibles and SSI recipients are deemed eligible for the Low Income Subsidy. They are automatically eligible because they qualify for Medicaid and/or SSI. They do not need to complete a separate application to receive the

<sup>2</sup> The “regional benchmark amount” is set by a complicated formula and changes annually. The amount is different in each of the 34 Prescription Drug Plan regions nationwide. If LIS beneficiaries join a plan with a premium above the benchmark amount, they will owe the difference between the plan's premium and the benchmark amount.

Low Income Subsidy. Information showing their eligibility status is automatically transferred from the states and/or SSA to CMS and then from CMS to the plans.

**Practice Note:** Delays are common in the deeming process. Advocates can shorten the process by providing information demonstrating Medicaid eligibility (e.g. a Medicaid card, a letter of award, etc.) directly to the Part D plan. Under a CMS policy called the Best Available Evidence policy, plans are required to accept evidence of Medicaid eligibility as proof of LIS eligibility.

Beneficiaries who do not receive Medicaid or SSI must affirmatively apply for the subsidy and be determined eligible. Applications can be filed:

- With SSA. Paper applications, Form SSA-1020, can be requested by phone at 1-800-772-1213; applications can be filed on line at [www.ssa.gov](http://www.ssa.gov); and applications can be filed in person at any SSA office. Although the application is available in only English and Spanish, instructions and assistance are available in 15 other languages: [www.ssa.gov/prescriptionhelp/](http://www.ssa.gov/prescriptionhelp/). Individuals with limited English proficiency can fill out information and bring it to an SSA office, where they are supposed to get assistance in their language. SSA relies primarily on data cross checks to determine eligibility so usually does not demand that an applicant include supporting documents with an application.
- With state Medicaid offices. The MMA guarantees the option of filing through state Medicaid offices using state procedures. In most cases, if an individual appears at a state office, state personnel will offer to assist the individual in completing the SSA form and send the form to SSA for processing. State personnel do not volunteer that state processing is available. Individuals who complete an application at the state Medicaid office should be screened for Medicaid and Medicare Savings Program eligibility.

The overwhelming majority of applications are being filed through SSA.

## **2.D For those who apply for the subsidy, what income and resources are counted?**

The definitions of countable income and resources for the Low-Income Subsidy are similar to those for Supplemental Security Income (SSI) determinations, but are more liberal with respect to resource counting. A primary residence, car, the value of a life insurance policy, and up to \$1500 set aside for burial expenses do not count as resources and a portion of earned income does not count as income. Unlike SSI, most other non-liquid resources also are exempt from resource counting. A detailed description of income and resources subject to counting is contained in CMS Guidance to States on the Low-Income Subsidy at [www.cms.hhs.gov/States/03\\_lowincomesubsidy.asp#TopOfPage](http://www.cms.hhs.gov/States/03_lowincomesubsidy.asp#TopOfPage).

## **2.E When does LIS eligibility begin? How long does it last?**

For individuals who are applying for the LIS (see 2.C above), eligibility is retroactive to the month the application is filed. As with SSI, a filing date (a “protective filing”) can be established with a telephone call to SSA. To retain the date, a completed application must be filed with SSA within 60 days of the initial call. Subsidy eligibility continues throughout the plan year, even if income or resources change. The only events that change eligibility mid-year are marriage, divorce, annulment, separation, co-habitation after separation, or death of a spouse.

In August of each year, SSA conducts a “redetermination” process. Most beneficiaries will simply be passively redetermined eligible for the following calendar year without receiving any notice and without having to take any action. Beneficiaries who have been identified by SSA as more likely to have had a change in income, resources or family size, however, will receive a redetermination form. Beneficiaries who receive this form must complete it within 30 days. Once SSA has received the completed form, it will reevaluate the beneficiary’s eligibility for the subsidy based on the information provided and a data match with other federal agencies. Beneficiaries will be notified in writing of the result of the redetermination. If the form is not returned within 30 days, SSA will notify the recipient that the subsidy will be terminated, after due process, effective January 1<sup>st</sup> of the coming year. (If the subsidy is terminated, the individual can reapply.)

