

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: Medicare Advantage – Prescription Drug Organizations
Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

SUBJECT: Medicare Prescription Drug Benefit Manual – Chapter 13

DATE: February 17, 2010

CMS is pleased to release a revised version of Chapter 13 of the Medicare Prescription Drug Benefit Manual (Premium and Cost-Sharing Subsidies for Low-Income Individuals). This revised version contains the following clarifications:

1. Added the definitions of generic drug, preferred drug, multiple source drug, and preferred multiple source drug, and clarified the cost sharing amounts that should be charged to the a subsidy-eligible individual when dispensing the generic or a lower cost, multiple-source drug.
2. Clarified where plans and beneficiaries may find information regarding appeals of subsidy determinations.
3. Described the different amounts used by CMS to calculate the low-income benchmark premium amount and describes, that this calculation will not be net of Parts A and B rebates for 2010.
4. Added a section on the Part D sponsor's use of the Weekly/Monthly transaction reply report (TRR).
5. Clarified the responsibility of Part D sponsors when beneficiaries are found retroactively eligible for LIS.
6. Clarified that one of the best available evidence (BAE) documents listed in this section must be included with the update sent to our contractor.
7. Revised the cost share charts and appendices for CY 2010.

The revised manual will be posted at
http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

Any questions regarding this manual chapter may be directed to Christine Hinds on (410)786-4578, or via email at christine.hinds@cms.hhs.gov.

Medicare Prescription Drug Benefit Manual

Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals

(Rev. 9, 02-05-10)

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Note: This chapter is subject to change to both periodic and annual updates, and currently reflects CY 2010 guidance.

10 - Introduction

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This chapter establishes the Part D sponsor requirements and limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan. The Medicare Prescription Drug Benefit, which went into effect January 1, 2006, provides extra help with prescription drug costs for eligible individuals whose income and resources are limited. This help takes the form of subsidies paid by the Federal government to the Part D sponsor. The low-income subsidy (LIS) provides assistance to certain low-income individuals to supplement the premium and cost-sharing (including deductibles and cost-sharing during the coverage gap) associated with the Part D benefit.

Except where specifically noted, these requirements apply to all Part D sponsors offering Part D coverage. Other requirements related to beneficiary protections are contained in other chapters of Pub. 100-18, Medicare Prescription Drug Benefit Manual, which can be accessed at: http://www.cms.hhs.gov/manuals/downloads/Pub100_18.pdf.

20 - Definitions

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Unless otherwise stated in this chapter, the following definitions apply:

Annual out-of-pocket threshold: The point in the Part D benefit when a beneficiary enters the catastrophic coverage phase. Detailed description is found in chapter 5, section 20.3.1 of this manual. For years subsequent to 2006, it is the annual out-of-pocket threshold for 2006 (\$3600) increased by the annual percentage increase specified at 42 CFR 423.104(d)(5)(iii). See Appendix A for the current calendar year annual out-of-pocket threshold.

Applicant: The Part D eligible individual applying for the low-income subsidy with either the Social Security Administration (SSA) or the State Medicaid agency.

Basic prescription drug coverage: Refer to chapter 5, section 20.1 of this manual for the description of this term.

Best Available Evidence: Documentation used by the Part D sponsor to support a favorable change to a low-income subsidy eligible beneficiary's LIS status.

Copayment Amounts: Applicable calendar year copayment/coinsurance amounts provided in Appendix A for full subsidy and partial subsidy eligible individuals.

Coverage Gap: The Part D benefit phase above the initial coverage limit and at or below the annual out-of-pocket threshold described at 42 CFR 423.104(d)(4) (and in chapter 5, section 20.3.1 of this manual).

Covered Part D drugs: Refer to chapter 6, section 10.2 of this manual for the description of this term.

Deductible Amounts: Applicable deductible amounts provided in Appendix A for partial subsidy eligible individuals.

Deemed Eligible Individual: An individual who is deemed as meeting the eligibility requirements for full subsidy eligible individuals if the individual is entitled to Medicare and:

- A full benefit dual eligible individual (eligible for full Medicaid benefits);
- A recipient of Supplemental Security Income (SSI) benefits; or
- Eligible for full Medicaid benefits, and/or the Medicare Savings Program as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI) under a State's Medicaid plan.

A full description is found at section 40.2 of this chapter.

Dual Status: Entitlement to Medicare and concurrent eligibility for a Title XIX benefit (i.e., Medicaid or a Medicare Savings Program).

Extra Help: The low-income subsidy (LIS) or subsidy.

Family Size: Includes the applicant, the spouse, if any, living in the same household and the number of individuals, if any, related to the applicant(s) living in the same household, and dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal Poverty Level (FPL): The income standard for poverty that is updated annually by the U.S. Department of Health and Human Services and generally used as the basis for determining the low-income subsidy level. *For more information regarding specific FPLs, see section 40.1.1 of this chapter.*

Full Benefit Dual Eligible Individual: An individual who is entitled to Medicare and is eligible for comprehensive Medicaid benefits and meets the requirements of the definition at 42 CFR 423.772.

Full Subsidy: The amount of reductions to a full subsidy eligible individual's costs under a Part D plan, including:

- 100% subsidy of the monthly premium for basic prescription drug coverage up to the regional low-income premium subsidy amount;
- Elimination of the annual deductible;

- Reduced cost-sharing if the copayment under the basic or enhanced portion of the plan's benefit package is more than the applicable LIS copayment amounts provided in Appendix A for Part D covered drugs (further explained in section 60.4);
- Elimination of the coverage gap;
- Elimination of cost-sharing above the annual out-of-pocket threshold; and,
- Waiver of late enrollment penalty.

A full description is found at 30.1 of this chapter.

Full Subsidy Eligible Individual:

- A subsidy eligible individual whose income is below 135 percent of the FPL applicable to the individual's family size and whose resources do not exceed the resources described in 42 CFR 423.773(b)(2)(ii). For current year resource limits see <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025>; and
- An individual deemed eligible as a full subsidy eligible individual.

***Generic:** A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.*

Income: Money received in cash or in-kind by the applicant or a spouse who is living with the applicant that can be used to meet their needs for food and shelter. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant. Effective January 1, 2010, income for support and maintenance in kind is not counted as income to the applicant.

Institutionalized Individual: A full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a calendar month, as defined in section 1902(q)(1)(B) of the Social Security Act.

Low-Income Subsidy (LIS) Individual's Premium Amount: The premium paid by the low-income subsidy beneficiary for basic prescription drug coverage after the premium subsidy amount is applied.

MA-PD plan: A plan offered by a Medicare Advantage (MA) organization that provides qualified prescription drug coverage.

Medicare Savings Program (MSP): For purposes of the Medicare Part D full subsidy eligibility, the Qualified Medicare Beneficiary (QMB) benefit, the Specified Low Income

Medicare Beneficiary (SLMB) benefit, or the Qualifying Individual (QI) benefit under title XIX of the Social Security Act.

Multiple source or multi-source drug: A drug defined in section 1927(k)(7)(A)(i) of the Social Security Act.

Part D sponsor: A prescription drug plan (PDP) sponsor, MA organization offering an MA-PD plan, a Program for All-inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

Partial Subsidy: Partial reductions in a beneficiary's costs imposed under a Part D plan, including:

- Reduction to the deductible when the deductible is greater than the maximum deductible amounts for partial subsidy eligible individuals (See Appendix A);
- 25% to 100% subsidy of the monthly premium for basic prescription drug coverage up to the regional low-income premium subsidy amount;
- Reduction to 15% coinsurance per prescription for covered Part D drugs, up to the annual out-of-pocket threshold, and copayments of not more than the maximum copayments for Partial subsidy eligible individuals above the annual out-of-pocket threshold (See Appendix A);
- Elimination of the coverage gap; and,
- Waiver of late enrollment penalty (LEP).

Partial subsidy eligible individual: Referred to as other low-income subsidy eligible individuals at 42 CFR 423.773, or a subsidy eligible individual who has:

- Income less than 150% of the Federal Poverty Level (FPL) applicable to the individual's family size; and
- Resources that do not exceed the amounts described in section 30.2 of this chapter (see <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025> for the current year resource limitations).

Personal representative: For purposes of this chapter, (1) an individual who is authorized to act on behalf of the applicant; (2) if the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or (3) an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Preferred drug: *A covered Part D drug on a Part D sponsor's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the sponsor's formulary.*

Preferred multiple source drugs: *A drug that is both a preferred drug and a multiple source drug, meaning that one version of that drug is placed on the sponsor's formulary with lower cost sharing than for a non-preferred drug.*

Prescription Drug Plan (PDP): Prescription drug coverage that is approved under 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS.

Reference Month: The month in the previous calendar year as identified by CMS for the calculation of the low-income benchmark premium amount. See 423.780(b)(2), 422.258(c)(1).

Resources: With the exception of the value of the individual's life insurance policy, the liquid resources of an LIS applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. Effective January 1, 2010, the value of any life insurance policy is not counted as a resource to the applicant.

Regional low-income premium subsidy amount: The greater of the PDP region's low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region as defined in section 50.2.1.

State: Each of the 50 States and the District of Columbia.

Subsidy: The low-income subsidy.

Supplemental drugs: Drugs that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under 42 CFR 423.100, and as described in chapter 6, section 20.1 of this manual. Because such drugs must have otherwise qualified as covered Part D drugs (as defined in chapter 6, section 10.2 of this manual) in order to be covered as a supplemental benefit, and because only prescription drugs are included in the definition of a Part D drug, over-the-counter drugs cannot be supplemental drugs, as discussed in chapter 6, section 10.10. Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in chapter 5, section 20.4.2 of this manual.

Transaction Reply Report (TRR): A report that CMS provides to Part D sponsors containing details of the rejected and accepted enrollment transactions that CMS has processed for a Part D sponsor's contract(s) over a specified time period. There are two types of TRRs: the Weekly TRR that covers the processing week (typically Sunday through Saturday) and the Monthly TRR that covers the payment processing month.

TrOOP or True Out-Of-Pocket costs – See chapter 5, section 30 of this manual for the description of this term.

30 - Eligibility Requirements

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes the requirements for Medicare beneficiaries with limited income and resources to qualify for the Part D LIS. Specifically, it discusses eligibility for the two categories of the LIS: the full subsidy and the partial subsidy.

The LIS described in this chapter is limited to Medicare beneficiaries who reside in the 50 States and the District of Columbia. U.S. Territories receive a Federal grant to operate their own programs to assist dual Medicare/Medicaid beneficiaries with the costs of the Part D benefit. Discussion of the U.S. Territories enhanced allotment program is described in section 90 of this chapter.

Individuals who receive prescription drug coverage through plans other than Part D plans, including those for whom employers are claiming a retiree drug subsidy, do not receive the benefits of the LIS. Low-income individuals must be enrolled in a Part D plan to have their premium, deductible, coverage gap, and cost-sharing subsidized by the low-income subsidy.

30.1 - Full Subsidy Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

An individual can qualify for the full subsidy in two ways. First, an individual qualifies if he or she applies and is determined to have:

(1) An annual income below 135 percent of the FPL as applicable to the individual's family size; and

(2) Resources that do not exceed the resource limitations specified at <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025> for the plan year. For subsequent years, the amount of resources allowed for the previous year will be increased by the annual percentage increase set forth by the U.S. consumer price index (all items, U.S. cities). The annual percentage increase will be determined by September of the previous year and will be rounded to the nearest multiple of \$10. The nearest multiple will be rounded up if it is equal to or greater than \$5 and rounded down if it is less than \$5.

The following individuals are deemed automatically eligible for the full subsidy based on their qualification for other Federal programs:

(1) Full-benefit dual eligible individuals;

(2) Recipients of Supplemental Security Income (SSI) benefits under title XVI of the Act or;

(3) Individuals eligible for Medicare Savings Programs as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

30.2 - Partial Subsidy Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

An individual is eligible for the partial subsidy if she/he applies and is determined to have:

(1) An annual income below 150 percent of the FPL as applicable to the individual's family size; and

(2) Resources that do not exceed the resource limitations at <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025> (including the assets and resources of the individual's spouse). For subsequent years, the amount of resources allowed for the previous year is increased by the annual percentage increase set forth by the U.S. consumer price index (all items, U.S. cities). The annual percentage increase is determined by September of the previous year and will be rounded to the nearest multiple of \$10. The nearest multiple will be rounded up if it is equal to or greater than \$5 and rounded down if it is less than \$5.

40 - Eligibility Determinations, Redeterminations, and Applications

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes the process for determining eligibility for the full or partial subsidy, and for deeming eligibility for the full subsidy. "Determining" is the term used to describe the process in which an individual must apply and be found eligible in order to qualify for the full subsidy. "Deeming" is the term that is used to describe the process in which an individual automatically qualifies for the full subsidy without applying, by virtue of having applied and been found qualified for certain other Federal programs. An individual's LIS status cannot begin earlier than his or her Part D eligibility.

