MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL – CHAPTER 4
Creditable Coverage Period Determinations/Late Enrollment Penalty

Under Section §1860D-13(b) of the Social Security Act, and 42 CFR §423.46 423.56(g), Medicare beneficiaries may incur a late enrollment penalty (LEP) if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period during which the individual was eligible to enroll, but was not enrolled in a Medicare Part D plan and was not covered under any creditable prescription drug coverage. "Creditable prescription drug coverage" is prescription drug coverage that is expected to pay at least as much as Medicare's standard prescription drug coverage. As outlined at 42 CFR 423.56(c) and (d), with the exception of Prescription Drug Plan (PDP) Sponsors, Medicare Advantage (MA) Organizations, Section 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans, entities that offer prescription drug coverage must make an annual determination of creditable coverage status and provide a disclosure notice to Medicare eligible individuals. Creditable prescription drug coverage includes, but is not limited to: some employer-based prescription drug coverage, including the Federal Employees Health Benefits Program; qualified State Pharmaceutical Assistance Programs (SPAPs); military-related coverage (e.g., VA, TRICARE); and certain Medicare supplemental (Medigap) policies. (See 42 C.F.R §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable. Additional information related to creditable coverage requirements for employer and union-sponsored plans and all other entities that sponsor prescription drug coverage may be found at http://www.cms.hhs.gov/CreditableCoverage/.)

Prescription Drug Plan (PDP) Sponsors, Medicare Advantage (MA) Organizations, Section 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans (hereafter referred to as "Part D plan sponsors") are responsible for determining, at the time of enrollment, whether a beneficiary was previously enrolled in Part D or had other creditable coverage prior to applying to enroll in their plan, and whether there were any lapses in coverage of 63 days or more. Part D plan sponsors shall inform CMS of these lapses in creditable coverage so that CMS can compute the LEP. The beneficiary is then billed the LEP (as part of the premium payment), or the LEP is included when his/her premium is paid through Social Security deductions.

This guidance describes the procedures that Part D plan sponsors are required to use in making creditable coverage period determinations, reporting them to CMS, and collecting the LEP. It is critical that Part D plan sponsors follow the procedures outlined in this document so that CMS can assess LEPs as required under the law.

Part D plan sponsors shall comply with all of these provisions by August 1, 2007, except for subsection 10.2.2. Sponsors shall comply with the provisions of that subsection by October 1, 2007.

10 Making a Creditable Coverage Period Determination

The Part D plan sponsor shall determine, at the time of enrollment, whether the enrollee had or will have had a continuous period of 63 days or more since the end of his/her Initial Enrollment Period (IEP) for Part D during which s/he did not have creditable coverage. The period in

question begins on the day following the beneficiary's Part D IEP and ends on the day before the beneficiary's enrollment becomes effective with the Part D plan sponsor.

Note: Please see Appendix: Special Opportunity to Enroll in 2006 and 2007 without LEP for information about beneficiaries not subject to the LEP.

10.1 Determining the Last Day of the Beneficiary's Initial Enrollment Period (IEP)

Unless otherwise informed by CMS, a Part D plan sponsor shall assume that the last day of a beneficiary's IEP is/was:

- May 15, 2006 for a beneficiary who was eligible for Medicare Part D in January 2006, or
- the last day of the 3rd month following the month of initial eligibility for Medicare Part D, for a beneficiary who became/ becomes eligible for Part D after January 2006.

As long as a beneficiary resides in a Part D plan service area, the month that s/he initially becomes eligible for Part D is generally the earlier of the first day of the month of entitlement to Medicare Part A and/or enrollment in Part B. These dates are on the beneficiary's enrollment request.

Example
Mrs. Smith's 65th birthday is April 20, 2006. Her enrollment request shows that her entitlement to Medicare Part A and B was effective April 1, 2006. Therefore, her IEP for Part D ended on July 31, 2006.

Note: Even if Mrs. Smith delayed enrolling in Part B, her IEP for Part D still ended on July 31, 2006 because the IEP is based on entitlement to Medicare Part A and/<u>or</u> enrollment in Part B.

Specific information on IEPs can be found in the applicable plan enrollment guidance.

If CMS or its designee informs the Part D plan sponsor of a different IEP end date, the Part D plan sponsor shall use this new date in determining uncovered months and shall include documentation of the new IEP end date in the beneficiary's file.

10.1.1 Subsequent IEPs

If an individual is eligible for Medicare prior to turning 65 (for example, based on disability), s/he will be assigned a new IEP based upon turning 65. For example, if an enrollee turns 65 while enrolled in the Part D plan sponsor's prescription drug coverage, and s/he has been paying an LEP, his/her LEP will end on the day before his/her new IEP begins. Therefore, before the enrollee's new IEP, the Part D plan sponsor shall report to CMS that the beneficiary had zero (0) uncovered months through the end of his/her new IEP. To inform the beneficiary of the elimination of his/her LEP based on attaining age 65, the Part D plan sponsor shall either use the model form supplied by CMS (see Exhibit 1: Model Notice for Beneficiary Attestation of Creditable Prescription Drug Coverage) or it shall create its own form using the requisite elements shown in the model, subject to CMS' marketing review procedures.