Individuals who receive Medicaid benefits (including a MSP) in any one month during the year are “deemed” eligible for the LIS retroactive to the first day of the month in which they became eligible for both Medicaid and Medicare. Deemed eligibility for the LIS continues through the end of the calendar year, even if Medicaid eligibility ends. Individuals who receive Medicaid in any one month after June (July-December) are deemed eligible for the LIS through the end of the current calendar year and the entire following calendar year.

Ms. Smith is a 67 year old Medicare recipient who qualifies for Medicaid effective March 2009. She is deemed eligible for the LIS through December 31, 2009. If Ms. Smith is still on Medicaid in July 2009, she will be deemed LIS eligible through December 31, 2010.

Mr. Jones is a 70 year old Medicare beneficiary who qualifies for Medicaid in September 2009. He will be deemed eligible for the LIS through December 31, 2010.

Individuals with a Share of Cost (SOC) or Spend Down who meet their SOC/Spend Down will be deemed eligible for the Low-Income Subsidy for the calendar year beginning in the month in which they meet their SOC/Spend Down – even if they do not meet their SOC/Spend Down in any other month during the year. An individual who

meets his or her SOC/Spend Down in July or any month thereafter, will also be determined eligible for the subsidy for the entire next calendar year.

Ms. Smith meets her SOC/Spend Down in October 2009. She will be deemed eligible for the Low-Income Subsidy from October 1, 2009 through December 31, 2009 AND all of 2010. However, if Ms. Smith met her SOC/Spend Down in January 2009, she would only be deemed eligible for the subsidy until December 31, 2009. She would have to meet her SOC/Spend Down again in a month after June 2009 to be deemed eligible for the subsidy for 2010.

If an individual already is enrolled in a Part D plan and is approved for LIS, the plan must reimburse the enrollee for overpayments of premiums and co-pays back to the first month of the LIS eligibility.

**Statutes, Regulations and Guidance:** The Low Income Subsidy is addressed at: 42 USC §1395w-101, 114; 20 CFR §§418.3001-418.33680 and 42 CFR §§ 423.104, 423.771-423.800. CMS Guidance to States on the Low-Income Subsidy is available at [www.cms.hhs.gov/States/Downloads/GuidancetoStatesonLimited-IncomeSubsidy.pdf](http://www.cms.hhs.gov/States/Downloads/GuidancetoStatesonLimited-IncomeSubsidy.pdf).

**More Resources:** NSCLC has developed various materials related to the Low Income Subsidy. See [www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates](http://www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates).

### **3. PART D ENROLLMENT**

#### **3.A How does a beneficiary sign up for Medicare Part D?**

Part D benefits are provided through plans offered by private insurance companies (plan sponsors) approved each year by CMS. Medicare beneficiaries enroll in Part D by enrolling into one of these Part D plans.

There are two types of Part D plans:

- PDPs: stand-alone prescription drug plans that provide only prescription drug coverage (these plans can be used in conjunction with traditional fee-for-service Medicare, Medicare Advantage Private Fee For Service (PFFS) plans that do not provide drug coverage, or Medicare Medical Savings Accounts (MSA)); and
- MA-PDs: Medicare Advantage plans that provide prescription drug coverage as well as Part A and Part B coverage. This group includes Medicare HMOs and PPOs, Private Fee For Service plans and Special Needs Plans (Medicare

Advantage plans that restrict their enrollment to individuals who are one of three “special needs” categories: dual eligibles, institutionalized individuals and persons with chronic conditions.).

PDPs are open to persons entitled to receive Medicare Part A *or* enrolled in Medicare Part B, and permanently residing in the service area of the plan. To enroll in MA-PD plans, in contrast, individuals must be entitled to Part A *and* enrolled in Part B.