For details on the eligibility determination processes discussed in the following sections, see 20 CFR Part 418 and the SSA Program Operations Manual System [POMS], available at <http://policy.ssa.gov/poms.nsf/aboutpoms>, under Health Insurance (HI) 030.

40.1 - Eligibility Through Application

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes the process for those who must apply and be determined eligible in order to qualify for the LIS.

A beneficiary who believes he or she may be eligible for the LIS (but is not deemed eligible by virtue of being Medicaid, MSP, or SSI-eligible) may apply for the subsidy through the Social Security Administration (SSA) or by requesting a State determination at

his or her State Medicaid agency. The agency (SSA or State Medicaid agency) that makes the subsidy decision is responsible for on-going case activity, including notices, redeterminations of subsidy eligibility, and appeals. If an application is filed with the State Medicaid agency, that agency is responsible for screening the applicant for eligibility for a Medicare Saving Program (MSP) and offering to enroll any applicant who qualifies. If a State Medicaid agency determines LIS eligibility, the applicant would be subject to state reporting requirements, which might result in different timeframes for reduction or termination of eligibility than under the process administered by SSA.

Eligibility determinations made by SSA are made in accordance with requirements set forth by the Commissioner of Social Security (see 42 CFR § 423.774). State Medicaid agencies, at the request of the applicant, must make subsidy eligibility determinations using the same financial rules used by SSA but apply the case processing standards (including time frames for making decisions and notifying applicants) that the State uses for its Medicaid cases. State LIS applications are available at the State Medicaid agencies. The Guidance to States on the Low-Income Subsidy (available at http://www.cms.hhs.gov/States/03_lowincomesubsidy.asp) provides policies and procedures for State LIS determinations. In order for LIS subsidy applications under this section to be considered complete, applicants (or personal representatives applying on the individual's behalf) are required to:

1. Complete all required elements of the application;
2. Provide any requested statements from financial institutions to support information in the application; and
3. Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

SSA verifies most information through data matches with existing SSA, Internal Revenue Service and other government files. The agency (SSA or State Medicaid agency) that makes the subsidy decision may request additional documentation if there are discrepancies between the data matches and the attestations on the application. If the individual, or his or her personal representative, files an application with the State or SSA seeking subsidy eligibility for any portion of an eligibility period covered by an earlier application, the later application is void if the individual has received a subsidy approval on that earlier application from the State or SSA.

SSA and the states notify CMS of individuals whom they have determined to be eligible for the LIS and CMS in turn provides the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. (For details on how CMS communicates LIS eligibility to Part D sponsors, see section 70 of this chapter.)

It is important to remember that the low-income subsidy provides no benefit if the beneficiary is not enrolled in a Part D plan. LIS-eligible beneficiaries have a continuous Special Enrollment Period and may enroll at any time by:

- Calling 1-800-MEDICARE;
- Filing a request with the On-Line Enrollment Center at www.medicare.gov; or
- Calling the Part D sponsor directly.

40.1.1 - Financial Standards for Low-Income Subsidy (LIS) Applications (Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

To qualify for the Part D low-income subsidy, Medicare beneficiaries must have resources and income no greater than the resource and income limits established by the Medicare Modernization Act (MMA). The financial standards applicable to LIS applications are those in effect on the date of application. When determining whether a beneficiary qualifies for LIS, \$1,500 in resources per person (applicant and spouse) are excluded from consideration if the beneficiary indicates that they expect to use some of their resources for burial expenses.

CMS is required by law to update the Part D income and resource limits each year. Resource limits for the next calendar year are updated based on the September Consumer Price Index (CPI) Resource limits (see <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025> for the current year resource limits). Early each year, the U.S. Department of Health and Human Services updates that income level equivalent to 100% of the Federal Poverty Level (FPL) for that same calendar year (see <http://aspe.hhs.gov/-/poverty/>). CMS calculates the corresponding FPL (income) levels necessary for qualifying for the LIS benefit, i.e., 135%, 140%, 145% and 150%, and notifies Part D sponsors of the updated levels via an HPMS memo by the end of January or early February. The new poverty guidelines are retroactive to January 1 of that year.

40.1.2 - Effective Date of Initial Determinations (Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

An individual who applies and is determined eligible for the LIS is eligible effective the first day of the month in which the individual submitted an application (but no earlier than January 1, 2006). In most cases, LIS applicant status is effective retroactively. The majority of new LIS applicants are already entitled to Medicare when they apply for LIS. For individuals who are entitled to Medicare at the point in time they submit an application, their LIS effective date will be retroactive to the first day of the month the application was filed. If a beneficiary is already enrolled in a Part D plan, the Part D sponsor must take steps to ensure that the beneficiary is made whole with respect to any premium or cost-sharing the member has paid that should have been covered by the subsidy (see section 70 for details on Part D sponsor obligations). This applies to both current and former members.

For individuals who are not yet entitled to Medicare, the LIS effective date is the first day of the month in which their Medicare Part D eligibility starts. Note that the beneficiary must be enrolled in a Part D plan in order to benefit from the subsidy.

Example 1: An individual who is already Medicare eligible applies at SSA for the LIS on April 22, 2010. SSA makes a determination on May 19, 2010, that the person qualifies for the subsidy. Their LIS is effective retroactive to April 1, 2010.

Example 2: An individual who is not yet Medicare eligible applies at SSA for the LIS on April 22, 2010. SSA makes a determination on May 19, 2010, that the person qualifies for the subsidy. The person's Medicare eligibility starts June 1, 2010, so the subsidy effective date is also June 1, 2010.

Initial LIS determinations are made for a period not to exceed 12 months. Thereafter, if the individual is found ineligible, the subsequent end date would be established by the agency that made the decision. The end date is always the last day of a calendar month but may occur in any month of the year, depending on the requirements of the agency (either the State or SSA) making the decision. On-going LIS eligibility will appear in the Medicare Beneficiary Database (MBD) as a span without an end date.

40.1.3 - Changes in Subsidy Level Within Established Span

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

For cases in which eligibility is established through application with SSA, report of a subsidy-changing event will trigger a redetermination of subsidy eligibility during the calendar year. This can result in changes to the individual's deductible, premium subsidy, cost-sharing subsidy, or even termination of their LIS. Subsidy changing events are:

- Marriage;
- Divorce;
- Death of spouse;
- Separation;
- Reunion after separation; and
- Annulment.

When SSA receives a report of a subsidy-changing event, the beneficiary is mailed a redetermination form to complete and return within 90 days. Any change (i.e., increase, decrease, or termination) in the level of the subsidy indicated by the completed redetermination form will take effect as of the first day of the month following the month of the initial report of the change.

Example: An individual who is subsidy-eligible reports to SSA on April 10, 2010, that her husband died on March 25, 2010. SSA mails a determination form to the beneficiary on April 13, 2010. The beneficiary must return the completed form by July 13, 2010. She returns the form on June 25, 2010, with information that she is now sole owner of resources that she and her deceased husband previously owned jointly. Based on this information, SSA finds her ineligible for the LIS based on excess resources effective May 1, 2010, the first of the month following the month of the initial report.

Part D sponsors are obligated to make the beneficiary whole with respect to overpaid premiums and cost-sharing or to collect any underpaid premiums and cost-sharing due from the beneficiary as discussed in section 70.3 of this chapter. This applies to both former and current members.

40.1.4 - Deeming After Eligibility Through Application

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

If, after establishing LIS eligibility through application, an individual is reported by his or her State Medicaid agency as Medicaid or MSP-eligible, or by SSA as SSI-eligible, deemed status is established for the individual. When this occurs, the LIS determination is terminated. The deemed status prevails over the application status and provides a subsidy benefit that is at least as good as the subsidy established through application.

Example: Beneficiary applies for the LIS with SSA on October 9, 2009, and is approved for a partial subsidy, effective October 1, 2009. In March, 2010, he is reported by his State as being eligible for Medicaid effective March 1, 2010. His eligibility as an LIS applicant for a partial subsidy is terminated effective February 29, 2010. His deemed status (and thus qualification for full subsidy) is effective March 1, 2010 through December 31, 2010.

Refer to section 70.3 regarding the Part D sponsor's obligation to make the member whole with respect to overpaid premiums and cost-sharing or to recoup any underpaid premiums and cost-sharing due from the beneficiary. This applies to both former and current members.

40.1.5 - Determining Agency Notification to Applicant

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Individuals who applied for LIS will be notified of the results of the eligibility determination, redetermination, or impact of subsidy-changing events by the agency (SSA or State Medicaid agency) that made the initial LIS determination.

40.1.6 - Redetermination Process

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The agency (SSA or State Medicaid agency) that makes the subsidy decision is responsible for on-going case activity, including redeterminations of LIS eligibility. CMS and the Part D sponsor may not be notified of an appeal decision until after the effective date in case of an appeal.

40.1.7 - Appeals

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When an individual disagrees with a determination of *his or her* subsidy eligibility, subsidy level, or subsidy termination, the individual may appeal the decision with either SSA or the State Medicaid agency, whichever agency made the initial determination. *Beneficiary information regarding the appeals process for subsidy determinations are further described in the determination letter sent by SSA or the Medicaid agency. Instructions regarding SSA appeals within the SSA Program Operations Manual System are found at: <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603040000!opendocument>.*

40.2 - Eligibility Through Deeming

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes how individuals are deemed automatically eligible for the full subsidy. Individuals are never deemed eligible for the partial subsidy.

40.2.1 - Source Data

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration.

SSA sends a monthly file of SSI-eligible beneficiaries to CMS.

Similarly, the State Medicaid agencies submit MMA files to CMS that identify beneficiaries who are:

- Eligible for full Medicaid benefits (full benefit dual eligible), or
- Eligible for a Medicare Savings Program (QMB, SLMB, or QI).

Data from States are also submitted to CMS in two additional ways:

1. From CMS' Point-of-Sale Eligibility Verification Contractor (The Point-of-Sale contractor provides immediate coverage at point of sale for subsidy eligible individuals who are not enrolled in a Part D plan. The eligibility verification contractor checks State eligibility data to confirm the individuals are full benefit or partial dual eligible individuals, and submits those data to CMS for the purpose of subsidy deeming).
2. From Part D sponsor-submitted data indicating best available evidence (BAE), which documents the individual's LIS eligibility (see section 70.5).

An individual needs to be reported eligible by SSA or the State for only 1 month in a calendar year to be deemed eligible from that month through the end of the year.

Example: An individual is reported by her State as Medicaid-eligible in March, 2010. She will be deemed eligible from March 1, 2010 through December 31, 2010.

40.2.2 - Effective Date of Initial Deemed Status

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

CMS deems individuals automatically eligible for LIS effective as of the first day of the month that the individual attains the qualifying status (i.e., when a Medicare beneficiary becomes eligible for Medicaid, QMB, SLMB, QI, or SSI). The end date is, at a minimum, through the end of the calendar year. Individuals who are deemed LIS eligible for any month during the period of July through December of a year are deemed eligible through the end of the following calendar year.

Once a beneficiary becomes deemed eligible through the end of a given calendar year, s/he remains deemed even if s/he is no longer reported by his or her Medicaid agency as a full benefit dual eligible individual or partial dual eligible individual, or by SSA as an SSI recipient, due to loss of eligibility.

In most cases, LIS deemed status is effective retroactively. The majority of newly deemed individuals are already entitled to Medicare and apply for Medicaid/QMB/SLMB/QI/SSI. When eligibility for these programs is retroactive, eligibility for LIS deemed status is also retroactive. If a beneficiary is already enrolled in a Part D plan, Part D sponsors must take steps to ensure that the beneficiary is made whole with respect to any premiums and cost-sharing the member has paid that should have been covered by the subsidy (see section 70 of this chapter for details on Part D sponsor obligations). This applies to current and former members.

Example 1: An individual becomes a full-benefit dual eligible individual effective March 1, 2010. The effective date of deemed status is March 1, 2010 through December 31, 2010.

Example 2: A Medicare individual becomes SSI eligible effective October 1, 2010. The effective date of deemed status is October 1, 2010 through December 31, 2011.

For individuals who are initially entitled to Medicaid or SSI-only, and are about to become entitled to Medicare, States and SSA attempt to submit the data for these individuals prior to the start of their Medicare eligibility to help ensure that LIS deemed status is established the first day of their Medicare entitlement.

40.2.3 - Changes to Subsidy Status Within the Established Deemed Span

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Within a given calendar year, an individual's deemed status may change based on data received from States or SSA subsequent to the initial deeming process. CMS uses any such data from States or SSA to determine whether the beneficiary may qualify for a lower copayment obligation. Thus, CMS changes an individual's deemed status mid-year only when such a change qualifies the beneficiary for a lower copayment obligation. The other

benefits of their LIS full subsidy – premium subsidy and elimination of deductible and coverage gap – remain unchanged.

Example 1: An individual is deemed for the \$2.50/\$6.30 copayment level for January 1 through December 31, 2010. Data are subsequently received indicating the individual now qualifies for the \$1.10/\$3.30 level effective March 1, 2010. For the period of March 1, 2010 through December 31, 2010, the individual is now deemed for the copayment level of \$1.10/\$3.30.