10.2 Determining Whether There Has Been a Break in Creditable Coverage

Note: For the purpose of receiving information related to creditable coverage period determination and/or the late enrollment penalty, the Part D plan sponsor shall treat the signature of a beneficiary's authorized representative the same as the signature of the beneficiary, as long as the authorized representative provides his/her name, address, phone number, and his/her relationship to the beneficiary.

10.2.1 Future enrollees (Enrollment requests received on or after August 1, 2007)

For enrollment requests received on or after August 1, 2007, the Part D plan sponsor shall follow the steps described below to determine whether the beneficiary had a continuous period of 63 days or more since the IEP end date during which s/he did not have creditable prescription drug coverage:

Step 1. Determine the last date of the beneficiary's IEP for Part D using the information on the beneficiary's enrollment request as described in Section 10.1. If the IEP has not ended, report to CMS that the beneficiary had zero (0) uncovered months, in accordance with Section 20, "Reporting a Creditable Coverage Period Determination to CMS." If 63 or more days have passed since the end of the IEP, proceed to Step 2.

Step 2. Using the Beneficiary Eligibility Query (BEQ), determine whether the beneficiary was either enrolled in a Part D plan or was covered by an employer receiving the retiree drug subsidy (RDS) since the IEP end date. (Note: The Part D plan sponsor shall conduct a BEQ for all new enrollees, consistent with the timely submission requirements described in the plan's enrollment guidance.)

If the BEQ indicates that the beneficiary was enrolled in a Part D plan or had RDS coverage since the end of the IEP, so that there is no gap in creditable coverage of 63 or more days, report to CMS that the beneficiary had zero (0) uncovered months, in accordance with Section 20, "Reporting a Creditable Coverage Period Determination to CMS." If not, proceed to Step 3.

Step 3. If the BEQ indicates that (1) the beneficiary was not enrolled in a Part D plan or RDS coverage after the IEP end date, or (2) the beneficiary was enrolled in such coverage but a gap in creditable coverage of 63 or more days occurred, the Part D plan sponsor shall send a form to the beneficiary that asks him/her to (1) attest to whether s/he had creditable prescription drug coverage in the past and (2) identify the source(s) and date(s) of coverage. The Part D plan sponsor shall either use the model form supplied by CMS (see Exhibit 1: Model Notice for Beneficiary Attestation of Creditable Prescription Drug Coverage) or it shall create its own form using the requisite elements shown in the model, subject to CMS' marketing review procedures. The Part D plan sponsor shall send the attestation form within 7 calendar days of receipt of the BEQ response. The beneficiary shall be instructed to return the form within 30 calendar days of the date on the form. The Part D plan sponsor shall retain the attestation form as part of the beneficiary's records.

Note: The steps described in this subsection shall be completed in accordance with the timeframes established in Section 20.2, "Timeframes for Reporting a Creditable Coverage Period Determination to CMS."

10.2.2 Current Enrollees (Enrollment requests effective from January 1, 2007 through August 1, 2007)

For enrollment requests effective from January 1, 2007 through August 1, 2007, the Part D plan sponsor shall use either of the methods described below to determine whether the member had a continuous period of 63 days or more since the IEP end date during which s/he did not have creditable coverage:

Method A (Using the Beneficiary Eligibility Query): The Part D plan sponsor submits a Beneficiary Eligibility Query (BEQ) to determine whether the beneficiary was previously enrolled in a Part D plan or was covered by an employer receiving the retiree drug subsidy (RDS) since the end of his/her IEP. If the BEQ indicates that the beneficiary was enrolled in a Part D plan or had RDS coverage since the end of the IEP, such that there is no gap in creditable coverage of 63 or more days, report to CMS that the beneficiary had zero (0) uncovered months, in accordance with Section 20, "Reporting a Creditable Coverage Period Determination to CMS."

However, if the BEQ indicates that (1) the beneficiary was not enrolled in a Part D plan or RDS coverage after the IEP end date, or (2) the beneficiary was enrolled in such coverage but a gap in creditable coverage of 63 or more days occurred, the Part D plan sponsor shall send a form to the beneficiary that asks him/her to (1) attest to whether s/he had creditable prescription drug coverage in the past and (2) identify the source(s) and date(s) of coverage. The Part D plan sponsor shall either use the model form supplied by CMS (see Exhibit 1: Model Notice for Beneficiary Attestation of Creditable Prescription Drug Coverage) or it shall create its own form using the requisite elements shown in the model, subject to CMS' marketing review procedures. The Part D plan sponsor shall send the attestation form within 7 calendar days of receipt of the BEQ response. The beneficiary shall be instructed to return the form within 30 calendar days of the date on the form. The Part D plan sponsor shall retain the attestation form as part of the beneficiary's records.