The country is divided into 34 PDP regions; PDPs must cover an entire region. There are 26 MA-PD regions, but MA-PD plans are permitted to offer narrower geographic coverage, and the number of MA-PD plans available varies considerably by county.

Within limits set by CMS, plans may have different formularies, different co-payment pricing tiers, and different utilization management requirements (e.g. dosage limits, step therapy requirements, etc.); they can affiliate with different pharmacies and can impose different paperwork and procedural requirements. Thus, comparing “basic” plans is not comparing apples to apples. Depending on an individual’s prescription drug needs, different “basic” plans could yield significantly different coverage results and out-of-pocket costs.

### **3.B How does a beneficiary choose and enroll in a Part D plan?**

Resources are available to help beneficiaries compare Part D plans. CMS maintains a Medicare Prescription Drug Plan Finder and a Formulary (Drug) Finder on its website, [www.medicare.gov](http://www.medicare.gov). These tools allow beneficiaries or their advocates to search for and compare plans by cost and coverage. Beneficiaries who do not have access to the internet can receive assistance comparing plans by calling 1-800-MEDICARE. State Health Insurance Assistance Programs (SHIPs) are also available to counsel beneficiaries looking for a Part D plan. State by state contact information is available at [www.shiptalk.org](http://www.shiptalk.org).

Once a plan has been chosen, beneficiaries may enroll by contacting the plan directly, by calling 1-800-MEDICARE, or by filling out an enrollment on the Medicare website, [www.medicare.gov](http://www.medicare.gov).

### **3.C What do dual eligibles and LIS recipients need to do to enroll in a Part D plan?**

Medicare Part D includes special rules and systems related to enrollment that are designed to protect Low Income Subsidy recipients.

Auto-enrollment: Full-benefit dual eligibles who do not choose a plan on their own are automatically enrolled in a Part D plan effective the first day of their dual eligibility. Beneficiaries are randomly enrolled into a basic Prescription Drug Plan (PDP) with a

premium below the regional benchmark amount (known as a “benchmark plan”).<sup>3</sup> There is no process by which CMS ensures that the plan into which the beneficiary is auto-enrolled actually covers the beneficiary’s drugs.

Since CMS, the states and the plans (and, in some cases, SSA) must all coordinate data in order for an individual’s coverage to show accurately at the pharmacy, the opportunities for time delays and errors are numerous. As a limited back-up, CMS has implemented a Point of Service system (also known as the POS system) which allows full-benefit dual eligibles for whom CMS records show no evidence of plan enrollment to be enrolled in a plan at the pharmacy. Pharmacists are not required to use the POS.

Facilitated-enrollment: All other LIS recipients are not auto-enrolled in Part D plans from the first day of their LIS eligibility. Instead, their enrollment is “facilitated” if, two months after CMS has identified individuals as LIS eligible, they do not enroll themselves in a Part D plan. Facilitated enrollment is always prospective, even if the beneficiary is retroactively eligible for the LIS.

Individuals may be enrolled via facilitated-enrollment into any one of the same benchmark plans available for auto-enrollment. As with auto-enrollment, facilitated enrollment is random and does not take into account the particular prescription drug needs of the individual. For both auto-enrollment and facilitated enrollment, CMS checks LIS rolls against enrollment lists of subsidized employer plans. If an employer has claimed a subsidy for an individual, CMS will not auto-enroll or facilitate the enrollment of that individual.

Continuous Special Enrollment Period: All LIS recipients have a continuous Special Enrollment Period that allows them to join or change or drop plans at any time. The change is effective the first day of the next month. This means that LIS beneficiaries are not stuck in the plan into which they are auto- or facilitated-enrolled. It also means that LIS recipients are likely to be subjected to marketing by plan representatives throughout the year.