Example 2: Effective January 1, 2010, an individual is reported as a full dual with income below 100% FPL and is assigned a copayment level of \$1.10/\$3.30. From August, 2010 onward, the individual is reported as QMB-only (who normally qualify for a level of \$2.50/\$6.30 in 2010). The individual's copayment level will remain \$1.10/\$3.30 through December 31, 2010.

The following example reflects an individual whose copayment level changed effective during the period of July through December of the calendar year.

Example: An individual is initially deemed eligible for the \$1.10/\$3.30 copayment level for April 1, 2009 through December 31, 2009. Data are subsequently received indicating the individual qualifies for \$0 copayment effective November 1, 2009. The individual is deemed at this new copayment level from November 1, 2009 through December 31, 2010.

40.2.4 - CMS Notices to Deemed Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

CMS provides notices to each individual when they are initially deemed eligible for the LIS informing them that they are full subsidy eligible individuals and that they automatically qualify for the LIS. See section 40.2.6 for information on CMS' notices to beneficiaries pursuant to the annual "re-deeming" process.

40.2.5 - Redetermination of Deemed Status ("Redeeming")

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

In July of each year CMS initiates its "re-deeming" process, and runs its re-deeming process monthly thereafter. During the re-deeming process, CMS identifies individuals who qualify in the current year and who will continue to be automatically deemed for the full subsidy in the next calendar year. Individuals who are eligible for Medicaid/QMB/SLMB/QI at any point during the period of July through December of the current year qualify to be re-deemed for the following calendar year, as do SSI recipients who are eligible in any month from July through December of the current year.

Example 1: An individual is initially deemed for January 1, 2009 through December 31, 2009, with a \$0 copayment, based on State data indicating the person is an institutionalized, full benefit dual eligible individual. The individual appears

on a State MMA file as institutionalized for July 2009. The individual is re-deemed for January 1, 2010 through December 31, 2010 with the \$0 copayment.

Example 2: An individual is initially deemed for January 1, 2009 through December 31, 2009, as a full benefit dual eligible individual with copayments of \$1.10/\$3.20, based on State data indicating that the individual's income is less than 100% of the Federal Poverty Level. Beginning in October 2009, the State reports the individual as a full benefit dual eligible individual and institutionalized. The individual's copayments are reduced to \$0 effective October 1, 2009 through December 31, 2010.

Example 3: An individual is initially deemed for January 1, 2009 through December 31, 2009 as a full benefit dual eligible individual with copayments of \$1.10/\$3.20, based on State data that the individual's income is less than 100% of the Federal Poverty Level. No State data is submitted for the individual from July 2009 through December 2009. Therefore, the individual loses deemed status on December 31, 2009. In February 2010, the State resumes reporting the individual, but as a Medicare Savings Program (MSP) recipient, effective November 2009. Based on the MSP status, the individual's copayments will be \$2.50/\$6.30 effective January 1, 2010. The copayment levels (\$1.10/\$3.20) for November through December 2009 are not affected because, for the deemed population, only favorable changes occur mid-year.

For individuals who do not qualify automatically for the next year, their LIS deemed status ends on December 31 of the current year. However, the Part D sponsor should encourage the individual to apply for the LIS, since they may re-qualify for the LIS through the application process.

Example 1: An individual loses deemed status and on October 15, applies with SSA to reestablish LIS eligibility for the next year. The application is approved and the individual's subsidy eligibility continues into the next calendar year.

Example 2: An individual loses deemed status and on January 5 of the next year applies with SSA to reestablish LIS eligibility. If the Part D plan offers a grace period for individuals who have proof of application for LIS, collection of premiums and cost sharing may be delayed, pending a decision on the application. The application is approved and the individual's subsidy eligibility is retroactively effective January 1 and continues through the end of the calendar year.

Example 3: An individual loses deemed status but does not apply with SSA to reestablish LIS eligibility until February 5 of the next year. The application is approved and LIS eligibility is retroactively effective February 1, creating a 1-month gap between the prior year's benefit that ended on December 31 and the newly approved benefit.

40.2.6 - CMS Notification to Beneficiaries Losing Deemed Status or Having a Copay Change

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

In September of each year, CMS sends a *gray* notice to beneficiaries who will lose deemed status effective the next calendar year. This notice includes an SSA subsidy application, along with a postage-paid return envelope. Also in September of each year, CMS sends Part D sponsors and State Medicaid agencies files of members who received the notice of loss of deemed status. This file is informational only and should be used for outreach to the affected beneficiaries. Plan sponsors should not update their systems until the December loss-of-subsidy file is received.

In October, CMS sends an orange notice to individuals who will continue to qualify automatically for the LIS in the next calendar year but will have a change in their co-payment level triggered by a change in their Medicaid eligibility. CMS does not send a special file to Part D sponsors, but sponsors may use the monthly LIS history file to identify those enrollees whose copayment level is changing in the following year.

40.2.7 - Appeals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

If a Part D enrolled beneficiary disagrees with the level of premium subsidy, or cost-sharing subsidy, the beneficiary should follow the appeals procedures of the agency (SSA or State Medicaid Agency) that provided the data on which deemed status is based.

40.2.8 - Grace Period for Those Losing Deemed Status

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors may choose to offer up to a 3-month grace period for the collection of premiums and cost-sharing to individuals who have lost their LIS deemed status and are able to demonstrate that they have applied for the LIS, provided this option is offered to all such individuals. If, after the expiration of the grace period, the member still does not appear to be LIS eligible according to the CMS' records or has not submitted BAE documentation to the Part D sponsor, sponsors must attempt to recoup unpaid premiums and cost-sharing amounts consistent with guidance provided in section 70.3 of this chapter. See section 70.2 of this chapter for details on the model notice.

Sponsors must confirm, either verbally or in writing, that an individual has applied for LIS prior to invoking the grace period. In other words, the grace period may not be applied automatically to all individuals losing LIS; instead, sponsors may apply the grace period only if an LIS application has been submitted. For example, for calendar year 20*10*, sponsors could send a letter to affected members instructing them to call the sponsor if they are interested in the grace period. Any communication with the members should advise them of the potential for retroactive liability for higher premiums and cost sharing as of January 1, 20*10*. The communication should also include information regarding the special

enrollment period for loss of deemed status and the need to take action by March 31, 2010, if they do not regain LIS status and wish to change plans. Sponsors should submit these notices or scripts to CMS for review and approval according to Medicare marketing guidelines (see chapter 2).

50 - Premium Subsidy

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Individuals who qualify for the LIS will be eligible for a premium subsidy, which may or may not cover their plan's entire Part D premium for basic prescription drug coverage. The premium subsidy will vary based upon the subsidy level for which the beneficiary qualifies. Additional discussion regarding how plan premiums attributable to basic prescription drug coverage are determined in the bidding process will be addressed in Chapter 10 - Bidding and Premiums, which is currently being developed.

50.1 - Calculation of the Low-Income Subsidy Individual's Premium Amount

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

The LIS individual's premium amount is the monthly premium attributable to basic prescription drug coverage after the premium subsidy, as calculated in accordance with sections 50.2 and 50.3 below. The premium subsidy is rounded to the nearest 10 cents before the premium subsidy is applied to the individual's monthly premium attributable to basic prescription drug coverage. *Any supplemental, enhanced, or MA premiums are then added to come to the final premium amount.*

50.2 - Calculation and Payment of the Premium Subsidy Amount for Full Subsidy Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount. The calculated premium subsidy amount is equal to the lesser of the plan's premium for basic prescription drug coverage or the regional low-income premium subsidy amount calculated in section 50.2.1.

50.2.1 - Calculation of the Regional Low-Income Premium Subsidy Amount

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The regional low-income premium subsidy amount is the greater of the PDP region's low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region. CMS performs this "greater of" test before it releases the regional low-income premium subsidy amounts for the PDP region.

The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in section 50.2.2. The weight for each PDP and MA-PD plans is equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

More information regarding the calculation of the regional low-income subsidy amount and low-income benchmark premium amount will be discussed in Chapter 10 (Bidding and Premiums), which is currently being developed.

50.2.2 - Premiums Used to Calculate the Low-Income Benchmark Premium Amount

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

The premium amounts used to calculate the low-income benchmark premium amount include:

Basic PDP - the monthly beneficiary premium.

Enhanced PDP - the portion of the monthly beneficiary premiums attributable to basic prescription drug coverage.

MA-PD - the monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Social Security Act).

Note that the MA monthly premium for basic prescription drug coverage that is used in this calculation *was* net of Parts A and B rebates *for 2006-2009. For 2010, in accordance with the “Medicare Demonstration to Revise the Part D Low-Income Benchmark Calculation,” as approved on August 11, 2009, the weighted average premium amounts described above are calculated using Part D premiums for MA-PD plans before they have been reduced by any applicable MA A/B rebates. The calculation does not include bids submitted by MA private fee-for-service plans, PACE programs under section 1894 of the Act, “800 series” plans, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act (“Cost Plans”).*

50.3 - Calculation of the Premium Subsidy for Partial Subsidy Eligible Individuals - Sliding Scale Premium

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Partial subsidy eligible individuals will be eligible for a premium subsidy based upon a linear sliding scale ranging from 100 percent to 25 percent of the premium subsidy amount as specified in section 50.2 and based upon the following chart:

FPL & Assets	Percentage of Premium Subsidy Amount
Income up to 135% FPL, and with assets that do not exceed the calendar year resource limits* for individuals or couples.	100%
Income above 135% FPL but at or below 140% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.	75%
Income above 140% FPL but at or below 145% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.	50%
Income above 145% FPL but below 150% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.	25%

*See <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025> for the calendar year resource limits.

50.4 - Waiver of Late Enrollment Penalty

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Depending upon when a beneficiary enrolls in a plan, s/he may be subject to late enrollment penalties. However, *low*-income subsidy eligible individuals are not subject to a late enrollment penalty *as of* the effective date of LIS eligibility. As long as these individuals stay continuously enrolled in a PDP or MA-PD, they will not be assessed an LEP, even if they lose their LIS eligibility. If LIS individuals disenroll and do not have creditable coverage for a continuous period of 63 days or longer, they will incur an LEP upon re-enrollment into a Part D plan if they are not LIS eligible; however, their uncovered months prior to LIS eligibility will not be a factor in the calculation of their LEP. Chapter 4 of this manual describes the late enrollment penalty in detail and how plans should administer this policy.

60 - Cost-Sharing Subsidy

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

The following section describes the application of the cost-sharing subsidy to full subsidy eligible and partial subsidy eligible individuals. The specific cost-sharing and deductible amounts are specifically referenced in Appendix A of this chapter.

60.1 - Full Subsidy Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.1.1 - Application to Deductible

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals as defined in section 30.1 are entitled to a full subsidy for the elimination of the Part D plan's annual deductible. Therefore, full subsidy eligible individuals will not be subject to any deductible under a Part D plan's basic prescription drug coverage. Refer to chapter 5 of this manual for a description of a Part D plan's deductible.

60.1.2 - Application to Cost-Sharing

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals will receive a reduction in cost-sharing for all covered Part D drugs under the PDP or MA-PD plan to the copayment amounts for full subsidy eligible individuals as provided in Appendix A.

The copayment amounts for full benefit dual eligible individuals with income at or below 100% of the FPL are increased annually by the annual percentage increase in the Consumer Price Index, All Urban Consumers (all item, U.S. city average) as of September of the previous year and rounded to the nearest multiple of 5 cents or 10 cents respectively.

The copayment amounts for non-institutionalized full subsidy eligible individuals with income above 100% of the FPL are increased annually by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals as of July of the prior year and rounded to the nearest multiple of 5 cents.

60.2 - Institutionalized Full Benefit Dual Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Institutionalized full benefit dual eligible individuals will not pay any cost-sharing (deductibles or copayments) towards the costs of their covered Part D drugs. For the purpose of this section, those individuals who are an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act, are considered institutionalized.

Specifically, a full benefit dual eligible beneficiary must be an inpatient in a medical institution or nursing facility in order to receive the zero cost-sharing exemption. The definition of medical institution and nursing facility are defined in regulation under Medicaid. The term “medical institution” for this portion of the Medicaid statute is further defined in Medicaid regulation at section 42 CFR 435.1009. These definitions do not include: home and community based waiver services, assisted living facilities, residential care homes and boarding homes.

The Medicaid definition also provides that a person is not considered institutionalized until the person is an inpatient in a medical institution or nursing facility for which payments are made under Medicaid throughout a month. (See section 1902(q)(1)(B) of the Act). This

being the case, a full benefit dual eligible individual who enters a nursing home or medical institution does not qualify for the zero copayment immediately.

Example: If a full benefit dual eligible person enters an institution in the middle of January, the individual will not be eligible for zero copayment in January, as s/he was not in the institution for that full calendar month. If the beneficiary stays at least until the end of February, and Medicaid has paid for the beneficiary's stay in the institution for the entire month of February, the "Medicaid payment throughout a month" requirement would be met for February. The individual will be deemed eligible for the zero copayment from February 1 through the end of the calendar year.