Method B (Using an Attestation Form): The Part D plan sponsor sends an attestation form that asks the beneficiary to attest whether s/he had creditable prescription drug coverage and to identify the source(s) and date(s) of his/her previous coverage. The Part D plan sponsor shall either use the model form supplied by CMS (see Exhibit 1: Model Notice for Beneficiary Attestation of Creditable Prescription Drug Coverage) or it shall create its own form using the requisite elements shown in the model, subject to marketing review procedures. The Part D plan sponsor shall retain the attestation form as part of the beneficiary's records.

Note: The steps described in this subsection shall be carried out by October 1, consistent with the timeframes established in Section 20.2, "Timeframes for Reporting a Creditable Coverage Period Determination to CMS."

10.2.3 Special Procedures for Beneficiaries Eligible for the Low-Income Subsidy or Affected by Hurricane Katrina

If the Part D plan sponsor determines that a beneficiary received the low-income subsidy in 2006 and/or 2007, it shall exclude from its report to CMS any uncovered months during the calendar year(s) in which the beneficiary received the subsidy. If the Part D plan sponsor determines that a beneficiary had a special opportunity to enroll without the LEP because s/he was affected by Hurricane Katrina, it shall exclude from its report to CMS any uncovered months during 2006 (See Appendix: Special Opportunity to Enroll in 2006 and 2007 without LEP).

10.2.4 Collecting Creditable Coverage Data from Employers and Unions

Employers and unions who enroll groups of beneficiaries into Medicare prescription drug coverage may attest to their members' creditable coverage history with the employer or union for purposes of reporting covered months. Part D plan sponsors shall accept and retain such attestations and provide such documentation upon CMS' request.

10.3 Determining the Number of Uncovered Months

If the Part D plan sponsor determines that there are no continuous periods of 63 days or more since the end of the beneficiary's IEP during which the beneficiary did not have creditable prescription drug coverage, it shall report zero (0) uncovered months to CMS, in accordance with Section 20, "Reporting a Creditable Coverage Period Determination to CMS."

Example:
Mrs. Brown submitted an enrollment request for Medicare Part D coverage on December 10, 2006. Her Part D IEP ended on May 15, 2006. A BEQ inquiry shows that she had Part D prescription drug coverage or coverage through a sponsor who received the retiree drug subsidy from January 1, 2006 until October 31, 2006. Since her Part D enrollment became effective on January 1, 2007, she had a total of 61 days without creditable prescription drug coverage (from November 1, 2006 to December 31, 2006). Thus, the Part D plan sponsor shall report to CMS that she had zero (0) uncovered months.

If, however, the Part D plan sponsor determines that there is at least one continuous period of 63 days or more since the end of the beneficiary's IEP during which the beneficiary did not have creditable coverage, the Part D plan sponsor shall report to CMS the number of <u>full</u> calendar months in that period (also described as "uncovered months.").

Example:
Mr. Robinson submitted an enrollment request for Medicare Part D coverage on December 16, 2006. His IEP ended on May 15, 2006. He attests that he had creditable prescription drug coverage from January 1, 2006 until September 30, 2006. Since his Part D enrollment became effective on January 1, 2007, he had a total of 92 days without creditable prescription drug coverage (from October 1, 2006 to December 31, 2006). Thus, the Part D plan sponsor shall report to CMS that he had three uncovered months: October, November, and December, 2006.

Note: If Mr. Robinson was eligible for the low-income subsidy in 2006, the Part D plan sponsor shall report to CMS that he had zero (0) uncovered months. Similarly, if Mr. Robinson was affected by Hurricane Katrina, the Part D plan sponsor shall report to CMS that he had zero (0) uncovered months. In either case, Mr. Robinson's three uncovered months in 2006 are not included in the calculation of any late enrollment penalty. (See Appendix: Special Opportunity to Enroll in 2006 and 2007 without LEP.)

Example:
Mr. Jones submitted an enrollment request for Medicare Part D coverage on December 23, 2006. His IEP ended on June 30, 2006. A BEQ inquiry does not show any record of Mr. Jones' enrollment in a Part D plan or a plan whose sponsor received the retiree drug subsidy. Mr. Jones attests that he had creditable prescription drug coverage through his employer from October 1, 2006 until December 31, 2006. Since his Part D enrollment became effective on January 1, 2007, he had a total of 92 days without creditable prescription drug coverage (from July 1, 2006 to September 30, 2006). Thus, the Part D plan sponsor shall report to CMS that he had three uncovered months: July, August, and September, 2006.

Note: As in Mr. Robinson's scenario above, if Mr. Jones was eligible for the low-income subsidy or if he was affected by Hurricane Katrina, the Part D plan sponsor shall report to CMS that Mr. Jones had zero (0) uncovered months.

