

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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## **CENTER FOR DRUG and HEALTH PLAN CHOICE**

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TO: All Part D Sponsors

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

SUBJECT: Medicare Prescription Drug Benefit Manual - Draft Chapter 13

DATE: July 31, 2008

Today, we are releasing for comment the draft of Chapter 13 of the Medicare Prescription Drug Benefit Manual. The draft of Chapter 13 consolidates previous guidance, questions and answers, and HPMS memoranda regarding the eligibility for, and administration of the Federal low-income subsidy program. In particular, the draft chapter contains information specific to the following areas:

- Eligibility requirements for the low-income subsidy;
- Part D plan's application of the premium and cost-sharing subsidy;
- Part D sponsor's responsibilities when administering the low-income subsidy; and
- The Best Available Evidence (BAE) policy.

Comments on the draft of Chapter 13 must be received by CMS no later than 5:00pm EST, Monday, August 18, 2008. Comments must be submitted via e-mail at [PartDBenefitImpl@cms.hhs.gov](mailto:PartDBenefitImpl@cms.hhs.gov). Please include Chapter 13 in the subject line of the email.

If you have questions, please contact Christine Hinds at (410) 786-4578.



# Medicare Prescription Drug Benefit Manual

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

DRAFT

*Note: This manual is subject to change to both periodic and annual updates, and currently reflects CY 2009 guidance.*

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## 10 – Introduction

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 the Prescription Drug Benefit Manual, which can be accessed at:

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

## 20 – Definitions

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 section 20.3.1 of Chapter 5 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 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:** Please refer to section 20.1 of Chapter 5 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 section 20.3.1 of Chapter 5 of the Prescription Drug Benefit Manual).

**Covered Part D drugs:** Please refer to section 10.2 of Chapter 6 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:

- A full benefit dual eligible individual (eligible for Medicare and full Medicaid benefits);
- A recipient of Supplemental Security Income (SSI) benefits; or

- Eligible for Medicaid 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 40.2 of this manual 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. Each January, 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 levels necessary for qualifying for the LIS benefit, i.e. 135%, 140%, 145% and 150%, and notifies plans of the updated levels via an HPMS memo by the end of January or early February.

**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 annual deductible;
- Reduced cost-sharing of no more than the applicable copayment amounts provided in Appendix A for Part D covered drugs;
- 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 manual 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 resources see Appendix B; and
- An individual deemed eligible as a full subsidy eligible individual.

**Income:** Money received in cash or in-kind by the applicant or their spouse who is living with them that they can use 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.

**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 Medicare Part D, the Qualified Medicare Beneficiary (QMB) benefit, the Specified Low Income Medicare Beneficiary (SLMB) benefit, or the Qualifying Individual (QI) benefit.

**Part D sponsor:** A prescription drug plan (PDP) sponsor, MA organization offering an MA-PD plan, a 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); and
- 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 30.2 and within Appendix B.

**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 multiple source drugs:** See section 10.2 of Chapter 5 for a description of this term.

**Prescription Drug Plan (PDP):** means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in section 42 CFR 423.272 of the Federal Regulations 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 422.780(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.

**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 prescription drug plan (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 section 20.1 of Chapter 6. However, because such drugs must have otherwise qualified as covered Part D drugs (as defined in section 10.2 of Chapter 6) 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 section 10.10 of Chapter 6. Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in section 20.4.2 of this chapter.

**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 section 30, chapter 5 for definition of this term.

### **30 – Eligibility Requirements**

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 low-income Medicare beneficiaries with the costs of the Part D benefit. Discussion of the U.S. Territories enhanced allotment program is described in section 80 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***

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 in Appendix B 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 individual;
- (2) Recipients of Supplemental Security Income (SSI) benefits under title XVI of the Act or;
- (3) Individuals eligible for Medicaid 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***

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 included in Appendix B (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**

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.

### ***40.1 Eligibility through Application***

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.