Institutional status is not interrupted by transfers between medical institutions or by bed hold days. Institutional status is only interrupted by a discharge to a community setting such as the home or an assisted living facility. However, even though the beneficiary may be discharged to a community setting, the individual remains deemed for zero co-pay throughout the remainder of the calendar year.

Not all beneficiaries who receive Medicaid and who are residents of nursing facilities or medical institutions are eligible for the zero cost-sharing. Beneficiaries with Medicaid coverage of premiums and/or cost sharing only (i.e., Medicare Savings Program beneficiaries), and who are not entitled to the entire Medicaid benefit, will not be eligible for the zero cost-sharing. It is likely, however, the majority of these beneficiaries will eventually "spend-down" to the full benefit dual eligible status when they enter a nursing facility and eventually receive the zero cost-sharing.

The State, as the Medicaid payer, reports to CMS the full benefit dual eligible individuals and the institutionalized individuals in their State. CMS in turn reports this information to the Part D sponsor. The Part D sponsor uses this information to set the beneficiary's co-payments to zero. In the example above, the State will acknowledge the beneficiary's institutionalized status in either late February or early March when the facility bills the state for the beneficiary's stay. The State must then report this individual to CMS. Given the time lags inherent in the reporting, the Part D sponsor may not receive this information from CMS until April or May. In the interim, however, a Part D sponsor must accept and use BAE (see section 70.5 on BAE policy) to substantiate the beneficiary's correct LIS cost-sharing level and correct the cost-sharing level in its own systems.

In a month in which co-pays are charged to the resident, these costs are the resident's liability. Under Medicaid, these costs are treated as a deduction from income when calculating the individual's contribution to the cost of institutional care, as are other medical and remedial services that remain the individual's responsibility. This deduction reduces the amount of income the resident is considered to have available to contribute toward the facility rate, and allows the resident to retain an amount necessary to satisfy the copayment liability. Because the income available to contribute toward the facility rate is less, the State payment under Medicaid to the facility will increase by the amount of the deduction. By contrast, the personal needs allowance (PNA) is a separate deduction for

incidental or personal expenses, and is not for medical expenses such as co-pays. If the individual has insufficient income to cover the full cost of the co-pays in a given month, the difference may be carried over to the following month(s) until the liability is satisfied.

60.3 - Partial Subsidy Eligible Individuals

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.3.1 - Application to Deductible

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Partial subsidy eligible individuals will be subject to a reduction in the annual deductible to the deductible amount specified in Appendix A for the current calendar year, unless the Part D plan benefit package has a deductible that is less than the deductible amount.

The deductible amount increases each year by the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals, rounded to the nearest multiple of \$1. If a plan's benefit package contains a deductible that is less than the deductible amount, the full deductible under the plan's benefit package is applied to the partial subsidy eligible individual's covered Part D prescription drug costs.

60.3.2 - Application to Cost-Sharing

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Partial subsidy eligible individuals will be subject to a reduction in cost-sharing to 15% coinsurance after any deductible described in section 60.3.1 has been met. If the Part D plan charges cost-sharing that is less than 15% coinsurance, no further reduction is taken.

60.4 - Administration of Cost-Sharing Subsidy

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.4.1 - *Application to Generic and Multiple-Source Drugs*

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When imposing cost sharing on low-income subsidy eligible individuals, sponsors are required to apply specific copayments for generic drugs as defined by regulation and in section 10 of this chapter. Specifically, 42 CFR 423.4 defines generic drugs as those drug products for which there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)). For purposes of Part D, what determines whether a drug is a generic drug is the type of application on file for that drug product with the Food and Drug Administration (FDA). If a drug product approval is based upon an abbreviated new drug application (ANDA), that drug is therefore a generic drug.

This definition applies regardless of whether the brand-name drug is no longer manufactured and there is only one remaining ANDA-approved drug product on the market, whether the sponsor's formulary includes the drug on its generic cost-sharing tier

or on a higher tier, or how a particular drug product is identified by the major drug listing services. Consequently, when sponsors by statute are required to apply specific copayments for generic drugs (that is, for generic drugs obtained by low-income subsidy eligible enrollees and enrollees with spending above the out-of-pocket threshold), they must ensure that the appropriate cost-sharing is applied to the generic drug as defined under CMS regulations and reflected in this manual.

For example, in accordance with 42 CFR 423.782(a)(2)(iii)(A), in 2010, non-institutionalized full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty level for their family size will pay no more than \$1.10 for generic drugs. Consequently, the sponsor must ensure that these individuals pay no more than a \$1.10 copayment for generic drugs, that is, all those drug products approved under an ANDA, even if a Part D sponsor places such a drug product in its preferred cost-sharing tier rather than its generic cost-sharing tier.

A multiple-source drug includes the branded product when the same drug is also available as a generic. A prescription may be filled with the generic version of a drug, or the pharmacy may choose to dispense a branded, multiple-source drug because the pharmacy purchased the branded, multiple-source drug at a better price. Under this scenario, the beneficiary pays the lower copayment for the generic/preferred multiple-source copayment (provided in Appendix A) regardless of whether they received the generic or branded multiple-source drug. Alternatively, the plan may have identified a specific branded multiple-source drug as a preferred product to be used whenever a generic could be dispensed and, therefore, the beneficiary would pay the lower cost sharing in this instance, as well. However, if the pharmacy is required to dispense a branded multiple-source drug (for instance, if a physician requires dispense as written), and that drug is not cheaper for the pharmacy nor identified by the plan as a preferred multiple-source drug, the beneficiary would be required to pay the higher copayment.

60.4.2 - Application to Days Supply

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors must apply the equivalent of one copayment for LIS eligible beneficiaries to each pharmacy transaction irrespective of days supply. For example, in 2010, a full subsidy eligible individual with incomes over 100% of the FPL who uses mail order to purchase his/her prescription medications may not be charged more than \$2.50 for a 90 day supply of a generic or preferred multiple source drug and more than \$6.30 for a 90 day supply of any other drug. This same policy applies to fills during the catastrophic coverage period as explained in chapter 5.

60.4.3 - Application of Cost Sharing Subsidy When Individual Chooses Enhanced Alternative Coverage

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Although the cost-sharing subsidy only applies to basic prescription drug coverage, it applies equally to beneficiaries enrolled in both basic and enhanced alternative plans.

When a Part D sponsor provides enhanced alternative coverage, thus reducing the cost sharing on a covered Part D drug, the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. Supplemental benefits provided under the plan are always applied before beneficiary liability and low-income subsidy (LICS) amounts are calculated. Therefore, the plan should determine the cost-sharing due under the enhanced alternative coverage after the supplemental benefit is provided, then apply the LICS amount to further reduce the LIS beneficiary's cost-sharing liability.

For example, the beneficiary qualifies for full subsidy benefits in 2010 and is only required to pay a maximum of \$3.30 per prescription. The cost of the drug is \$100. Under the plan's basic benefit package, the cost sharing for a non-LIS beneficiary would be 25% of \$100, or \$25. Since the beneficiary qualifies for LIS, the Part D sponsor would receive \$21.70 in LICS payments (\$25-\$3.30) under the basic benefit package. Under the enhanced alternative plan, the cost sharing is supplemented by the plan an additional \$10 resulting in the cost share of \$15. The Part D sponsor would receive \$11.70 in LICS for the LIS beneficiary (\$15-\$3.30).

The LIS only applies to covered Part D drugs. For supplemental drugs covered by a Part D plan, the LIS beneficiary pays the same amount of cost-sharing as any other beneficiary under their benefit package.

60.4.4 - *Application of Lesser of Cost Sharing Amounts Test* ***(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)***

Since the cost sharing subsidy is a reduction in beneficiary liability at the point-of-sale (POS), Part D sponsors must perform a calculation that compares the *amount* due from a non-low income subsidy (non-LIS) individual under the plan, to the statutory cost sharing provisions described in Appendix A. For each dispensing event, the Part D sponsor must compare the amount of cost-sharing due from a non-LIS beneficiary under the plan's benefit package to the maximum cost-sharing and deductible amounts due from a low-income subsidy eligible beneficiary. The low-income subsidy beneficiary should be charged the lesser of the two amounts. The calculation of the cost-sharing subsidy to be advanced to the Part D sponsor for these situations will be explained further in Chapter 11 - Payments.

60.4.5 - *Cost Sharing When Claims for LIS Individuals Cross Multiple Benefit Phases* ***(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)***

When a claim crosses multiple phases of the prescription drug benefit that all have co-payments, Part D sponsors must charge beneficiaries only one co-payment per prescription. Starting in 2008, Part D sponsors are specifically required to charge all beneficiaries the co-payment applicable to the phase of the benefit in which the claim began. For example, a beneficiary is enrolled in an enhanced alternative plan that has a generic co-payment of \$5 in the initial coverage period and a generic co-payment of \$15 in the coverage gap. If the beneficiary purchases a generic drug and that purchase moves the beneficiary from the

initial coverage period to the coverage gap phase of their prescription drug benefit, the plan must charge the beneficiary a \$5 co-payment because the claim started in the initial coverage period. Note that this policy does not apply to claims that cross multiple benefit phases in which any of the benefit phases have coinsurance.

If a claim crosses multiple benefit phases in which any of the benefit phases have coinsurance, the beneficiary is responsible for the applicable coinsurance in each phase that the claim crosses. However starting in 2008 for LIS beneficiaries, when a claim crosses from the coverage gap to the catastrophic phase of the benefit, Part D sponsors are required to charge the cost sharing applicable to the portion of the claim below the out-of-pocket threshold only. For example, a partial subsidy LIS beneficiary is enrolled in a defined standard plan in 2008 and has \$4,035 in true out-of-pocket costs (TrOOP). If the beneficiary purchases a covered Part D brand drug that has a total cost of \$150, the plan must charge the beneficiary \$2.25 in coinsurance (15%) for the \$15 in gross covered drug cost applicable to the coverage gap phase. The plan would not charge the LIS beneficiary the additional \$5.60 co-payment for the portion of the drug cost applicable to the catastrophic phase.

70 - Part D Sponsor Responsibilities When Administering the Low-Income Subsidy

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Part D sponsors are responsible for charging LIS beneficiaries the correct premium, deductible, copayments and/or coinsurance for the correct effective dates. To do so, Part D sponsors must update their systems appropriately based on CMS file notifications, as well as establish procedures to react promptly to evidence indicating that beneficiaries should have a more advantageous cost-sharing than indicated by CMS data. Sponsors are responsible for notifying members when they become LIS eligible, when their LIS levels change, and when their LIS eligibility terminates. Since LIS changes are frequently effective retroactively, sponsors must establish procedures to reimburse current and former members for cost-sharing (including deductible and copayments) and premiums paid before notification of LIS eligibility. The following subsections describe these requirements in detail, as well as the LIS notification requirements that are the responsibility of the Part D sponsor.

70.1 - *Establishing Low-Income Subsidy Status*

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

In order to establish the correct premium, *cost sharing* and deductible levels with the correct effective dates for current, *prior, and prospective* enrollees, Part D sponsors should *refer to the Weekly/Monthly Transaction Reply Report (TRR)*. Part D sponsors will receive data indicating new or modified LIS eligibility status for former, *current, and prospective* members of their Part D plan via the weekly TRR.

In addition, twice each year, CMS issues special files related to Part D sponsors' LIS members. These are the September and December versions of the Loss of Subsidy file.

The September file informs sponsors who in their plan is getting CMS' "undeemed" letter, and is to be used for outreach purposes. However, the December file is the definitive file of those losing *LIS* status, and is to be used to update sponsors' systems and to identify to whom they should send the *LIS* termination notice. CMS will send guidance notifying Part D Sponsors of the specific dates of these special files and reminding them of their purpose. For more information on these files' purpose, see section 40.2.6; for *additional details and technical specifications, see the Plan Communications User Guide (PCUG)* <http://www.cms.hhs.gov/MMAHelp/>.

70.2 - Member Notifications

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors are required to notify members when they initially become LIS-eligible; when their LIS levels change; and when their LIS eligibility terminates. In addition, certain notifications are required pursuant to the BAE policy (see section 70.5). The descriptions below explain the different LIS notifications, when Part D sponsors must mail these notifications to their member beneficiaries and where the current year model notifications are located in this chapter's appendices:

- **LIS Rider** - Part D Sponsors must send the LIS Rider at least once a year to their members at the same time as the combined Evidence of Coverage (EOC) and Annual Notice of Change (ANOC). Part D sponsors must also send an LIS rider at other times of the year if an enrollee becomes newly LIS eligible, or experiences a change in the level of LIS for which he/she qualifies (for terminations of LIS, see notices below). The LIS rider must be sent within 30 days of receiving systems' notification from CMS for changes effective in the current calendar year. "Notification" means any of the sources identified in Appendix E. When notifications are received starting July that an individual is re-deemed for LIS for the following calendar year, the LIS Rider conveying the following year's status need not be sent until the combined ANOC/EOC. If a sponsor did not send the LIS Rider with a beneficiary's EOC/ANOC (because no notification had been received before that mailing), but notification is subsequently received, the sponsor must send an LIS rider within 30 days of the notification.
- **Notice *for Beneficiaries* Whose *Low-income* Subsidy is Terminated** (Appendix B) – Part D sponsors must send this notice to affected members when the member's *LIS* terminates. Part D sponsors should use this notice when CMS sends data terminating LIS via the TRR. *This notice contains variable language for deemed beneficiaries and LIS applicants. For deemed individuals the beneficiary is directed to apply to the SSA in order to be determined if he/she is eligible for LIS.*
- **Notice of Removal of LIS Period(s)** – (Appendix C) – *Part D sponsors are responsible for collecting any underpaid cost sharing or premiums when a beneficiary is retroactively found not eligible, or qualifies at a less generous cost sharing level per section 70.3.1. Sponsors should make reasonable attempts to notify affected members to advise them of their*

retroactive liability for higher premiums and cost sharing, when LIS eligibility is removed. This notification should also include information regarding the special enrollment period for loss of LIS status if they wish to change plans.