10.4 Information Retention Requirements

Any information collected concerning a creditable coverage period determination, whether from the beneficiary, CMS, or another source, shall be kept as part of the beneficiary's application for enrollment into the Part D plan by the plan sponsor in accordance with enrollment record retention requirements. (See the appropriate CMS enrollment guidance for more information about these requirements.). Similarly, Part D plan sponsors shall also retain copies of any evidence of creditable coverage, including late attestation forms, and any information regarding reconsideration decisions. (For more information on LEP reconsideration procedures, please see Section 80.7.1 of Chapter 18.)

20 Reporting a Creditable Coverage Period Determination to CMS

20.1 Reporting a Creditable Coverage Period Determination to CMS using an Enrollment Transaction or Change Transaction

The Part D plan sponsor shall report a creditable coverage period determination to CMS by including it on the enrollment transaction (transaction codes 60, 61 and 71) or separately on a change transaction (code 72) if the determination is made after the enrollment transaction has been submitted. Unless otherwise noted, the Part D plan sponsor has the discretion to use either submission vehicle, provided it meets the timeframes outlined in this chapter and in the plan's enrollment guidance.

Note: If the sponsor does not have sufficient information in time to report its creditable coverage period determination on an enrollment transaction, it shall report to CMS that the beneficiary had creditable coverage (creditable coverage flag = 'Y," number of uncovered

months = ‘000’) on the enrollment transaction, followed by a change transaction, if necessary, based on any creditable coverage information received later.

Revised creditable coverage period determinations as a result of reconsiderations shall be reported using a change transaction (code 72) since such revised determinations generally occur after enrollment. For more information on LEP reconsideration procedures, please see Section 80.7.1 of Chapter 18.

CMS file format details for enrollment transactions (codes 60, 61 and 71), and the change transaction (code 72), including the creditable coverage data items, are provided in Appendix E.7 of the Plan Communications Users Guide which is available at www.cms.hhs.gov/medicaremangcaresys/ on the web. There are 2 data elements that shall be provided, as follows:

Field	Description
Creditable Coverage Flag	‘Y’ if covered, ‘N’ if not covered
Number of Uncovered Months	Count the total months without drug coverage, leading zeroes or right justified. - Count must be greater than or equal to two (002) when the “Creditable Coverage Flag” is ‘N’. - Count must be zero (000) when “Creditable Coverage Flag is ‘Y”.

The number of uncovered months submitted shall reflect the actual months upon which the LEP will be based. This is the number of full calendar months that occurred during any continuous period of 63 days or more, after the end of the beneficiary’s IEP, in which s/he did not have Medicare prescription drug coverage or other creditable prescription drug coverage.

20.2 Timeframes for Reporting a Creditable Coverage Period Determination to CMS

20.2.1 Determination based on BEQ Query

If the Part D plan sponsor conducts a BEQ query, and does not need to send an attestation form to the beneficiary, it shall report its creditable coverage period determination to CMS within 14 calendar days of receiving the BEQ response.

20.2.2 Determination based on Timely, Complete Attestation Form

If the Part D plan sponsor sends an attestation form to a beneficiary, it shall report its creditable coverage period determination to CMS within 14 calendar days of receiving the timely, complete attestation form.

Note: If the Part D plan sponsor receives a timely, complete attestation form after it has submitted an enrollment transaction to CMS on behalf of that beneficiary, but before receiving confirmation of that beneficiary’s enrollment from CMS, the sponsor shall wait

for CMS to confirm the beneficiary's enrollment before reporting its creditable coverage period determination to CMS. In this case, the sponsor shall report its creditable coverage period determination within 14 calendar days of receiving confirmation of that beneficiary's enrollment.

20.2.3 Determination based on Timely, Incomplete Attestation Form

The Part D plan sponsor shall consider an attestation form complete if it contains:

1. The signature of the beneficiary, or the signature of the beneficiary's authorized representative, along with the authorized representative's name, address, phone number, and his/her relationship to the beneficiary, AND
2. A '√' in the box that indicates that the beneficiary never had creditable coverage, or a '√' in any other box on the attestation form.

If the Part D plan sponsor receives an incomplete attestation form by the stated deadline, it shall contact the beneficiary promptly to attempt to obtain complete information and report its creditable coverage period determination to CMS within 21 calendar days of receipt of the incomplete form. The Part D plan sponsor shall document its efforts to obtain the missing information and date any additional information as soon as it is received.

20.2.4 Determination based on Missing Attestation Form

If the beneficiary fails to return the attestation form by the stated deadline, the Part D plan sponsor shall report to CMS, within 7 calendar days after the stated deadline date, the appropriate number of uncovered months based on the available information.