Eligibility determinations made by SSA are made in accordance with requirements set forth by the Commissioner of Social Security (see 42 CFR § 423.774 and 20 CFR §418. Also, see the SSA Program Operations Manual System [POMS], available at <http://policy.ssa.gov/poms.nsf/aboutpoms>, under HI 03050). 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 **[insert when posted]**) 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 manual 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. Beneficiaries may enroll during valid election periods by:

- Calling 1-800-MEDICARE;
- Filing a request with the On-Line Enrollment Center at [www.medicare.gov](http://www.medicare.gov); or
- Calling the Part D sponsor directly.

#### 40.1.1 Financial Standards for Low-Income Subsidy (LIS) Applications

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 Appendix B). Each January, 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.

#### 40.1.2 Effective Date of Initial Determinations

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). 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. Please note that 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. 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 costs the member has paid that should have been covered by the subsidy (see section 70 for details on Part D sponsor obligations).

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. Please 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, 2008. SSA makes a determination on May 19, 2008 that the person qualifies for the subsidy. Their LIS is effective retroactive to April 1, 2008.

Example 2: An individual who is not yet Medicare eligible applies at SSA for the LIS on April 22, 2008. SSA makes a determination on May 19, 2008 that the person qualifies for the subsidy. The person's Medicare eligibility starts June 1, 2008, so the subsidy effective date is also June 1, 2008.

Initial LIS determinations are made for a period not to exceed one year. 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 making the decision.

#### 40.1.3 Changes in Subsidy Level within Established Span

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 include:

- 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, 2008 that her husband died on March 25, 2008. SSA mails a determination form to the beneficiary on April 13, 2008. The beneficiary must return the completed form by July 13, 2008. She returns the form on June 25, 2008 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, 2008, the first of the month following the month of the initial report.

Part D sponsors are obligated to collect any underpaid cost-sharing due from the beneficiary as discussed in section 70.3 of this chapter.

#### 40.1.4 Deeming after Eligibility through Application

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, 2007 and is approved for a partial subsidy, effective October 1, 2007. In March, 2008, he is reported by his State as being eligible for Medicaid effective March 1, 2008. His eligibility as an LIS applicant for a partial subsidy is terminated effective February 29, 2008. His deemed status (and thus qualification for full subsidy) is effective March 1, 2008 through December 31, 2008.

Refer to section 70.3 regarding the Part D sponsor's obligation to recoup any underpaid cost sharing due from the beneficiary.

#### 40.1.5 Determining Agency Notification to Applicant

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 that made the initial LIS determination.

#### 40.1.6 Redetermination Process

The agency (SSA or State Medicaid agency) that makes the subsidy decision is responsible for on-going case activity, including redeterminations of LIS eligibility. In some redeterminations of LIS eligibility, a termination date or date of reduction of the subsidy level may be delayed to allow the individual time to respond and request an appeal. In these cases, the termination date may be effective in February or later, rather than December 31 of the prior year. CMS and the Part D sponsor may not be notified of the appeal decision until after the effective date in case of an appeal.

#### 40.1.7 Appeals

When an individual disagrees with a determination of their subsidy eligibility or subsidy level, the individual may appeal the decision and request a redetermination by either SSA or the State Medicaid agency, whichever agency made the initial determination.

### ***40.2 Eligibility through Deeming***

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

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). (Effective July 2008, States will have the ability to submit these files up to daily, and CMS will, absent system problems or other demands placed on CMS's systems such as scheduled systems processing, process each MMA file on the day the MMA file is received or on the first business day after it is received.)

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, and 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), as specified in section 70.5, documents the individual's LIS eligibility.

An individual needs to be reported eligible by SSA or the State for only one 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, 2008. She will be deemed eligible from March 1, 2008 through December 31, 2008.

#### 40.2.2 Effective Date of Initial Deemed Status

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 full dual or partial dual or by SSA as an SSI recipient, due to loss of eligibility.

Please note that 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 costs the member has paid that should have been covered by the subsidy (see section 70 of this manual chapter for details on Part D sponsor obligations).

Example 1: An individual becomes a full-benefit dual eligible individual effective March 1, 2008. The effective date of deemed status is March 1, 2008 through December 31,

2008. Example 2: A Medicare individual becomes SSI eligible effective October 1, 2008. The effective date of deemed status is October 1, 2008 through December 31, 2009.