- Notice of Error in Premiums and Cost Sharing (Appendix D) – Part D sponsors must send this notice when they grant an optional grace period per section 40.2.8 for those losing deemed status, and for an individual who does not regain LIS eligibility within the grace period.

70.3 - Sponsor Requirements When Retroactive Changes to Subsidy Levels Occur

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

As noted in section 40, the effective date of LIS eligibility is often retroactive for those newly eligible for LIS. The retroactive date may extend to the previous calendar year, and may affect former members. The Part D sponsor offering the Part D plan must reimburse all LIS eligible individuals, as well as other payers of prescription drug coverage paying cost-sharing or premiums on behalf of such individuals, if the beneficiary is found retroactively eligible for the LIS.

Example: A beneficiary is enrolled in a plan effective January 1, 2010, and has been paying the appropriate cost-sharing associated with his/her benefit package. In May, the Part D sponsor is notified by CMS that the individual is eligible for LIS, retroactive to March 1, 2010. The Part D sponsor reimburses the beneficiary accordingly and revises the prescription drug event (PDE) to reflect the availability of the subsidy to the individual.

70.3.1 - Refunds and Recoupments of Cost-Sharing *and Premiums*

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

CMS regulations at 42 CFR 423.800(c) require the Part D sponsor to reimburse subsidy-eligible individuals, and any organizations paying cost sharing on behalf of such individuals (e.g., State Pharmaceutical Assistance Programs (SPAPs)), any excess premium or cost sharing paid by such individual or organization. This includes the refunding of cost sharing amounts that were paid during the period of LIS retroactive coverage. The intent of this provision is to direct the Part D sponsor to make reasonable efforts to determine the party that should be reimbursed for excess cost sharing before making reimbursement.

That is, when a retroactive change to an individual's LIS level occurs, the sponsor must determine the excess cost-sharing and premium amounts and reimburse the beneficiary, or other party who paid on the beneficiary's behalf, automatically; i.e., without a direct request for reimbursement. It should be noted that this policy cannot apply in situations where both the LIS status change and the Part D enrollment are retroactive, as the sponsor will not have the paid claims information for the retroactive period and will therefore still require documentation from the beneficiary or other payer to handle the refund.

CMS expects that sponsors will develop standard operating procedures (SOPs) to address the research and determination of liability for cost sharing reimbursements, and will not adopt a “one size fits all” approach, such as always cutting checks directly to the beneficiary. Part D sponsors should consider such variables as institutionalized status or the presence of secondary payers reported on the Coordination of Benefit (COB) files in their SOPs. Moreover, any direct request for reimbursement with appropriate evidence of payment should be handled expeditiously.

When implementing retroactive subsidy level changes for a full-benefit dual eligible individual who meets the definition of an institutionalized individual but is incorrectly charged cost-sharing, sponsors should not automatically reimburse beneficiaries residing in long-term care (LTC) facilities. In such situations, it is unlikely that LTC pharmacies have collected the applicable cost-sharing from beneficiaries due to the expectation that the Part D sponsor eventually would reimburse the pharmacy retroactively for such amounts. This may also be the case in non-LTC pharmacies, though probably not to the same degree, since the LTC pharmacy is more likely to hold a receivable balance on its books, or may have recourse to the LTC facility for uncollected amounts.

Part D sponsors should work with their network pharmacies to provide them with direct reimbursement for any cost-sharing amounts not collected from LIS-eligible enrollees. Before reimbursement is made, Part D sponsors should ensure that the pharmacies in question have not collected cost-sharing amounts, or otherwise have waived the cost-sharing charges, and, in fact, are carrying a debt for the amounts incorrectly charged to the beneficiary. For auditing purposes, sponsors should ensure that pharmacies certify that the amounts reimbursed are appropriate, owed, and payable. Providing direct reimbursement to pharmacies for excess cost-sharing charges that have not been paid by Part D enrollees or that have not been waived by the pharmacy does not conflict with the requirement in 42 CFR 423.800(c) that beneficiaries be made whole. Such amounts were never paid by either the enrollee or others on his or her behalf.

Part D sponsors are also responsible for collecting any underpaid cost-sharing or premiums when a beneficiary is retroactively found not eligible, or qualifies at a less generous cost sharing level. CMS’ rules on uniformity of benefits require recouping such amounts in order to ensure that similarly situated individuals are treated the same, and in order to avoid any waiver of the cost-sharing. Thus, Part D sponsors should make reasonable attempts to collect the outstanding cost-sharing. (Note: This assumes the pharmacy has not waived or reduced this cost-sharing consistent with the safe harbor for pharmacy waiver, or reduction of Part D cost-sharing.) When attempting to collect substantial underpayments, Part D sponsors should consider recovering from the beneficiary over an extended period of time as not to adversely impact the low-income beneficiary’s access to prescriptions and medical services during the period of recovery. *Effective 2010, Part D sponsors should offer these enrollees the option to pay their premium arrearage by lump sum, by monthly installments spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Part D sponsor.*

70.3.2 - Adjustments to Prescription Drug Event Data (Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The Part D sponsor must adjust the PDE when a reconciliation results in a refund or recoupment situation. Although both the LIS and Patient Pay amounts are TrOOP-eligible amounts, the LIS amount must be corrected because LICS is a cost-based payment mechanism and CMS uses the LIS Amount field to calculate the Part D Payment Reconciliation for LIS. For refunds, the adjustment PDE shows that LIS increases and Patient Pay decreases by the same amount (provided the beneficiary does not receive assistance from a TrOOP-eligible other payer like an SPAP). For recoupments, the adjustment PDE shows that LIS decreases and Patient Pay increases by the same amount (provided the beneficiary does not receive assistance from a TrOOP-eligible other payer like an SPAP). Plans must use the “Report-As-Adjusted” method to show changes in every affected PDE, and not the “Report-As-Administered” method, anytime a change in LIS amounts is involved.

Part D sponsors should consult the latest version of Prescription Drug Event Guidance at <http://www.cms.hhs.gov/DrugCoverageClaimsData/>.

70.3.3 - Refunds of Overpaid Premiums (Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

When a beneficiary is found retroactively eligible for LIS, the Part D sponsor must refund premium amounts in excess of the allowed premium charges for LIS beneficiaries mandated by statute. Part D sponsors should not automatically reimburse the beneficiary for overpaid premiums if it is known by the Part D sponsor that the beneficiary is a member of a State Pharmaceutical Assistance Program that has paid for the beneficiary’s premiums.

70.4 - Low-Income Subsidy and TrOOP Calculation (Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

All low-income, cost-sharing subsidy payments made by the Federal government on behalf of the subsidy eligible individual are counted towards the beneficiary’s annual out-of-pocket threshold. Once the annual out-of-pocket threshold is reached for a full subsidy eligible individual, cost-sharing is reduced to zero for this beneficiary. When the annual out-of-pocket threshold is reached for the partial subsidy eligible individual, cost sharing is reduced to the applicable calendar year copayment amounts provided in Appendix A. Part D plans are responsible for tracking a beneficiary’s TrOOP costs as defined in chapter 5, section 30 of this manual. When the beneficiary reaches his/her TrOOP limit, a Part D plan will adjust the beneficiary’s cost-sharing accordingly.

70.5 - Best Available Evidence (BAE) (Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

When situations arise that result in incorrect LIS cost-sharing data at the point-of-sale, Part D sponsors must comply with the “Best Available Evidence” (BAE) policy. This policy

requires sponsors to update their systems to reflect the appropriate cost-sharing subsidy for Part D eligible individuals who are full benefit Medicare/ Medicaid dual eligible individuals, MSP, and receiving SSI-only when presented with evidence that information showing the beneficiary to be ineligible is not correct. This section outlines the requirements Part D sponsors must follow when applying the BAE policy to its members.

70.5.1 - BAE Policy Communication and Oversight

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Part D sponsors must develop appropriate member services and pharmacy help desk scripting to identify cases involving a situation in which the BAE policy applies, and to allow callers either to submit BAE pursuant to the requirements described in section 70.5.2 or to request assistance pursuant to the requirements described in section 70.5.3.

Sponsors must also provide a link on their Web site to the section of CMS' Web site regarding BAE policy and make information about the BAE policy readily available for those who contact the plan's call center. The Web site address is:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp

Given the importance of this policy to low-income beneficiaries, CMS has also established a separate complaint tracking category for BAE issues and will be closely monitoring Part D sponsor compliance with this policy.

70.5.2 - Required Documentation and Verification

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors are required to accept any of the following forms of evidence to establish the subsidy status of a full benefit dual eligible or MSP-eligible beneficiary when provided by the beneficiary or the beneficiary's pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary. *Sponsors must include a copy of one of the following BAE documents with every update request submitted to CMS' contractor (see section 70.5.4):*

1. A copy of the beneficiary's Medicaid card that includes the beneficiary's name and an eligibility date during a month after June of the previous calendar year;
2. A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year;
3. A print out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year;
4. A screen print from the State's Medicaid systems showing Medicaid status during a month after June of the previous calendar year;

5. Other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year;
6. A letter from SSA showing that the individual receives SSI; *or*,
7. *An Important Information letter from SSA confirming that the beneficiary is "...automatically eligible for extra help..." (see Appendix M)*

Part D sponsors are required to accept any one of the following forms of evidence from the beneficiary or the beneficiary's pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary to establish that a beneficiary is institutionalized and qualifies for zero cost-sharing:

1. A remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year;
2. A copy of a state document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year;
3. A screen print from the State's Medicaid systems showing that individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

The sponsor may also prepare a report of contact as evidence of a beneficiary's status as a full benefit dual eligible individual or institutionalized individual when the sponsor makes a verification call to the State Medicaid Agency. The report of contact must include the date of the verification call and the name, title and telephone number of the state staff person who verified the Medicaid status during a month after June of the previous calendar year.

The documents listed above are valid for the purpose of establishing the correct LIS cost-sharing level and effective date for individuals who should be deemed eligible for LIS, and are the only documents permissible for submission to CMS' contractor for deeming updates.

- As soon as one of the forms of BAE listed above is presented, provide the beneficiary access to covered Part D drugs at a reduced cost-sharing level which is no greater than the higher of the LIS cost-sharing levels for full subsidy eligible individuals (in 2010, this level was \$2.50 per generic or preferred brand name drug; \$6.30 per brand name drug), or at zero cost-sharing if the BAE also verifies the beneficiary's institutional status.
- Update sponsor systems to reflect the correct LIS status based upon BAE documentation, override the standard cost-sharing, and maintain an exceptions process for the beneficiary to obviate the need to require the re-submission of

documentation each month pending the correction of the beneficiary's LIS status in CMS systems. Part D sponsors will be required to update their systems within 48-72 hours of their receipt of BAE documentation. The requirement that Part D sponsors update their systems within 48-72 hours is in addition to the requirement that Part D sponsors provide access to covered Part D drugs as soon as BAE is presented to them.

- Verify that CMS' systems do not already reflect the beneficiary's correct LIS status. If CMS' systems do not already reflect the updated information for "deemed" beneficiaries, the sponsor must submit a request for correction in accordance with the manual LIS status correction process discussed later in this section. A separate process is under development to permit plans to submit requests to update CMS' systems for LIS applicants.

70.5.3 - Part D Sponsors Responsibility When BAE is not Available

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors must respond to requests for assistance in securing BAE from a beneficiary or a beneficiary's pharmacist, advocate, family member or other individual acting directly or on behalf of the beneficiary in accordance with the following process outlined below. Note that this process is not intended to serve as a general alternative to the subsidy eligibility confirmation process. Thus, it does not permit pharmacy organizations or any other parties to send beneficiary records directly to the Part D sponsor for research in the absence of a request for assistance from the beneficiary (or other individual on the beneficiary's behalf) or in lieu of making reasonable efforts to acquire the documentation from, or on behalf of, the beneficiary. Part D sponsors are required to take the following actions:

1. Complete columns A through F of the CMS BAE Assistance Worksheet with plan and beneficiary information. The worksheet is found at http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp
2. Ask the beneficiary (or the beneficiary's advocate, pharmacist, authorized representative or other individual acting on the beneficiary's behalf) what date the beneficiary will run out of medication. If provided, include that information in the worksheet (Column G) and include the appropriate phrase in the subject line of the e-mail to the CMS Regional Office (CMS RO) as shown below:
 - a. If the beneficiary has less than 3 days of medication remaining, indicate the phrase "Immediate BAE Assistance Needed" in the subject line.
 - b. If the beneficiary has 3 or more days of medication remaining, indicate "Non-Immediate BAE Assistance Needed" in the subject line.