### **3.D When can a beneficiary enroll in a plan or change plans?**

Non-LIS eligible individuals can join or change plans only during designated enrollment periods:

- All newly Medicare-eligible individuals have an Initial Enrollment Period (IEP) that commences three months prior to their Medicare eligibility and continues through the month of their eligibility and for three months thereafter, for a total of seven months.

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<sup>3</sup> See Footnote 2 for more information on regional benchmark amounts.

- All Part D eligible individuals have an Annual Election Period (AEP) in which to join, change or drop plans. The Annual Enrollment Period lasts from November 15 through December 31 each year with enrollment effective January 1 of the following year.
- Special Enrollment Periods (SEPs) are available when an individual moves out of the coverage region; when an individual was not enrolled in a plan because of an error by a federal employee; in connection with certain events related to “creditable” coverage or employer coverage; in other circumstances where a plan is discontinued; when an enrollee can show that a plan violated a material provision of its contract with the individual; and in other special circumstances.
- An Open Enrollment Period (OEP) is available in connection with Medicare Advantage plans. The period allows individuals to make some plan changes, but it cannot be used to enroll in Part D for the first time. The following actions can be taken during this period: individuals in a MA-PD plan can 1) switch to another MA-PD plan or 2) switch to original Medicare with a PDP; individuals in a MA plan with no prescription coverage can 1) switch to another MA plan with no prescription drug coverage or 2) enroll in original Medicare; individuals in original Medicare with a PDP can enroll in a MA-PD. Individuals can only make one change during this period. The OEP is January 1 to March 31.

Dual eligibles, individuals in nursing homes and qualifying low-income beneficiaries have additional opportunities to join or change plans:

- As mentioned above, all LIS recipients have a continuous Special Enrollment Period (SEP) which allows them to join or change or drop plans at any time. The change is effective the first day of the next month.
- Nursing home residents also have a continuous SEP.
- Individuals who lose LIS-eligibility have a one-time SEP that extends from January 1 through March 31 of each calendar year OR from the month they receive notification of a loss of LIS through the next 2 months, whichever occurs later in the year.

For more information on enrollment periods see NSCLC’s Prescription Drug Enrollment Periods Chart at [www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides/copy\\_of\\_article.2007-09-10.7115807774/at\\_download/attachment](http://www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides/copy_of_article.2007-09-10.7115807774/at_download/attachment).

### 3.E When should a Medicare beneficiary NOT enroll (or opt out of enrollment) in a Part D plan?

An individual who has “creditable coverage,” i.e., coverage that is actuarially as good as or better than Part D standard coverage, usually from an employer or union or governmental entity, needs to consider carefully whether enrolling in a Part D plan is appropriate. All plans are required to send enrolled Medicare beneficiaries letters (or other information, e.g., a newsletter) stating whether their coverage is “creditable.”

Because the structures of employer plans can vary greatly, a decision to drop creditable coverage should only be made with full information. Beneficiaries should check with the specific program or employer plan before making any decisions since the issues are plan specific. Factors to consider include:

- Under some employer plans, if an individual enrolls in Part D, the individual AND dependents will be dropped from the ENTIRE employer health insurance plan, not just the drug coverage. Once dropped from the employer plan, re-enrollment is often barred. In these cases, enrolling in a Part D plan can result in serious degradation in total coverage.
- Some employer plans with comparable coverage (e.g., TRICARE for Life) do NOT drop a member if that individual enrolls in Part D. Dual eligibles and other LIS individuals paying little or no premium may save money and obtain expanded coverage by continuing in the employer plan and also enrolling in Part D.
- Some employer plans offer wrap-around coverage that complements Part D coverage.
- Some employer plans add little to Part D coverage and entail additional premium payments. Dual and LIS eligibles, after comparing benefits, may find that dropping the employer plan saves money and does not hurt overall coverage.

**Practice Note:** Dual eligibles who have been auto-enrolled and need to drop their Part D coverage to protect their employer coverage must disenroll from the Part D plan to which they have been assigned and *opt out* of further enrollment. They must make it clear, preferably in writing, that they are opting out of all enrollment in Part D and not just disenrolling from an assigned plan. Otherwise, they may be auto-enrolled again the next month.