20.2.5 Determination following Reconsideration

The Part D plan sponsor shall report a revised creditable coverage period determination to CMS within 14 calendar days of receiving a reconsideration decision from the Independent Review Entity (IRE) under contract with Medicare. The Part D plan sponsor shall refer to Chapter 18, Section 80.7.1, of this manual for detailed guidance on LEP reconsideration procedures.

20.3 Procedures and Beneficiary Notification following Receipt of Late Attestation Form

20.3.1 Reviewing and Reporting Requirements

If the Part D plan sponsor receives an attestation form after the stated deadline, it has the discretion to review and report upon it, provided that (1) the sponsor meets the reporting timeframes outlined in Section 20.2.4, "Determination based on Missing Attestation Form," and (2) the sponsor applies a consistent policy for all late attestation forms.

20.3.2 Notification to Beneficiary

If the Part D plan sponsor does not accept, review, and/or report upon the late attestation form, it shall notify the beneficiary, within 7 days of receipt, that the form was not considered in the creditable coverage period determination because it was received after the

deadline. The Part D plan sponsor shall use model content supplied by CMS (see Exhibit 2: Model Notice for Creditable Coverage Information Received After Deadline Date), or it shall create its own letter using the requisite elements shown in the model, subject to marketing review procedures.

30 Communications regarding Creditable Coverage and/or the Late Enrollment Penalty

CMS is the only entity authorized to calculate and impose an LEP. While a Part D plan sponsor might be able to estimate a beneficiary's LEP based on the number of uncovered months reported to CMS, the Part D plan sponsor shall not estimate or inform a beneficiary of any LEP amount until it receives formal notification of such from CMS, as described in Section 40.2, "Notification of the Late Enrollment Penalty from CMS."

30.1 Notification to Beneficiaries of the Late Enrollment Penalty

The Part D plan sponsor shall notify each plan member of the imposition of, or adjustment to, an LEP in writing within 10 calendar days of receiving notice of the LEP from CMS. The letter to the beneficiary shall include the following elements:

1. Beneficiary's name;
2. Monthly premium (in dollar and cents) for the current year, and what portion of that amount is the LEP;
3. Effective date of the penalty;
4. Basis for LEP in terms of the number of uncovered months reported to CMS; and
5. Information about the beneficiary's right to request reconsideration (review) of the LEP and the reconsideration filing deadline, including a notice titled "Your Right to Ask Medicare to Review Your Part D Late Enrollment Penalty." This notice can be found in Chapter 18 of this manual (Appendix 14).
6. An LEP Reconsideration Request Form. This notice can be found in Chapter 18 of this manual (Appendix 15).

Note: A Part D plan sponsor <u>shall not</u> include elements #5 or #6 when notifying a beneficiary of an LEP adjustment due to a reconsideration decision.

If an employer or union sponsors prescription drug coverage for its members through the Part D plan sponsor, and the employer or union elects to pay the LEP on behalf of its members, the Part D plan sponsor shall inform the beneficiary that the employer or union has agreed to pay the LEP on his/her behalf. The Part D plan sponsor shall also inform the beneficiary that, if the coverage is terminated by him/her or by the employer or union sponsoring the Part D plan sponsor, the beneficiary will be responsible for paying the LEP if and when s/he enrolls into another Medicare drug plan.

The Part D plan sponsor shall either use the appropriate model form supplied by CMS (see Exhibit 3: Model Notice Informing Beneficiary of LEP or Exhibit 4: Model Notice to Confirm Adjustment of Premium upon Reconsideration of Late Enrollment Penalty), or it shall create its own letter using the requisite elements shown in the appropriate model, subject to marketing review procedures.

30.2 Notification following Reconsideration

The IRE will notify beneficiaries and the Part D plan sponsor of the final reconsideration decision. The Part D plan sponsor shall refer to Chapter 18, Section 80.7.1, of this manual for detailed guidance on LEP reconsideration procedures.

30.3 Responding to Inquiries about Creditable Coverage and/or the Late Enrollment Penalty

If the Part D plan sponsor receives a general inquiry about creditable coverage or the LEP from one of its enrollees, it shall inform the enrollee of the process by which CMS assesses the LEP, and if applicable, the number of uncovered months the Part D plan sponsor reported to CMS. If it has not already done so, the Part D plan sponsor shall also advise the beneficiary of his/her right to request reconsideration of the LEP, when and if an LEP is assessed. The Part D plan sponsor may also choose to send the one-page reconsideration notice titled: "Your Right to Ask Medicare to Review Your Part D Late Enrollment Penalty" (found in Chapter 18 of this manual (Appendix 14)).

If an inquiry is made about the likelihood of a beneficiary being assessed an LEP, but no enrollment request has been submitted on behalf of that beneficiary, the Part D plan sponsor shall only explain CMS' policy in general terms. The Part D plan sponsor shall exercise care when using hypothetical scenarios with beneficiary-specific information to explain the policy, since they might be interpreted as official creditable coverage period determinations.