- c. Send the worksheet via an encrypted e-mail to the CMS RO Part D mailbox based on where the individual resides. The list of CMS RO contacts and mailboxes *are* located at:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp.
3. Absent unusual circumstances, submit the worksheet to the CMS RO within 1 business day of being notified that the beneficiary claims to be subsidy eligible but cannot provide the sponsor with one of the documents listed above. After recording the case in the CMS complaint tracking module (CTM), the CMS RO will attempt to confirm with the State Medicaid agency whether the beneficiary is eligible for LIS, and will return the worksheet to the plan with the CMS portion (Columns H through Q) completed with any information received from the State.
4. Upon receipt of the worksheet from CMS, update the plan sponsor's internal systems to reflect LIS status, as appropriate, and submit a request for correction to *the CMS contractor* in accordance with the procedures outlined in section 70.5.4 of this chapter.
5. Notify the beneficiary of the results of CMS' inquiry as follows:
 - a. Sponsors must make an initial attempt to notify the beneficiary of the results of the CMS RO inquiry within 1 business day of receiving those results.
 - b. If a sponsor is unable to reach the beneficiary as a result of this initial attempt, it must attempt to notify the beneficiary until it succeeds or until it has attempted to do so a total of four times.
 - c. The fourth attempt, if necessary, shall be in writing, using one of two CMS Model Notices. Both Model notices are located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp as clarified in the BAE guidance (v08.04.08). If CMS determines that the beneficiary is LIS eligible, use the "Determination of LIS Eligibility" Model Notice. If CMS determines that the beneficiary is not LIS eligible, or is unable to confirm the beneficiary's LIS status, use the "Determination of LIS Ineligibility".
 - d. If a request for a subsidy was made on the beneficiary's behalf by an advocate or authorized representative, it shall be sufficient for the sponsor to contact that advocate or representative. If, however, the only request made on the beneficiary's behalf was by a pharmacist, the sponsor must also contact the beneficiary directly. Beneficiaries must be notified that if they do not agree with the results of the inquiry, the sponsor will provide them with appropriate contact information for the appropriate CMS RO. The list of CMS RO contacts is within the BAE guidance (v08.04.08) located at:

6. As soon as the sponsor receives confirmation from the CMS RO that a beneficiary is subsidy eligible, the sponsor must provide the beneficiary access to covered Part D drugs at a reduced cost-sharing level no greater than the higher of the LIS cost-sharing levels for full subsidy eligible individuals, or at zero cost-sharing if the RO also verifies the beneficiary's institutional status.
7. Close out the case in the CTM in the new "Beneficiary Needs Assistance with Acquiring Medicaid Eligibility Information" category. The date entered must be the date of the plan sponsor's final attempt to notify the beneficiary of the results of CMS' inquiry, in accordance with the procedures described above.

70.5.4 - Transmitting and Timing of Manual LIS Status Correction

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors should provide data to CMS' contractor when BAE is confirmed for an individual who should be deemed, or deemed at a more advantageous copayment level or earlier effective date. This process is called the manual LIS status correction process. It is not intended to supplant State MMA data files, in which States report their dual eligible beneficiaries to CMS. It is important to note that a manual update will not be necessary in all BAE cases, as updated information on a subsequent State MMA file may automatically correct the data in CMS systems.

Prior to submitting a manual correction request, Part D sponsors should allow a reasonable time for updated information to be automatically entered into the CMS systems and reported to the plan. CMS recommends that the delay be a minimum of 30 and a maximum of 60 days, as it is likely that a significant portion of those who qualify under BAE policy in 1 month will be deemed for LIS via the normal process within the next several weeks.

Part D sponsors should verify that CMS's systems do not already reflect the beneficiary's correct status prior to submitting a request for correction. Verification may be accomplished by checking the most recent LIS History Report from CMS or via the Marx Common User Interface.

LIS Status Correction Requests must be submitted to CMS' contractor via an Excel file, certified per section 70.5.5 and consistent with the transmission security requirements in section 70.5.6. CMS recommends that Part D sponsors establish a schedule for the monthly transmission of these requests. Each Excel file should contain information for all beneficiaries identified since the prior request is necessitating an LIS status correction. In other words, the correction request file should not be a cumulative record of previously submitted beneficiaries. The required Excel file format can be found in Appendix F.

Sponsors must include a copy of the supporting BAE documentation with every update request submitted to CMS' contractor. The documentation may be hard copies or scanned onto the Excel spreadsheet. The "Type of Documentation Supporting Request" field in the

drop-down menu on the Excel spreadsheet must match the documentation included with the spreadsheet. Failure to submit documentation or to correctly indicate the “Type of Documentation Supporting Request” by the sponsor will result in rejection of the sponsor’s correction request.

Prior to submitting the request, Part D sponsors should ensure that all beneficiary identifying information, such as name, date of birth, and HICN, is correct.

70.5.5 - Certification

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

A certification of the LIS status correction request signed by an authorized representative of the Part D sponsor must be submitted to CMS’ contractor. The certification form is available in Appendix F. Once the certification is signed, the document should be scanned, saved as a pdf. file and included on the disk that must be used to transmit each Excel correction request file. The disk must include the plan sponsor’s contract number (H#, S#, R#).

70.5.6 - Transmission Security Requirements

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors should submit requests for LIS deemed status corrections to *the appointed CMS contractor*. To ensure the security of the beneficiary information contained in the Excel spreadsheet, the document must be encrypted using a Federal Information Processing Standards approved encryption method. A list of the approved encryption modules is available on the National Institute of Standards and Technology Web site at <http://csrc.nist.gov/groups/STMcmvp/validation.html>.

Part D sponsors should submit the encrypted document via a disk containing a password-protected Excel spreadsheet, along with attestations, to:

Reed & Associates, CPAs, 14301 FNB Parkway, Omaha, NE 68154

In addition, Part D sponsors should email the password for the spreadsheet to clientservices@reedassociates.org. Once the password has been provided, *Reed & Associates* will keep it on file. Part D sponsors will not need to either (1) change the password; or, (2) re-email the password.

70.5.7 - CMS Reporting to Part D Sponsors

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Once CMS' contractor has completed action on the requests in the spreadsheet, the contractor will complete the three fields specified for CMS use and include in the attached Excel file format to report that the new data have been entered. The contractor will return a copy of the updated file to the Part D sponsor’s primary point of contact as reflected on the file.

70.5.8 - Timing of CMS Systems Updates

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Once a correction request is processed by CMS, the new data will be stored in the MBD. CMS systems will then update the data during the next deeming process and the subsequent weekly TRR will report the updated information verifying the change has been implemented in CMS systems.

The Transaction Reply Code (TRC) 194 Deemed Copay Correction (DEEMD COPAY CORR) is the unique TRC for these manual updates indicating that CMS has added or updated a deemed co-pay period. The effective dates for the added or updated deemed co-pay period are shown in the TRR fields.

70.5.9 - Evidence Retention Requirements

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

To accommodate subsequent periodic Government audits, Part D sponsors must maintain for 10 years the original documentation used to substantiate the request for manually updating the CMS system.

An alternative to the Part D sponsor maintaining the BAE documentation would be for the Part D sponsor to delegate this activity to trusted business partners, such as a long-term care pharmacy provider. The partners must be contractually obligated to secure BAE, attest to the beneficiary's LIS status, and retain the documentation until requested by the Part D sponsor to support an audit. Since the risk associated with the delegation would be on the Part D sponsor, the business partner could be required to indemnify the Part D sponsor for the incorrect cost-sharing amount if the partner was unable to produce the required documentation when requested by the Part D sponsor.

70.5.10 - CMS/SSA Documentation Supporting a Beneficiary's LIS Cost Sharing Level

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

There may be instances in which CMS' data correctly reflect a beneficiary's LIS status, but the Part D sponsor's data do not. The following CMS LIS notices sent to the beneficiary reflecting effective dates during the discrepant period may be used by the LIS beneficiary to show they qualify for LIS:

- Deeming notice – pub.no. 11166 (purple notice);
- Auto-enrollment notice – pub.no.11154 (yellow notice);
- Full-facilitated notice – pub.no. 11186 (green notice);
- Partial-facilitated notice – pub.no.11191 (green notice);
- Copay change notice – pub.no.11199 (orange notice);

- Reassignment notice – pub.no. 11208 and 11209 (blue notice).

Part D sponsors should confirm LIS status using the batch eligibility query (BEQ) or the integrated user interface (IUI), and should correct their systems promptly. See the following Web site for the most recent version of these beneficiary notifications:
http://www.cms.hhs.gov/States/11_NotificationstoBeneficiaries.asp#TopOfPage

70.6 - Interpreting the Social Security Administration's Low-income Subsidy Letters

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Beneficiaries who are not deemed eligible for the LIS, but who apply and qualify for LIS with SSA, are awarded either the full or partial subsidy based on their income and resources. When SSA takes an action on an LIS award, it provides the beneficiary with a letter that indicates whether the award is for a full subsidy or a partial subsidy, specifies the reduced deductible and reduced co-payments, and identifies the effective date of the action. If the award is for a partial subsidy, the letter will explain the percentage of the premium subsidy award. *Examples of these letters can be found at Appendices I through L.*

When a beneficiary presents an SSA notice to the Part D sponsor, the notice being presented only applies to the addressee of the letter. If both spouses apply for LIS, each will have his/her own letter. On occasion, there will be reference to a spouse in the body of the letter; however, this reference is solely for the purpose of counting a spouse's income/resources, not to whether the spouse qualifies for LIS.

70.6.1 - Determining the Subsidy Effective Date

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Part D sponsors must accept the following four (4) SSA notices as evidence of a member's low-income subsidy entitlement:

- **Notice of Award** (sample provided in Appendix G) - This letter is provided to a beneficiary when the LIS subsidy is first awarded.

To determine the effective date, look at either of the worksheets that will be attached to the letter. These worksheets are similar and both contain the date information. Just below the header, the effective date is in the phrase "For <month, year> and continuing". See Appendix G for the sample of the letter and Appendix H for sample of the Income Worksheet and Appendix L for the Resource Worksheet.

- **Notice of Change** (sample provided in Appendix I) - This letter is provided to a beneficiary when SSA has made a redetermination on an LIS award AND the award will be increased, such as from a 25% premium subsidy to a 50% premium subsidy.

The effective date is on the first page, in the first paragraph under “Your Help Will Change”.

- **Notice of Planned Action** (sample provided in Appendix J) - This letter is provided to a beneficiary when SSA has made a redetermination on an LIS award AND the award will be reduced, such as from a 75% premium subsidy to a 50% premium subsidy.

The effective date is on the first page, in the first paragraph under “Your Help Will Change”.

- **Important Information** (sample provided in Appendix K) - This letter is provided to a beneficiary when SSA has made a redetermination on an LIS award AND the award will not change.

To determine the effective date, look at either of the worksheets that will be attached to the letter. These worksheets are similar and both contain the date information. Just below the header, the effective date is in the phrase “For <month, year> and continuing”. See Appendix K for the sample of the letter and Appendix H for sample of the Income Worksheet and Appendix L for the Resource Worksheet.

The Notice of Change, Notice of Planned Action, and Important Information are provided when SSA has made a redetermination on an LIS award. Beneficiaries are selected for redetermination randomly or when a change in their circumstance has been reported. The name of the letter can be found in the upper left hand corner of the first page of the letter. Note that it is not uncommon for an individual’s last correspondence from SSA to be a year or more in the past. Part D sponsors must accept SSA notices dated 15 months in the past.

Samples of these letters are also listed under “HI 03094: Medicare Part D Exhibits of Notices” on SSA’s Web site at <https://secure.ssa.gov/apps10/poms.nsf/subchapterlist!openview&restricttocategory=06030>.

70.6.2 - Determining the Premium Subsidy Level, Deductible, and Co-payment Amounts from SSA Letters

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When a beneficiary is awarded 25%, 50%, or 75% premium subsidy, the beneficiary’s plan benefit package’s deductible is reduced, if greater than the maximum allowable deductible (e.g., \$63 for \$2010). The SSA notices identify key LIS levels as follows:

- Premium subsidy percentage (25%, 50%, 75% or 100%) is on the first page.
- Deductible information is on the first page.

- “No prescription drug annual deductible” means that the beneficiary has a \$0 deductible.
- “Reduced prescription drug annual deductible” means that the beneficiary will pay no more than the maximum allowable deductible for partial subsidy individuals (See Appendix A for maximum deductible amounts) or less, if the plan benefit package’s deductible is less.