### 3.F What are late enrollment penalties? Do they apply to LIS recipients?

In general an individual who, for 63 consecutive days after the close of his or her Medicare Initial Enrollment Period, is not enrolled in either a Part D plan or a plan with creditable coverage will be subject to a late enrollment premium penalty when he or she

later enrolls in a Part D plan. The penalty is at least 1% per month of the “base beneficiary premium” (a composite premium derived from a complex formula) for every month after the close of the Initial Enrollment Period in which the individual is not enrolled in a plan. The penalty continues as long as the individual is enrolled in Part D and rises each year as the base beneficiary premium rises.

LIS recipients are not subject to a late enrollment penalty.

**Statutes, Regulations and Guidance:** Part D enrollment is addressed at 42 USC §1395w-101 and 42 CFR §§423.30-423.56. CMS Guidance to plans regarding enrollment, Chapter 3 of the Medicare Prescription Drug Manual is available at [www.cms.hhs.gov/PrescriptionDrugCovContra/12\\_PartDManuals.asp](http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp). CMS guidance to Medicare Advantage plans, Chapter 2 of the Medicare Managed Care Manual is available at [www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019326](http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019326).

**More Resources:** NSCLC has developed various materials related to Part D Enrollment. See [www.nslc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides](http://www.nslc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides).

## **4. PART D COVERAGE**

### **4.A Do all Part D plans cover the same drugs?**

No. Each plan may offer its own formulary, or list of covered drugs, subject to certain limits set by CMS:

- Plans must offer at least two drugs in each of most major therapeutic categories.
- Plans must offer all or virtually all drugs in the following six categories: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, anticancer, and immunosuppressants. However, they may impose prior authorization or utilization management requirements for these drugs.

### **4.B Are any categories of drugs always excluded from Part D coverage?**

Yes. By law, certain drugs may not be covered by Part D. They are: drugs for anorexia, weight loss or gain; for fertility; for cosmetic purposes or hair growth; for relief of cold symptoms; or for erectile dysfunction; prescription vitamins and minerals (except niacin, prenatal vitamins and fluoride preparations); non-prescription drugs (over-the-counter);

and certain anti-anxiety and anti-seizure drugs (barbiturates and benzodiazepines are the most common).

However, most state Medicaid programs are continuing to provide Medicaid recipients with those excluded drugs that had been covered by Medicaid in the past.

Part D plans also have the option of including these drugs in their enhanced plans, but do not receive a government subsidy for them. Enrollee expenditures for excluded drugs do not count toward the catastrophic limit.

#### **4.C Can plans change their formularies?**

Yes. Plans can change their formularies annually. In addition, they can change formularies during the plan year with 60 days notice to individuals directly affected. CMS also has limited the options for plans to make negative formulary changes absent health and safety reasons. Except when a formulary change is a result of safety concerns, plans must exempt enrollees currently taking the affected drug from the formulary change for the remainder of each plan year. A change in formulary does not trigger the right of an enrollee to change plans (except for LIS recipients, who can change plans at any time).

#### **4.D What other restrictions can plans place on drug availability?**

Plans may impose step therapy requirements, also called “fail first” (plan requires beneficiary to try another medication or treatment before receiving the requested medication), prior authorization requirements (plan requires physician to provide additional information before authorizing payment for the requested medication), and dosage limits (plan limits the quantity or delivery method, e.g., tablet, capsule, liquid, of a medication that will be available to a recipient).