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

#### 40.2.3 Changes to Subsidy Status within Established Deemed Span

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 copay obligation. Thus, CMS changes an individual's deemed status mid-year only when such a change qualifies the beneficiary for a lower copay obligation. The other benefits of their LIS full subsidy – premium subsidy and elimination of deductible and coverage gap – remain unchanged.

Example: An individual is deemed for the \$2.25/\$5.60 copay level for January 1 through December 31, 2008. Data are subsequently received indicating the individual now qualifies for the \$1.05/\$3.10 level effective March 1, 2008. For the period of March 1, 2008 through December 31, 2008, the individual is now deemed for the copayment level of \$1.05/\$3.10.

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 \$1.05/\$3.10 copayment level for April 1, 2008 through December 31, 2008. Data are subsequently received that indicating the individual qualifies for \$0 copayment effective November 1, 2008. The individual is deemed at this new copay level from November 1, 2008 through December 31, 2009.

#### 40.2.4 CMS Notices to Deemed Individuals

CMS provides purple 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")

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 from July through December of the current year.



- Example 1: An individual is initially deemed for January 1, 2007 through December 31, 2007, with a \$0 copay, 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 2007. The individual is re-deemed for January 1, 2008 through December 31, 2008 with the \$0 copay.
- Example 2: An individual is initially deemed for January 1, 2007 through December 31, 2007, as a full benefit dual eligible individual with copays of \$1.05/\$3.10, based on State data indicating that the individual's income is less than 100% of the Federal Poverty Level. Beginning in October 2007, the State reports the individual as a full benefit dual eligible individual and institutionalized. The individual's copays are reduced to \$0 effective October 1, 2007 through December 31, 2008.
- Example 3: An individual is initially deemed for January 1, 2007 through December 31, 2007 as a full benefit dual eligible individual with copays of \$1.05/\$3.10, 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 2007 through December 2007. Therefore, the individual loses deemed status on December 31, 2007. In February 2008, the State resumes reporting the individual, but as a Medicare Savings Program (MSP) recipient, effective November 2007. Based on the MSP status, the individual's copays will be \$2.25/\$5.60 effective January 1, 2008. The copay levels (\$1.05/\$3.10) for November through December 2007 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. The application is approved and the individual's subsidy eligibility is retroactively effective January 1 and continues into the next 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 one-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

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.

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.

#### 40.2.7 Appeals

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 that provided the data on which deemed status is based.

#### 40.2.8 Grace Period for Those Losing Deemed Status

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 Best Available Evidence (BAE) documentation to the Part D sponsor, sponsors would then recoup unpaid premiums and cost-sharing amounts consistent with existing CMS guidance.

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 2009, 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, 2009. The letter should also include information regarding the special enrollment period for loss of deemed status (described in **Chapter 3** of this manual) and the need to take action by March 31, 2009, if they do not regain LIS status and wish to change plans. Sponsors should submit these notices to CMS for review and approval according to Medicare marketing guidelines (see Chapter 2).

### **50 – Premium Subsidy**

Individuals that 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.

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

The LIS individual's premium amount is the monthly premium attributable to basic prescription drug coverage after the premium subsidy, as calculated under 50.2 and 50.3 below. The premium subsidy is rounded to the nearest ten cents before the premium subsidy is applied to the individual's monthly premium attributable to basic prescription drug coverage.

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

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 50.2.1.

#### **50.2.1 Calculation of the Regional Low-Income Premium Subsidy Amount.**

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 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) when published.

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

The premium amounts used to calculate the low-income benchmark premium amount includes the monthly beneficiary premiums for a PDP that is for basic prescription drug coverage; the portion of the monthly beneficiary premiums attributable to basic prescription drug coverage for a PDP that is enhanced alternative prescription drug coverage, and the MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Social Security Act) for a MA-PD plan. Note that the MA monthly premium for basic prescription drug coverage that is used in this calculation is net A/B rebates.

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

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

<b>FPL &amp; Assets</b>	<b>Percentage of Premium Subsidy Amount</b>
Income at 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 Appendix B for the calendar year resource limits.