The specific copayment level is not stated explicitly, but can be determined as follows:

- “No prescription drug deductible” means that the beneficiary’s copayment is no more than the maximum copayments for non-full benefit dual eligible individuals (See Appendix A for maximum copayment amounts).
- “Reduced prescription drug annual deductible” means the beneficiary will pay no more than 15% coinsurance after the reduced deductible is satisfied.

80 - Application of Low-Income Subsidy to Employer Group Waiver Plans

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

There are additional low-income subsidy requirements that must be adhered to by Employer Group Waiver Plans. CMS addresses these requirements in chapter 12, Employer/Union Sponsored Group Health Plans of this manual.

90 - Enhanced Allotment for Low-Income Residents of the Territories

(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The assistance provided to low-income Medicare beneficiaries enrolled in Part D and residing in the U.S. Territories is different than the low-income subsidy program.

Under Section 1860D-14(a)(3)(F) of the Act, Treatment of Territorial Residents, and 42 CFR 423.907, Treatment of Territories, Part D eligible individuals who are not residents of the 50 States or the District of Columbia are not eligible for the low-income subsidy program, but may be eligible for additional financial assistance with their prescription drug expenses under Section 1935(e) of the Act. Territories receive an enhanced allotment to their Medicaid grants that must be used to provide coverage of Part D drugs for their full benefit dual eligible populations. The additional prescription assistance provided under a territory's enhanced allotment plan is implemented through its Medicaid program, by:

1. Supplementing the Part D plan-enrolled beneficiary cost sharing,
2. Paying a Part D sponsor additional premiums to provide the wrap-around coverage,
3. Providing prescription assistance through its Medicaid program.

Additional guidance regarding the application of these amounts will be included in chapter 10, Payment and Bidding of this manual, which is currently being developed.

Appendices

Disclaimer: CMS LIS and Model Notices contained within these appendices are subject to change and may not be updated in this chapter in a timely manner. For the most recent copy of LIS notifications, see - <http://www.cms.hhs.gov/LimitedIncomeandResources/>
For LIS model notices, see - <http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp>

Appendix A - Part D Benefit Parameters and LIS Cost-Sharing Levels
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D Benefit Parameters	2008	2009	2010
Standard Benefit Design Parameters			
Deductible	\$275	\$295	\$310
Initial Coverage Limit	\$2,510	\$2,700	\$2,830
Out-of-Pocket Threshold	\$4,050	\$4,350	\$4,550
Total Covered Part D Drug Spend at OOP Threshold (2)	\$5,726.25	\$6,153.75	\$6,440.00
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit			
Generic/Preferred Multi-Source Drug	\$2.25	\$2.40	\$2.50
Other	\$5.60	\$6.00	\$6.30
Full Subsidy Eligible Individual			
Full Benefit Dual Eligible Parameters			
Copayment Amounts for Institutionalized Beneficiaries	\$0.00	\$0.00	\$0.00
Copayment Amounts for Non-Institutionalized Beneficiaries			
Up to or at 100% FPL			
Up to Out-of-Pocket Threshold (1)			
Generic/Preferred Multi-Source Drug (3)	\$1.05	\$1.10	\$1.10
Other (3)	\$3.10	\$3.20	\$3.30
Above Out-of-Pocket Threshold	\$0.00	\$0.00	\$0.00
Over 100% FPL			
Up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	\$2.25	\$2.40	\$2.50
Other	\$5.60	\$6.00	\$6.30
Above Out-of-Pocket Threshold	\$0.00	\$0.00	\$0.00
Non-Full Benefit Dual Eligible Full Subsidy Parameters			
Resources ≤ \$6,290 (individuals) or ≤ \$9,440 (couples) (4)			
Copayment Amounts up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	\$2.25	\$2.40	\$2.50
Other	\$5.60	\$6.00	\$6.30
Above Out-of-Pocket Threshold	\$0.00	\$0.00	\$0.00
Resources bet \$6,290-\$10,490 (ind) or \$9,440-\$20,970 (couples) (4)			
Deductible (3)	\$56.00	\$60.00	\$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%	15%
Above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	\$2.25	\$2.40	\$2.50
Other	\$5.60	\$6.00	\$6.30

Partial Subsidy Eligible Individual			
Resources < \$10,490 (ind) or \$20,970 (couples)			
Deductible (3)	\$56.00	\$60.00	\$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%	15%
Copayment Amounts above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	\$2.25	\$2.40	\$2.50
Other	\$5.60	\$6.00	\$6.30

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.

(3) The increases to the LIS deductible, generic/preferred multi-source drugs (as defined in chapter 5 of this manual) and other drugs copayments are applied to the unrounded 2009 values of **\$60.13**, **\$1.08** and **\$3.23**, respectively.

(4) The actual amount of resources allowable will be updated for contract year 20**10**.

Appendix B - *Model Notice for Beneficiaries Whose Low-Income Subsidy is Terminated* (for PDPs, MA-PD Plans, and Cost Plans *that offer Part D*) (Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

(The marketing material code for this model notice is **7006**. If the sponsor uses this model notice without modification, CMS will waive the **5** day waiting period before the sponsor can use the notice in the marketplace.)

[Member #-if member # is SSN, only use last 4 digits]

[RxID]

[RxGroup]

[RxBin]

[RxPCM]

<Date>

Dear <Name of Member>:

Beginning <effective date>, you no longer qualify for extra help with your Medicare prescription drug costs. You will continue to be a member of <Plan name>.

How will your monthly premium change?

The monthly premium you pay to <Plan name> will increase from <insert dollar amount> to <insert dollar amount>. [Add the following if the member currently has premium withhold option. Because your premium is deducted from your monthly Social Security check, the amount withheld from your check will increase.]

How will your other prescription drug costs change?

[Describe plan's cost sharing structure including the deductible, if applicable, for non-LIS members]

Once you spend <current Out-of-Pocket Threshold> in a year, your co-payment amount(s) will go down. You will pay <current copay for generics> for generic or preferred drugs and <current copay for brand names> for any other drug, or 5% coinsurance, whichever is higher, for the rest of the year.

These changes to your prescription drug costs begin <effective date>. This date may have already passed when you get this letter. If you have filled prescriptions since <effective date>, you may have been charged less than you should have paid. If you do owe us money, we will let you know how much.

[NOTE: If Beneficiary is Deemed, insert the following language:

You may still qualify for extra help, but you must apply to find out. If you haven't already filled out an application for extra help, you can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778.]

[NOTE: If sponsors offer the optional grace period for the collection of premiums and cost-sharing for deemed beneficiaries who have applied for LIS and are waiting for a decision, insert the following language, if applicable:

If you applied for extra help and haven't received a response from Social Security, <Plan name> will allow you to continue to pay for your prescriptions at <2008 LIS premium and cost sharing levels> until <date>. Please contact <customer service number> or send a copy of the letter saying Social Security received your application or appeal to <address>.

If you don't qualify for extra help or are approved at a higher premium and cost sharing level, you may owe money back to January 1, 2009. <Plan name> will send you a notice telling you what you owe for past charges.

If you don't qualify for extra help from Social Security, you can change plans if you wish to do so. You must join the new plan by March 31, 2009.]

What are your options?

Option 1: You can stay a member of our plan

You can continue to be a member of <plan name>. You will pay the costs described above for your coverage.

Option 2: You can switch to a new plan

Because you no longer qualify for extra help, you can switch to a different Medicare drug plan starting <effective date> until <2 months later>. [If the effective date is January 1, enter March 31. For any other effective date, enter 2 months later.] You may want to choose a different drug plan for next year with costs and coverage that better meet your needs.

Visit www.medicare.gov on the Web or call 1-800-MEDICARE (1-800-633-4227) for more information about Medicare drug plans available in your area. TTY users should call 1-877-486-2048.

Option 3: You can find other ways to get help with your prescription drug costs

Your state may have programs that can help pay your prescription drug costs. Contact your State Medical Assistance (Medicaid) office for more information. Call 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov on the Web for their telephone number. TTY users should call 1-877-486-2048.

[NOTE: If Beneficiary is an Applicant, insert the following language:

What To Do If Your Situation Changes

You can file a new application for extra help at any time. You can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778.

If You Disagree With This Decision

If you think your extra help was terminated in error, you can call Social Security to appeal at 1-800-772-1213. TTY users should call 1-800-325-0778.

For More Information

If you have any questions about this letter, please contact <Customer/Member> Services at <toll-free number><days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Marketing Material ID Number><CMS Approval Date>

Appendix C - Model Notice *of Removal of LIS Period(s) for*
PDPs, MA-PD Plans, and Cost Plans that offer Part D
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

{**NOTE:** The marketing material code for this model notice is 7012. If the *plan* uses the model notice without modification, CMS will waive the 5-day waiting period before the *plan* can use the notice in the marketplace).

Dear <Name of Member>:

Medicare has informed us that your eligibility for extra help has been terminated from <start date> to <end date>. This means you did not qualify for extra help with your Medicare prescription drug costs during this period. You will continue to be a member of <plan name>.

Since you didn't qualify for extra help or were approved at a higher premium and cost sharing level for this period, you may owe money back to <Plan name>. <Plan name> will send you a notice telling you what you owe for past charges. If you filled prescriptions during <start date> to <end date>, you may have been charged less than you should have paid. If you do owe us money, we will let you know how much.

[If the beneficiary was deemed, insert the following language:

You may still qualify for extra help, but you must apply to find out. If you haven't already filled out an application for extra help, you can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778. *If you don't qualify for extra help from Social Security, you can change plans if you wish to do so.]*

What are your options?

Option 1: You can stay a member of our plan

Even if you don't qualify for extra help, you can continue to be a member of <plan name>. You will pay the *following* costs for your coverage. *[Insert standard cost sharing]*

Option 2: You can switch to a new plan

If you no longer qualify for extra help, you can switch to a different Medicare drug plan starting *<date>*. You may want to choose a different drug plan with costs and coverage that better meet your needs.

- [Insert, if applicable: we offer (an)other plan(s) that may lower your prescription drug plan costs]
- Visit www.medicare.gov on the Web or call 1-800-MEDICARE (1-800-633-4227) for more information about Medicare drug plans available in your area. They can

also refer to you a State Health Insurance Program in your state to obtain additional assistance on choosing another plan. TTY users should call 1-877-486-2048.

Option 3: You can find other ways to get help with your prescription drug costs

Your state may have programs that can help pay your prescription drug costs. Contact your State Medical Assistance (Medicaid) office for more information. Call 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov on the Web for their telephone number. TTY users should call 1-877-486-2048.

For More Information

If you have any questions about this letter, please call <Customer/Member> Services at <toll-free number><days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.

Appendix D - Model Notice of Error in Premiums and Cost Sharing **(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)**

{This letter is to inform a member that s/he is liable for cost-sharing amounts you have paid on his or her behalf. You will use this model to notify any members who lost deemed status, used the Optional Grace Period, and was subsequently not approved by SSA for an LIS award. The marketing material code for this model notice is **7008**. If you use this model notice without modification, CMS will waive the 5-day waiting period associated with file and use pieces.}

[Member#-if member # is SSN, only use last 4 digits]

[RxID]

[RxGroup]

[RxBin]

[RxPCN]

<Date>

Dear <Name of Member>:

Since <Date>, <Plan name> has been charging you a premium of <insert LIS premium amount that had been charged> and/or a copayment of <insert LIS copayment level that had been charged> for each prescription you filled because you provided us with proof you have applied for extra help with your prescription drug costs.

Because <Plan name> has <not been able to confirm by <last day of grace period/March 31> that you qualify for extra help> or has <been informed that you do not qualify>, your Medicare prescription drug costs are changing. Effective <date>, you will pay.

- [insert plan premium] per month for your <Plan name> premium,
- [insert deductible amount] for your yearly prescription drug plan deductible, and
- [insert amount] when you fill a prescription covered by <Plan name>.

The Medicare Program requires <Plan name> to charge you for past prescription drug costs for any premiums, deductible or cost sharing amounts you should have paid since <date>. <Plan name> will send you a notice telling you what you owe for past charges.

If you have any questions, please call our Member Services at <phone number><days and hours of operation>. TTY users should call <TTY number>.

Appendix E - Establishing Low-Income Subsidy Status
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

In order to establish the correct premium, cost sharing and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Weekly/Monthly Transaction Reply Report (TRR). The memo “Announcement of Spring Software Release” dated January 9, 2009, outlined the technical changes to the TRR related to LIS status that became effective July, 2009. As discussed in Section 1 of the memorandum, the Weekly and Monthly TRRs will provide full replacement Low Income Subsidy (LIS) profiles to plans in response to Part D enrollments and PBP changes as well as any LIS change that impacts a Part D enrollment period. Therefore, the TRR will become the definitive source of LIS eligibility information. It is important to note that these changes represent a shift in reporting methodology. Unlike much of the data provided in the TRR, LIS eligibility information will not be based on current payment month (CPM) reporting.