#### **4.E What is “transitional assistance” or a “transition fill”?**

CMS requires that Part D plans must have a transition process for new enrollees to get a first fill of continuing prescriptions, even if they are not on the formulary of the plan or if the formulary restricts their use. Transition supplies also are required for existing enrollees if a plan changes its formulary at the start of the plan year. One 30 day fill is required, although CMS has urged plans, on a case-by-case basis, to continue transition supplies if an exception is pending. Nursing home residents are entitled to longer transition fills than other beneficiaries. CMS requires at least a 90 day transition for nursing home residents. Plans also must have transition policies for enrollees who experience a change in level of care, e.g., entering or leaving a nursing home or leaving a hospital.

In practice, transition fill policies have varied widely among plans and, in many cases, have not been well understood by dispensing pharmacists or followed by plans.

#### **4.F What can an enrollee do if a needed drug isn't on the formulary or is in an expensive tier?**

When a plan denies coverage for a drug that an enrollee's prescribing physician believes is medically necessary, the enrollee, the enrollee's representative or the enrollee's doctor can request a "coverage determination." Most coverage determinations are requests for "exceptions" to a plan's formulary, prior authorization requirements, tiering structure or usage limitations (e.g., requirement for step therapy).

Exception requests must be supported by a statement by the prescribing physician. The required statement for a formulary or tiering exception must show that the drug is "medically necessary," that is, that other drugs on the formulary or drugs on the lower tier would not be as effective or would cause adverse effects. Plans must accept written statements and can decide to also accept statements orally. Dosing and step therapy exception criteria are similar.

If an exception is granted, it continues through the rest of the plan year. The plan has the option of extending it further without requiring another exception request.

**Practice Note:** LIS recipients and nursing home residents have the option of changing plans if their exception request is denied. Other enrollees do not. Nursing home residents have additional protections. Under the Nursing Home Reform Law, the facility is responsible for providing all necessary medical care, and should provide uncovered medications. Also, for dual eligibles in nursing homes, the Medicaid rules regarding incurred medical expenses should allow the purchase of uncovered drugs and a reduction in the resident's share of cost or spenddown, causing no additional expense for residents on Medicaid with a share of cost or spenddown.

#### **4.G What is the timeframe for handling exceptions?**

For a standard exceptions request, a plan must make a ruling within 72 hours of receiving the supporting statement of the prescribing physician. For an expedited exceptions request, the plan must rule within 24 hours or earlier if the enrollee's condition requires it. A request *must* be expedited when the prescribing physician asserts that a delay may place the enrollee's life, health, or ability to regain maximum function in serious jeopardy. If the enrollee is seeking reimbursement after having already paid for and received the drug, expedited consideration will not be granted. See Section 5.A, below, for steps beneficiaries can take if these timelines are not met.

#### **4.H If an exception is denied, what appeals are available?**

If the plan denies an exception request, five levels of appeal are available:

1. Redetermination by the plan. A different decision-maker within the plan reviews the file.
2. Review by an Independent Review Entity (IRE). This is the first level of review outside the plan.
3. Review by an Administrative Law Judge at CMS.
4. Review by the Medicare Appeals Council.
5. Review by federal courts, beginning with Federal District Court.

Enrollees have 60 days in which to file each level of appeal. For redeterminations by plans and by IREs, the time limits for handling expedited appeals and standard appeals are 72 hours and 7 days, respectively. At the ALJ and MAC level, decision-makers face a 90 day deadline.

#### **4.I What is the grievance process?**

If enrollees have complaints that are not about specific determinations on drug availability or cost based on the individual's medical needs, they may file a grievance. Grievances may cover such issues as poor or rude service, plan structure, and complaints about delays in handling exceptions. Plans must investigate grievances and provide responses within 30 days.

**Statutes, Regulations and Guidance:** Formularies, exceptions, appeals and grievance are addressed at 42 USC §1395w-104; 42 CFR §§423.560-423.638. CMS Guidance to plans regarding exceptions and appeals (Chapter 18), formularies (Chapter 6) and transition policies (Chapter 6) are available at [www.cms.hhs.gov/PrescriptionDrugCovContra/12\\_PartDManuals.asp](http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp)

**More Resources:** NSCLC has developed various materials related to transition protections and to Part D Exceptions and Appeals. See [www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides](http://www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides)

### **5. PART D PROBLEMS**

#### **5.A How can beneficiaries report and receive assistance resolving Part D problems?**

If an individual experiences a problem accessing medications, it is important to follow up on the problem and seek resolution.