#### ***50.4 Waiver of Late Enrollment Penalty***

Effective January 1, 2009 the Medicare Improvements for Patients and Providers Act of 2008 revised sections 1860D-13(b) and 1860D-14(a)(1)(A) of the Act to specifically waive low-income subsidy eligible beneficiaries from an increase to their Part D premiums due to the imposition of the late enrollment penalty under 1860D-13(a) of the Act.

### **60 – Cost-Sharing Subsidy**

#### ***60.1 Full Subsidy Eligible Individuals***

##### 60.1.1 Application to Deductible

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 for an explanation of the Part D plan's deductible.

##### 60.1.2 Application to Cost-Sharing

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**

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 manual 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-share 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 generally do not include: 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 copay 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 copay 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 copay from February 1, 2008 through December 31, 2008.*

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. 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 “Medicaid card-carrying beneficiaries” who are residents of nursing facilities or medical institutions are eligible for the zero cost-sharing. Beneficiaries with Medicaid coverage of premiums or cost sharing only, and who are not entitled to the entire Medicaid benefit will not be eligible for the zero cost-sharing. Therefore, a beneficiary who simply presents a Medicaid card and who enters a facility may not immediately qualify for the zero cost-sharing. 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, institutionalized individuals in their State; CMS reports this information to the Part D sponsor. The 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, Part D sponsors must accept and use best available evidence or 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 their 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***

#### **60.3.1 Application to Deductible**

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**

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.

### ***60.4 Administration of Cost-Sharing Subsidy***

#### **60.4.1 Application to Days Supply**

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 2009, a full subsidy

beneficiary with incomes over 100% of the FPL who uses mail order to purchase his/her prescription medications may not be charged more than \$2.40 for a 90 day supply of a generic or preferred multiple source drug and more than \$6.00 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.

#### 60.4.2 Application of Cost Sharing Subsidy when Individual Chooses Enhanced Alternative Coverage

Although the low-income 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 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 (LIS) 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 LIS amount to further reduce the LIS beneficiary's cost-sharing liability.

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.

#### 60.4.3 Application of Lesser of Cost Sharing Amounts Test

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 cost-sharing or deductibles due from a non-low income subsidy (non-LIS) individual under the plan, to the statutory cost sharing provisions described above. 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.

#### 60.4.4 Cost Sharing When Claims for LIS Individuals Cross Multiple Benefit Phases

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 script. 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. Please 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**

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 initially become LIS eligible, when their LIS levels change, and when their LIS eligibility terminates. Finally, since LIS changes are frequently effective retroactively, sponsors must establish procedures to reimburse members for cost-sharing (including deductible and copayments) and premiums paid before notification of LIS eligibility. The following subsections describe these requirements in detail.

### ***70.1 Hierarchy of LIS Notifications***

For purposes of establishing the correct premium, copayment, coinsurance, and deductible levels with the correct effective dates for current enrollees (including those with a future enrollment effective date in the Part D Sponsor's plan), Part D Sponsors should follow the hierarchy of Part D data sources found in the table located in Appendix H. This table explains the different reports generated by CMS systems that will assist the sponsor when setting a beneficiary's LIS copay and premium level. Sponsors may also consult the Plan Communications User Guide (PCUG) for additional details and technical specifications on these data sources.

Part D sponsors will likely receive data indicating new or modified LIS eligibility status for former members of their Part D plan. These data will be transmitted via the weekly LIS history report. They will not be transmitted via the TRR. Part D sponsors can confirm by using the batch eligibility query (BEQ) mechanism described in Step 3 of the table in Appendix H or follow Best Available Evidence described in Step 5 of the table in Appendix H. The Common UI may be queried for former members, but displays only current month information (i.e., provides no information for previous months) if a beneficiary is not a current enrollee of the Part D plan.

### ***70.2 Member Notifications***

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 table below explains 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 (Appendix D)* - Part D Sponsors must send the LIS Rider at least once a year to their members at the same time as the EOC, regardless of when the EOC is mailed. 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. The LIS notice must be sent within 30 days of receiving systems' notification from CMS.

*Notice to LIS Applicants Whose Subsidy is Terminated (Appendix E)* – Part D sponsors must send this notice to the affected members when the member's subsidy terminates.