30.4 Creditable Coverage Information Received without an Enrollment Request

If the Part D plan sponsor receives creditable coverage information without an accompanying enrollment request, it shall return such information to the beneficiary within 10 calendar days. If the Part D plan sponsor does not have the beneficiary's address, it shall document that it was unable to return the creditable coverage information.

40 Calculation, Billing, and Collection of the LEP

40.1 LEP Calculation

In 2006 and 2007, the LEP is assessed as 1% of the national base beneficiary premium for the coverage year times the total number of uncovered months, regardless of the year(s) in which those months occurred. The national base beneficiary premium is <u>not</u> the Part D plan sponsor's premium, but is a national amount that is a function of the national average bid for the year in which the beneficiary is enrolled in a Part D plan sponsor. Therefore, even if there is no change in the number of uncovered months, the LEP may change each year because it is recalculated using the total number of uncovered months and the national base beneficiary premium for that particular year.

Due to systems constraints, the LEP is rounded to the nearest ten cents.

40.2 Notification of the Late Enrollment Penalty from CMS

CMS will inform the Part D plan sponsor about the LEP amount (and other LEP-related information) through the data files and reports summarized below. These data files and reports are described in detail in the Plan Communications Users Guide (PCUG), which is available at www.cms.hhs.gov/medicaremangcaresys/ on the web.

PCUG Appendix #	Name of Data File / Report	Availability	Type of LEP-information	
			Beneficiary-specific	Totals
E.15	Weekly/Monthly Transaction Reply Activity Data File	Weekly / Monthly	X	
E.16	Special Transaction Reply Report Data File	CMS will announce availability	X	
E.17	Full Enrollment Data File	Monthly	X	
E.18	Low-Income Subsidy/Late Enrollment Penalty (LIS/LEP) Data File	Monthly		X
E.19	Bi-Weekly Deemed LIS/Premium Report Data File	Bi-Weekly	X	
I.12	Plan Payment Report	Monthly		X

40.3 Billing and Collection of the LEP

The LEP is calculated based on the national base beneficiary premium, not the plan's premium resulting from the annual bidding process. Therefore, the LEP is billed to applicable members even if the plan's Part D basic premium is $0.

For plan members in direct-bill status, the Part D plan sponsor is required to bill the beneficiary for the LEP at the same time that it bills for his/her Part D plan premium. However, the Part D plan sponsor shall always allow the member the option of paying his/her LEP on a monthly basis. Plans may establish other billing cycles (e.g., quarterly or annual), but the member must be presented with monthly billing as one of the choices. The member must actively make a choice between the various billing cycles a plan may provide. The Part D plan sponsor does not need to bill a beneficiary whose premium is withheld from Social Security benefits; the Social Security Administration (SSA) will collect the LEP amounts from a beneficiary who elected the SSA premium withhold option. SSA takes this action by increasing the withhold amount by the amount of the LEP.

Part D plan sponsors shall continue to bill the LEP as part of the premium even if a beneficiary has filed for reconsideration. If a reconsideration decision changes the Part D plan sponsor's initial creditable coverage period determination (i.e., if the reconsideration decision changes the

number of uncovered months the Part D plan sponsor initially reported to CMS, including reducing the number of months to 0), the Part D plan sponsor shall submit a change transaction that reflects the reconsideration decision. CMS then will inform the Part D plan sponsor of the new LEP amount to bill or refund to the beneficiary. If the beneficiary's premium is withheld from Social Security benefits, CMS and SSA will take the necessary action to adjust and/or refund the LEP withheld as part of the premium.

40.4 Billing the LEP to Employer or Union Sponsors

If an employer or union sponsors prescription drug coverage for its members though the Part D plan, the Part D plan sponsor shall bill the employer or union directly for any LEP if both the Part D plan sponsor and the employer or union agree.

40.5 Nonpayment of LEP

The Part D plan sponsor shall disenroll a beneficiary for nonpayment of the LEP consistent with its policy with respect to disenrollment due to nonpayment of premium. For more information on disenrollment under these circumstances, see the CMS enrollment guidance applicable to the Part D plan sponsor's type.

40.6 Refund of LEP

If a reconsideration decision reduces the amount of the LEP or determines that no LEP should be imposed, the Part D plan shall refund the LEP due to the beneficiary as soon as possible. If the beneficiary's premium was withheld from Social Security benefits, CMS and SSA will take the necessary action to refund the LEP withheld as part of the premium.

Appendix: Special Opportunity to Enroll in 2006 and 2007 without LEP

Medicare beneficiaries who qualify for the low-income subsidy for Medicare prescription drug coverage may enroll in a Medicare prescription drug plan with no penalty through December 31, 2007. As long as these individuals stay continuously enrolled in a Medicare drug plan, they will not be assessed an LEP in 2006, 2007, or afterwards. If these individuals disenroll after 2007, and then have a continuous period of 63 days or more since the end of their IEP without creditable prescription drug coverage, they will incur an LEP upon re-enrollment into a Medicare drug plan; however, their uncovered months in 2006 and 2007 will not be a factor in the calculation of their LEP.