According to CMS protocol for filing complaints, beneficiaries and advocates experiencing a problem should first file a complaint with their Part D plan. If the plan does not respond to or provide a satisfactory resolution of the complaint, the beneficiary or advocate should file a complaint with 1-800-MEDICARE. The complaint will be entered into Medicare's Complaint Tracking Module (CTM).

The plan will be notified that a complaint was filed and that it is required to take additional action. If the complaint is still not resolved by the plan, the beneficiary or advocate should then contact the CMS regional office for further assistance. Individuals and advocates may contact the regional office by phone or email. Utilizing email ensures that a paper trail of the communication is created.

If the problem does not involve a plan (e.g. problems getting information from 1-800-MEDICARE, a dual eligible who has not been enrolled in a plan, etc.), it is best to file the complaint directly with the CMS regional office. Appendix A includes CMS regional contact information as well as contact information for a variety of other resources for helping individuals to access medications.

For further information on Medicare Part D, please see our website [www.nsclc.org](http://www.nsclc.org) or contact NSCLC's Oakland Office.

Updated April, 2009

## APPENDIX A: CMS REGIONAL OFFICE CONTACTS AND HELPFUL WEBSITES

### CMS REGIONAL OFFICES - MEDICARE CONTACTS

	States	Phone	Email
Region I - Boston	Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont	(617) 565-1322	PartDComplaints_RO1@cms.hhs.gov
Region II - New York	New Jersey, New York, Puerto Rico, Virgin Islands	(212) 616-2222	PartDComplaints_RO2@cms.hhs.gov
Region III - Philadelphia	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia	(215) 861-4326	PartDComplaints_RO3@cms.hhs.gov
Region IV - Atlanta	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee	(404) 562-7500	PartDComplaints_RO4@cms.hhs.gov
Region V - Chicago	Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin	(312) 886-2566	PartDComplaints_RO5@cms.hhs.gov
Region VI - Dallas	Arkansas, Louisiana, New Mexico, Oklahoma, Texas	(214) 767-6401	PartDComplaints_RO6@cms.hhs.gov
Region VII - Kansas City	Iowa, Kansas, Missouri, Nebraska	(816) 426-5783	PartDComplaints_RO7@cms.hhs.gov
Region VIII - Denver	Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming	(303) 844-4024	PartDComplaints_RO8@cms.hhs.gov
Region IX - San Francisco	American Samoa, Arizona, California, Commonwealth of the Northern Mariana Islands, Guam, Hawaii, Nevada	(415) 744-3628	PartDComplaints_RO9@cms.hhs.gov
Region X - Seattle	Alaska, Idaho, Oregon, Washington	(206) 615-2354	PartDComplaints_RO10@cms.hhs.gov

**HELPFUL WEBSITES**

National Senior Citizens Law Center	<a href="http://www.nsclc.org">www.nsclc.org</a>
Center for Medicare Advocacy	<a href="http://www.medicareadvocacy.org">www.medicareadvocacy.org</a>
The Medicare Rights Center	<a href="http://www.medicarerights.org">www.medicarerights.org</a>
National Health Law Program	<a href="http://www.healthlaw.org">www.healthlaw.org</a>
State Health Insurance Assistance Program	<a href="http://www.shiptalk.org">www.shiptalk.org</a>
Medicare (consumer info, plan finder)	<a href="http://www.medicare.gov">www.medicare.gov</a>
CMS site	<a href="http://www.cms.hhs.gov/home/medicare.asp">www.cms.hhs.gov/home/medicare.asp</a>
Social Security Administration	<a href="http://www.ssa.gov">www.ssa.gov</a>