*Notice for Beneficiaries Whose Deemed Status is Terminated (Appendix F)* – Part D sponsors are required to send LIS notices to affected individuals when their deemed status terminates. Within this notice, the beneficiary is directed to apply to the SSA in order to be determined if he/she is eligible for LIS.

*Notice of Error in Premiums and Cost Sharing (Appendix G)* – Part D Sponsors must send this notice when an LIS individual's subsidy level changes and there is a retroactive correction to the beneficiary's cost sharing.

### **70.3 Sponsor Requirements When Retroactive Changes to Subsidy Levels Occur**

As noted in section 40, the effective date of LIS eligibility is often retroactive for those newly eligible for LIS. 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 has enrolled in a plan effective January 1, 2008, 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, 2008. The Part D sponsor reimburses the beneficiary accordingly and revises the PDE to reflect the availability of the subsidy to the individual.*

#### **70.3.1 Refunds and Recoupments**

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 or SPAPs), any excess premium or cost sharing paid by such individual or organization. The intent of this provision is to direct the plan to make reasonable efforts to determine the party that should be reimbursed for excess cost sharing before making reimbursement. Therefore, CMS expects that plans will develop standard operating procedures (SOPs) to address the research and determinations 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 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 as it has been the case in the LTC setting, where 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 been waived by the pharmacy does not conflict with the requirement in 42 CFR 423.800(c) that beneficiaries be made whole, since 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. Our 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. (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.) In unusual cases, CMS may evaluate the extent of the underpayment on a case-by-case basis using the information provided by the Part D sponsor to determine if we would permit the Part D sponsor to not seek recovery.

#### 70.3.2 Adjustments to Prescription Drug Event Data

The Part D sponsor should ensure that once it refunds or recoups any cost-sharing, the prescription drug event (PDE) is adjusted. Although both the LIS and Patient Pay amounts are TrOOP-eligible amounts, the LIS amount must be correct 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 receives no 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 receives no 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.

In addition, the plan should ensure that once it recoups any cost-sharing, the PDE is adjusted. Although both LIS and Patient Pay amounts are TrOOP-eligible amounts, the LIS amount must be correct because LIS is a cost-based payment mechanism and CMS uses the LIS Amount field to calculate the Part D Payment Reconciliation for LIS. The adjustment PDE shows that LICS decreases and Patient Pay increases by the same amount (provided the beneficiary receives no 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.

#### ***70.4 Low-Income Subsidy and TrOOP Calculation***

All low-income, cost-sharing subsidy payments made by the Federal government on behalf 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 true out-of-pocket (TrOOP) costs as defined in section 30 of Chapter 5. 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)***

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 establish the appropriate cost-sharing subsidy for Part D eligible individuals who are full benefit dual eligible individuals or who are recipients of supplemental security income when presented with evidence that information showing the beneficiary not to be eligible is incorrect. 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**

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 website to the section of CMS’ website regarding BAE policy and make information about the BAE policy readily available for those who contact the plan’s call center. The website address is:

[www.cms.hhs.gov/PrescriptionDrugCovContr/17\\_Best\\_Available\\_Evidence\\_Policy.asp](http://www.cms.hhs.gov/PrescriptionDrugCovContr/17_Best_Available_Evidence_Policy.asp)

[website not available yet]

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

#### 70.5.2 Required Documentation and Verification

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 beneficiary when provided by the beneficiary or the beneficiary’s pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary:

- 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;
- A copy of a State document that confirms active Medicaid status during a month after June of the previous calendar year;
- A print out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year;
- A screen print from the State’s Medicaid systems showing Medicaid status during a month after June of the previous calendar year;
- Other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year.

Part D sponsors must also accept a copy of the SSA award letter as evidence to establish the subsidy status of a beneficiary who is not deemed, when provided by the beneficiary or beneficiary's pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary.

To establish that the full benefit dual eligible individual is institutionalized and qualifies for a zero cost-sharing level, the Part D sponsor must accept any one of the following forms of proof:

- 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;
- 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 year; or
- 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 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 full dual or institutionalized 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.