Certain Medicare beneficiaries who were affected by Hurricane Katrina were allowed to enroll in a Medicare prescription drug plan with no penalty through December 31, 2006. As long as these individuals stay continuously enrolled in Part D, they will not be assessed an LEP in 2006 or afterwards. If these individuals disenroll after 2006 and then have a continuous period of 63 days or more without creditable prescription drug coverage, they will incur an LEP upon re-enrollment into a Medicare drug plan; however, their uncovered months in 2006 will not be a factor in the calculation of their LEP.

Medicare beneficiaries affected by Hurricane Katrina were considered eligible for this opportunity if, at the time of the hurricane (August 2005), they resided in any of the parishes or counties declared as meeting the level of “individual assistance” by the Federal Emergency Management Agency (FEMA). FEMA has identified the parishes and counties declared eligible for "individual assistance" as a result of Hurricane Katrina. The list of parishes and counties can be found at www.fema.gov/news/disasters.fema?year=2005.

Exhibit 1: Model Notice for Beneficiary Attestation of Creditable Prescription Drug Coverage

<Member ID #>

<Date>

<Name of Member>:

Our records show that you were first eligible to join a Medicare drug plan through <*insert last month of IEP in mm/yyyy format*> and

[Insert the following for "Future Enrollees" AND "Current Enrollees (Method A)": that you did not have Medicare prescription drug coverage or other creditable prescription drug coverage (as good as Medicare's) during the following period(s): <insert period here>. **If you disagree with this, please complete this form and return it to <Plan Name> at <Plan Address> within 30 days of the date of this letter. We will use the information you provide to determine if you have a late enrollment penalty and the amount of the penalty. If you don't return this form, we will assume you didn't have creditable prescription drug coverage during the period in question.**]

[OR insert the following for "Current Enrollees (Method B)": we need to know if you had creditable prescription drug coverage (as good as Medicare's) since then. **Please complete this form and return it to <Plan Name> at <Plan Address> within 30 days of the date of this letter. We will use the information you provide to determine if you have a late enrollment penalty and the amount of the penalty. If you don't return this form, we will assume you didn't have creditable prescription drug coverage during the period in question.**]

Please check all boxes that apply to you.

☐ I joined a Medicare drug plan before December 31, 2006, and at the time of Hurricane Katrina (August 2005), I resided in a parish or county declared as meeting the level of "individual assistance" by the Federal Emergency Management Agency (FEMA). (Check this box even if you joined a Medicare drug plan in 2006, but your drugs weren't covered until January 1, 2007. The list of parishes and counties that FEMA declared eligible for "individual assistance" as a result of Hurricane Katrina can be found at www.fema.gov/news/disasters.fema?year=2005.)

☐ I got extra help from Medicare to pay for my prescription drug coverage in 2006/2007. (Circle year(s).)

☐ I got/get my creditable prescription drug coverage from the source(s) listed below:
(Give the date(s) of your coverage. Use another sheet if necessary.)

☐ **State-sponsored Plan, including Medicaid, State Pharmaceutical Assistance Program (SPAP), or State High-Risk Pool**	**from (mm/yy): _____ to (mm/yy): _____**
☐ **Employer/Union, including the Federal Employees Health Benefits Program (FEHBP) Name: _____**	**from (mm/yy): _____ to (mm/yy): _____**

☐ **Veterans, survivor, or dependent benefits (VA) and/or military coverage, including TRICARE**	**from (mm/yy): _____ to (mm/yy): _____**
☐ **A Medigap (Medicare Supplemental) policy with drugs**	**from (mm/yy): _____ to (mm/yy): _____**
☐ **Indian Health Service, a Tribe or Tribal organization, or an Urban Indian organization (I/T/U)**	**from (mm/yy): _____ to (mm/yy): _____**
☐ **PACE organization**	**from (mm/yy): _____ to (mm/yy): _____**
☐ **Other source: _____**	**from (mm/yy): _____ to (mm/yy): _____**

☐ I never had creditable drug coverage.

☐ I got a letter stating that my penalty was reduced or "reconsidered." Date of letter (mm/yy): _____

Please complete this section: "I attest (promise) that the information on this form is true and correct to the best of my knowledge. I understand that if I didn't have creditable prescription drug coverage and/or don't give proof of creditable drug coverage if asked, my premium may be higher.

I understand that my signature (or the signature of the person authorized to act on behalf of the individual under the laws of the State where the individual resides) on this document means that I have read and understand the contents of this attestation. If signed by an authorized individual (as described above), this signature certifies that: 1) this person is authorized under State law to complete this enrollment and 2) documentation of this authority is available upon request by <Plan Name> or by Medicare."