Changes in LIS Data Reporting

- *CMS will no longer return LIS data in association with the Transaction Reply Codes (TRCs) generated in response to enrollment and Plan Benefit Package (PBP) change transactions. Specifically, LIS data will no longer accompany enrollment and PBP change TRCs 011, 100, 117, 118, 210, and 212. Instead, LIS TRCs will independently accompany enrollment and PBP change transaction responses.*
- *CMS will also no longer identify specific LIS changes. Instead, plans will be provided full replacement LIS profiles in response to low-income subsidy changes that accumulate over the weekly and monthly reporting cycles. Replacement profiles will be established using data known to CMS at the end of each reporting cycle. Reported data will span a PBP enrollment.*
- *To more clearly communicate these changes, CMS will eliminate TRCs 167 and 168. Two existing TRCs (121 and 194) have been retained but the definition of each has been slightly modified. One new TRC (223) has been added and will identify LIS periods that have been removed from and are no longer affecting an enrollment. For more detailed information and a complete list of changes regarding these TRCs, refer to PCUG Code description H-2: Transaction Reply Codes.*
- *Full replacement LIS profiles will be represented by an ensemble composed of one or more of the TRCs 121, 194, and 223. Each profile will return LIS period start and end dates, premium subsidy percentage, co-payment level, enrollee type flag, and low income subsidy source code. Low-income premium subsidy percentage and co-payment level values retain their current definitions. The enrollee type flag will now identify a beneficiary as being a prior, current, or prospective enrollee. The source code will now identify whether the LIS period is the result of CMS deeming or Social Security Administration (SSA) approval.*

Other Sources of LIS Data

Although the TRR will become the primary source of LIS eligibility information, plans will continue to receive a number of reports and/or data sources containing LIS information. While each of these files may contain some LIS information about sponsors' enrollees, none of these contain the comprehensive LIS profile that is provided on the TRR.

- 1. **Batch Completion Status Summary (BCSS):** This report is in response to plan submitted transactions. Because it is not provided for CMS generated transactions (i.e., auto/facilitated enrollments), it is not intended to be a source of LIS data.*
- 2. **Low Income Subsidy/Late Enrollment Penalty Data File:** This data file contains beneficiary level low income subsidy and the late enrollment penalty payment and adjustment details. Late enrollment penalty details are provided for direct bill beneficiaries only.*
- 3. **LIS/Part D Premium Data File:** This data file displays beneficiaries from the premium profile table who have a low income designation. It is provided on a bi-weekly basis and is the reference file that is used to determine the LIS Match Rate.*
- 4. **LIS History Data File (LISHIST):** This report provides a comprehensive list of a sponsor's current LIS membership. The data on each beneficiary spans the most recent 36 consecutive months of contract enrollment. Near year end, this report will also inform plans whether beneficiary is LIS in the next calendar year.*
- 5. **Weekly LIS Activity History (LISAHD):** This report informs plans holding current, prior, and prospective enrollments that some element of LIS changed during the beneficiary's enrollment in the contract.*

In addition to using data in the regularly issued reports above, in December of each year, Part D sponsors should consult the one-time Loss of Subsidy File. This file reports those who have lost their deemed status for the following calendar year. The TRC used for this special file type is TRC-996, and the record layout is E.18 in the PCUG.

Appendix F - Sponsor Request for LIS Changes
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Organization Name:										Primary Contact Name:					
Contract Number:										Primary Contact Phone:					
Organization Mailing Address:										Primary Contact E-Mail Address:					
										Secondary Contact Name:					
										Secondary Contact Phone:					
										Secondary Contact E-Mail Address:					
Request to Update CMS Medicaid Cost-Sharing Information													For CMS Only		
Bene Health Insurance Claim Number	Bene Last Name	Bene First Name	Bene Date of Birth	Bene Gender	Bene State of Residence	Start of Medicaid/Medicaid Institutional Status (MM/CCYY)	Most Recent Month of Medicaid/Medicaid Institutional Status (MM/CCYY)	Dual Eligible Status (Full/Partial)	Institutional Status (Yes/No/Unknown)	Type of Documentation Supporting Request	Description of "Other" State Documentation	Date Request Entered by CMS	Updated by	Comments	

Certification:

“I have read the contents of the LIS Status Correction Request dated (indicate month, day and year) for the above-stated Part D plan contract number and attest that the information contained herein, based on best knowledge, information, and belief as of the date indicated below, is true, correct, and complete, and that our organization will retain the original supporting documentation for requested changes for as long as it is required under Federal regulations and for as long as it may be required for subsequent Government audit. I further certify that I am an authorized representative of the business organization that is a Medicare Part D sponsor.”

Part D Sponsor Signature

Date

Instructions:

Complete General Information About Your Organization:

Organization Name

Contract ID

Organization Mailing Address

Primary and Second Points of Contact

Enter Organization's Legal Name

Enter CMS Assigned Contract ID, e.g. S1234 or H1234 (format as text field)

The specifications for each data field are as follows:

Health Insurance Claim Number (HICN)

Bene Last Name

Bene First Name

Bene Date of Birth

Bene Gender

Bene State of Residence

Start of Medicaid/Medicaid Institutional Status

Most Recent Month of Medicaid/Medicaid Institutional Status

Dual Eligible Status

Institutional Status

Type of Documentation Supporting Request

Description of "Other" State Documentation

Format as text field; do not insert dashes, e.g. 123456789A

Format as text field

Format as text field

Format as M/D/CCYY, e.g. 5/6/1950

Format as text field; Valid values are "M" or "F" for Male/Female

Format as text field; spell entire state name, e.g. Michigan

Format as date field and enter the start date as MM/CCYY, e.g. 05/2007 for May, 2007

Format as date field and enter the most recent month as MM/CCYY, e.g. 05/2007 for May, 2007

Format as text field; valid values are "Full" or "Partial" for Full Dual/Partial Dual

Format as text field; valid values are "Yes", "No" or "Unknown"

Select from pull-down list.

Format as text field

Date Request Entered by CMS

Updated by

Comments

FOR CMS COMPLETION ONLY

FOR CMS COMPLETION ONLY

FOR CMS COMPLETION ONLY

Appendix G - Notice of Award Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Social Security Administration
Medicare Prescription Drug Assistance
Notice of Award

Great Lakes Program Service Center
600 West Madison Street
Chicago, Illinois 60661-2474
Date: November 23, 2005

JOHN Q. PUBLIC
123 MAIN ST
SPRINGFIELD OH 45501

You are eligible for extra help with your Medicare prescription drug plan costs. To take advantage of this benefit, you must enroll in a Medicare approved prescription drug plan or Medicare Advantage plan with prescription drug coverage, if you are not already enrolled in one. If you do not choose a Medicare prescription drug plan, Medicare will choose one for you to be sure you get this benefit. You will receive more information from Medicare.

The rest of this letter explains the extra help with the prescription drug plan costs, the information used to determine your eligibility, how to sign up for a Medicare prescription drug plan, what to do if your situation changes, and your appeal rights.

Information About This Help With Your Prescription Drug Plan Costs

You are eligible for full help to pay your Medicare prescription drug premium, also known as subsidy, because your income is below the limits established by the law. Because your resources are less than or equal to \$6000, you are also eligible for lower prescription drug co-payments and

- **XX% subsidy to help pay your Medicare prescription drug plan premiums;**
- **<No/Reduced> prescription drug annual deductible; and**
- **Reduced co-payment amounts when you have a prescription filled.**

(Refer to Appendix H and/or L to find the effective date)

Appendix H - Income Determination Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

SOCIAL SECURITY ADMINISTRATION

How We Counted <Your/Your and Your Spouse's> Income To Determine Your Subsidy
For the <Month, Year> and continuing

<Income Type 1>	<u><amount></u>
<Income Type 2>	<u><amount></u>
.	<u><amount></u>
.	<u><amount></u>
.	<u><amount></u>
<Income Type n...>	<u><amount></u>
(General Income Exclusion)	<u><(amount)></u>
Subtotal of <Your/Your and Your Spouse's> Income We Count	<u><amount></u>
Total Income We Count	<u><amount></u>
Income Limit for Subsidy Eligibility	<u><amount></u>

Appendix I - Notice of Change Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Social Security Administration
Medicare Prescription Drug Assistance
Notice of Change

Great Lakes Program Service Center
600 West Madison Street
Chicago, Illinois 60661-2474
Date: December 1, 2006
Social Security Number: 123-00-6789

JOHN Q. PUBLIC
123 MAIN ST
SPRINGFIELD OH 45501

We are changing the amount of the extra help you get with Medicare prescription drug plan costs. The rest of this notice explains how we figured the change, when it will change, what information was used to make this decision, what to do if your situation changes, and your appeal rights.

Your Help Will Change

You will receive increased help, also known as the subsidy, because of a change in your income. **Beginning <Month, Year>**, you are eligible for:

- **XX% subsidy to help pay your Medicare prescription drug plan premiums;**
- **<No/Reduced> prescription drug annual deductible; and**
- **Reduced co-payment amounts when you have a prescription filled.**

Appendix J - Notice of Planned Action Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Social Security Administration
Medicare Prescription Drug Assistance
Notice of Planned Action

Great Lakes Program Service Center
600 West Madison Street
Chicago, Illinois 60661-2474
Date: October 4, 2006
Social Security Number: 123-00-6789

JOHN Q. PUBLIC
123 MAIN ST
SPRINGFIELD OH 45501

We are changing the amount of the extra help you get with Medicare prescription drug plan costs. The rest of this notice explains how we figured the change, when it will change, what information was used to make this decision, what to do if your situation changes, and your appeal rights.

Your Help Will Change

You will receive reduced help, also known as the subsidy, because of a change in your income. **Beginning <Month Year>**, you are eligible for:

- **XX% subsidy to help pay your Medicare prescription drug plan premiums;**
- **<No/Reduced> prescription drug annual deductible; and**
- **Reduced co-payment amounts when you have a prescription filled.**

Appendix K - Important Information Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Social Security Administration
Medicare Prescription Drug Assistance
Important Information

Great Lakes Program Service Center
600 West Madison Street
Chicago, Illinois 60661-2474
Date: October 4, 2006
Social Security Number: 123-00-6789

JOHN Q. PUBLIC
123 MAIN ST
SPRINGFIELD OH 45501

We have completed our review of your and your spouse's eligibility for extra help with Medicare prescription drug plans costs. You and your spouse will continue to receive the same extra help that you have been receiving. The rest of this notice explains how we figured the change, when it will change, what information was used to make this decision, what to do if your situation changes, and your appeal rights.

Your Eligibility

Your and your spouse's eligibility for extra help, also known as the subsidy, will continue as follows:

- **XX% subsidy to help pay your Medicare prescription drug plan premiums;**
- **<No/Reduced> prescription drug annual deductible; and**
- **Reduced co-payment amounts when you have a prescription filled.**

(Refer to Appendix H and/or L to find the effective date)

Appendix L - Resource Worksheet Sample
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

SOCIAL SECURITY ADMINISTRATION

How We Counted <Your/Your and Your Spouse's> Resources To Determine Your Subsidy

For the <Month, Year> and continuing

<Resource Type 1>	<u><amount></u>
<Resource Type 2>	<u><amount></u>
.	<u><amount></u>
.	<u><amount></u>
.	<u><amount></u>
<Resource Type n...>	<u><amount></u>

Resource Limit for Subsidy Eligibility	<u><amount></u>
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Amount Over the Resource Limit	<u><amount></u>
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We counted only the resources listed above. We do not count the value of your home, your vehicle, or your personal possessions.

Appendix M – An Important Information Letter from SSA Sample

(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

*Social Security Administration
Medicare Prescription Drug Assistance
Important Information*

*FIELD OFFICE
RETURN ADDRESS*

*Date: <date>
Social Security Number:*

*CLAIMANT NAME
ADDRESS
CITY STATE ZIP CODE*

On <date>, you submitted an Application for Help with Medicare Prescription Drug Plan costs. You are automatically eligible for extra help with Medicare prescription drug plan costs because you are/receive Supplemental Security Income, Medicaid, or participate in the Medicare Savings Program. We do not need to process your application.

If You Have Any Questions

For information about the Medicare prescription drug plans or other Medicare issues, visit www.medicare.gov on the Internet or call toll-free 1-800-MEDICARE (1-800-633-4227). If you are deaf or hard of hearing, you may call the Medicare TTY number toll-free at 1-877-486-2048.

For information about the extra help with the costs related to the Medicare prescription drug plans or general information about Social Security, visit our Website at www.socialsecurity.gov. You may also call Social Security toll-free at 1-800-772-1213. If you are deaf or hard of hearing, you may call our TTY number toll-free at 1-800-325-0778. We can answer most questions by phone.

If you do call, please have this letter with you. It will help us answer your questions.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R9PDB	02/05/2010	Chapter 13 of the Medicare Prescription Drug Benefit Manual-Premium and Cost-Sharing Subsidies for Low-Income Individuals	01/01/2010	N/A
R7PDB	11/21/2008	Initial release of chapter	11/21/2008	N/A