Once one of the forms of BAE listed above is presented, the sponsor shall:

- 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

eligibles, or at zero cost-sharing if the BAE also verifies the beneficiary's institutional status.

- Update sponsor systems to reflect the corrected LIS status, override 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. Beginning in 2009, Part D sponsors will be required to update their systems within 48 to 72 hours of their receipt of the BAE documentation. The requirement that Part D sponsors update their systems within 48 to 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 procedures set forth in section 70.5.4 of this chapter. 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

Part D sponsors must provide assistance to their members who claim to be subsidy eligible but cannot provide one of the documents listed above. CMS has established a new process for assisting individuals who claim to be subsidy eligible based on being full or partial dual eligibles but who cannot provide the documentation described above. Part D sponsors are required to take the following actions:

1. Complete columns A through F of the new CMS BAE Assistance worksheet with plan and beneficiary information. A copy of this worksheet is found in Appendix J.
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.
3. Send the worksheet via an encrypted e-mail to the CMS RO Part D mailbox based on where the individual resides. (See the list of CMS RO e-mail boxes and contacts in Appendix M.)
4. Absent unusual circumstances, submit the worksheet to the CMS RO within one 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 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.

5. 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 IntegriGuard in accordance with the procedures outlined in section 70.5.4 of this chapter.
6. 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 one 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 (see Appendices K and L). If CMS determines that the beneficiary is LIS eligible, use the "Determination of LIS Eligibility" Model Notice provided as Appendix K. 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" Model Notice provided as Appendix L. (Note: We have provided the appropriate marketing codes at the bottom of each model so that plans can send these notices under our "file and use" policy.)
  - 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. (See **Appendix M** for primary and back-up contacts at each CMS RO.)
7. 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 eligibles, or at zero cost-sharing if the RO also verifies the beneficiary's institutional status.
8. 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

Part D sponsors should provide data to CMS' contractor when BAE is confirmed for an individual who should be deemed, or deemed at a better copay 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. CMS suspects 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 one 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 Medicaid/Medicare institutional status for the purposes of establishing appropriate low-income cost-sharing status prior to a 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 most recent prior request is requiring 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 I.

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

A certification of the LIS status correction request signed by an authorized representative of the Part D plan sponsor must be submitted to CMS' contractor. The certification form is available in Appendix I. 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

Part D sponsors should submit requests for LIS deemed status corrections to IntegriGuard, 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 website 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:

IntegriGuard, 2121 North 117th Avenue, Suite 200, Omaha, NE 68164

In addition, Part D sponsors should email the password for the spreadsheet to [sroach@integriguard.org](mailto:sroach@integriguard.org) and [vdawson@integriguard.com](mailto:vdawson@integriguard.com). Once the password has been provided, IntegriGuard 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

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

Once a correction request is processed by CMS, the new data will be stored in Medicare Beneficiary Database or 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

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

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:

- a. Deeming notice – pub.no. 11166 (purple notice);



- b. Auto-enrollment notice – pub.no.11154 (yellow notice);
- c. Full-facilitated notice – pub.no. 11186 (green notice);
- d. Partial-facilitated notice – pub.no.11191 (green notice);
- e. Copay change notice – pub.no.11199 (orange notice);
- f. 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.

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

There are additional low-income subsidy that must be adhered to by Employer Group Waiver Plans. For those additional requirements, please refer to Chapter 12 of this manual.

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

The assistance provided low-income beneficiaries of the Medicare prescription drug program in the U.S. Territories is different than the low-income subsidy program provided to the Medicare beneficiaries in the 50 states.

Under Section 1860D-14(a)(3)(F), 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 Social Security 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's 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 additional amounts will be included in Chapter 10 (Payment and Bidding).

## **Appendices**

Disclaimer: Model LIS Notices contained within these appendices are subject to change and may not be updated in this chapter in a timely manner. Part D sponsors should periodically refer to the following website to ensure they have the most recent version of the LIS Model notices - [http://www.cms.hhs.gov/States/11\\_NotificationstoBeneficiaries.asp#TopOfPage](http://www.cms.hhs.gov/States/11_NotificationstoBeneficiaries.asp#TopOfPage)