Signature:_____ Date: _____ (mm/dd/yy)

If you are the authorized representative, you must provide the following information:

Name:_____

Address:_____ City/State/Zip: _____

Phone Number: (_____) _____- _____

Relationship to Enrollee _____

If you have questions about the information in this form, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Exhibit 2: Model Notice for Creditable Coverage Information Received after Deadline Date

<Date>

Dear <Name of Beneficiary>:

We sent you a form on <date on form> asking you to tell us if you had creditable prescription drug coverage (as good as Medicare's). If you did not receive that form, please call us at <toll-free number>. We asked you to return our form by <deadline date on form>. Because we received your information after that date, we did not consider it when we reported to Medicare whether you had creditable prescription drug coverage.

You may soon receive a letter from us telling you that your premium is higher because you did not have creditable prescription drug coverage. If you get that letter, but think that you should not be charged the late enrollment penalty, you can ask Medicare to review its decision. Please follow the instructions sent with the letter.

If you ask Medicare to review its decision, we will send Medicare the information you have sent to us.

If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.

Exhibit 3: Model Notice Informing Beneficiary of LEP

<Date>

Dear <Name of Member>:

We are writing to tell you that that **starting <effective date>, your new premium will be <new premium> per month.**

[Insert the following to inform the beneficiary that his/her premium includes an LEP:]
You are being charged an additional <LEP amount> each month because our records show that you didn't have creditable prescription drug coverage (as good as Medicare's) for <# of uncovered months> months after you were first eligible to sign up for Medicare prescription drug coverage.

[OR insert the following to inform the beneficiary that his/her premium does not include an LEP:]
You are no longer being charged a late enrollment penalty each month because the late enrollment penalty is not charged during an Initial Enrollment Period for Part D (Part D IEP), and our records show that you <have>/<had> another Part D IEP based on your turning 65. As long as you have Medicare prescription drug coverage or other creditable prescription drug coverage (as good as Medicare's) after the end of this Part D IEP, you will not be charged a late enrollment penalty.

[Insert the following if employer or union is paying the LEP amount on behalf of beneficiary:]
<Name of employer or union sponsoring the Plan> has agreed to pay <LEP amount>, the amount of your late enrollment penalty, on your behalf. If your coverage is terminated by you or <name of employer or union sponsoring the Plan>, or if <name of employer or union sponsoring the Plan> stops paying your late enrollment penalty, you will be responsible for paying that amount.

[Insert the following if the letter is informing the beneficiary that his/her premium includes an LEP:]
If you disagree with your late enrollment penalty, you can ask Medicare to reconsider (review) its decision. (For example, you might disagree with the penalty if you were affected by Hurricane Katrina or if you got/get extra help from Medicare to pay for your prescription drug coverage in 2006 and/or 2007, or if you were not informed that you did not have creditable prescription drug coverage (as good as Medicare's).) A notice explaining your right to a reconsideration of the late enrollment penalty is included with this letter. **You must submit your reconsideration request within 60 days of the date of this letter, or Medicare may not consider your request.**

If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.

Exhibit 4: Model Notice to Confirm Adjustment of Premium upon Reconsideration of Late Enrollment Penalty

<Date>

Dear <Name of Member>:

We are writing to let you know that your premium amount has been adjusted based on Medicare's decision about your late enrollment penalty.

Starting <effective date>, your new premium amount will be <new premium> per month.

[Insert the following if the premium still includes an LEP:]
This amount includes a late enrollment penalty because Medicare wasn't able to confirm that you had creditable prescription drug coverage (as good as Medicare's) for <# of uncovered months> months.
[OR insert the following if the premium no longer includes an LEP:]
This amount does not include a late enrollment penalty because Medicare decided you had creditable prescription drug coverage (as good as Medicare's) and so you are not required to pay any additional amount. Any late enrollment penalty you have already paid *[Select method of LEP refund:] will be refunded to you as soon as possible OR will be applied to reduce your next bill*.

Medicare's decision about your late enrollment penalty is not subject to further review. If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.

Exhibit 5: Model Notice for Return of Creditable Coverage Information Received without an Accompanying Enrollment Request

<Date>

Dear <Name of Beneficiary>:

We got information from you that showed you had creditable prescription drug coverage (as good as Medicare's), but our records don't show that you have applied to join <Plan Name>. Since we don't have from you an application to join our plan, we are returning your creditable coverage information to you.

If you want to join <Plan Name>, please call us at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. We may need you to send us another application. After we get your application, we will let you know if we need you to send us creditable coverage information.

Remember, if you don't keep Medicare prescription drug coverage or other creditable prescription drug coverage (as good as Medicare's) after you are eligible to join a Medicare drug plan, you may have to pay a late enrollment penalty for each month you were eligible to join but didn't. You will then have to pay the penalty as long as you have Medicare prescription drug coverage.

If you have questions about this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. Or, visit www.medicare.gov on the web or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.