Responses to Public Comments on Draft Reporting Requirements Document

Background:

Draft reporting requirements were posted to the CMS website on March 23, 2005 for public comment. The document that follows reflects a summary of comments and questions received by close of business on April 8, 2005, and our responses to these questions and concerns.

General Questions:

The following responses address global questions and comments regarding the overall Reporting Requirements document:

1. Commenters suggested reporting timeframes be adjusted. The majority of commenters suggested moving 30 day to 60 day timeframes, although CMS did receive a request to extend to 45 day timeframes.
   - Response: For all data elements originally proposed to have reporting deadlines of 30 days, CMS has extended these reporting deadlines. Please refer to each section of the final reporting requirements for the revised deadlines.

2. CMS received requests to clarify if various data requirements are to be reported at the Plan level, Contract level, or Sponsor level.
   - Response: Each section of the final reporting requirements document clearly indicates the level of data requested. Within particular sections, CMS has added an explanation if the Sponsor is to determine the level of reporting, e.g. Section VIII: Call center measures.

3. CMS was asked which of these reporting requirements are applicable to MA-PD organizations providing Part D coverage.
   - Response: Part D data is needed separately from Part B and Part C data in order to perform accurate oversight and evaluation of the Part D benefit. All MA-PD organizations must comply with these reporting requirements, except for those within the Licensure and Solvency, Business Transactions and Financial Requirements section (required only for PDP organizations).

4. CMS was asked which of these reporting requirements are applicable to PACE organizations providing Part D coverage.
   - Response: The following reporting requirements are applicable to PACE organizations offering Part D coverage: Section I. Enrollment/Disenrollment, Section IV. Generic Dispensing Rate, Section IX. Overpayment, and Section X. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions. PACE Organizations utilizing formularies will also need to comply with reporting requirements listed in Section VI. Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions.

5. Commenters stated if significant changes were made to the final reporting requirements, compliance by Part D Sponsors may be diminished as a result of the relatively short timeframe to incorporate these changes.
   - Response: CMS believes the changes made to the final reporting requirements should not impose large administrative or other types of burdens on Part D Sponsors. CMS will continue to consider time and resources needed for Part D Sponsors to comply with these reporting requirements.

6. Questions were received about the layout of reporting requirements and the mechanisms of data reporting into HPMS.

- Response: While CMS acknowledges the suggestions received, which include providing examples of data fields, layouts for each report/file, default values, expected output, and/or calculations, the final document lists sufficient descriptions. Additional technical instructions for either manual entering or uploading of data will be available in the future. Regarding the mechanisms for data reporting, each section of the final document also states how data will be sent to CMS. The Appendix Table is another reference that may be utilized to determine which data elements are uploaded or manually entered into the HPMS.

7. CMS was asked if compounded prescriptions should be included or excluded from all reporting requirements.
   - Response: Compounded prescriptions should be included for all reporting requirements.

8. CMS was asked when specific reporting requirements for the following areas will be released: Formulary, TrOOP, COB, Payment and 1/3 Audit, Employer Subsidy, Low Income Subsidy, and Fallback, and if all reporting requirements may be combined to one general document.
   - Response: Guidance and reporting requirements have already been released for some areas, including Formulary. The remaining areas are expected to have similar guidance and reporting requirements issued in the future. CMS encourages all interested parties to utilize the CMS website, http://www.cms.hhs.gov/pdps/ as it provides the most timely and accurate summary of available draft and final guidance documents released by CMS.

9. It was asked that CMS removes the notation that reporting timelines are based on dates of service.
   - Response: This change was made to each section of the final reporting requirements document. Whenever appropriate, additional details were provided about reporting periods.

Section Specific Questions:

The following sub-sections provide responses to specific questions and comments raised regarding the respective section of the Reporting Requirements Document:

Section I. Enrollment/Disenrollment

1. CMS was asked if Plans will be able to change previously submitted enrollment data.
- Response: HPMS will allow Plans to directly submit corrected data and explanation for previous reporting periods.

2. CMS was asked why various enrollment data, including disenrollment due to death, would be collected in addition to that which is already collected via current reporting systems.
- Response: CMS acknowledges similar data is reported via current reporting systems; however this information is needed on a timely basis for oversight purposes, and to ensure accurate payments are being made. Also, other current reporting systems do not allow Plans to indicate other reasons for disenrollment.

3. Clarification was requested around disenrollment due to a beneficiary moving to a different service area.
- Response: Clarification was added to the final reporting requirements document.

4. Clarification was requested if dates of service indicate the effective dates of services or dates of processing.
- Response: The final reporting requirements states that reporting periods are based on effective enrollment dates. Effective enrollment date is defined as the start date of a beneficiary's Part D coverage.

5. CMS was asked if MA-PDs need to report MA disenrollment and Part D disenrollment.
- Response: For this reporting requirement, MA-PDs must only report beneficiary disenrollment from Part D coverage.

6. CMS was asked to verify if enrollment data are to be reported at the Plan or Sponsor level.
- Response: CMS requests enrollment data at the Plan level.

7. CMS was asked to verify if enrollment data are to be reported as of the end date of the reporting period.
- Response: CMS requests enrollment data as of the end date of the reporting period.

8. A commenter asked if there would be separate mechanisms to report enrollment data for beneficiaries who are auto-enrolled.
- Response: Beneficiaries who are auto-enrolled should be included in these data, and will not be reported separately.

Section II. Reversals

1. CMS received comments that final disposition should be based on out-of-cycle reversal, and not in-cycle reversals because of the potential volume and resources needed to track in-cycle reversals.
- Response: In order to reduce reporting burden, CMS will change its requirement to obtain out-of-cycle reversal and final disposition, rather than in-cycle reversals.

2. Some commenters recommended that this section be eliminated due to the administrative burden associated with capturing and storing reversal transactions, and be replaced with other methods for data capture in order to satisfy CMS' intended outcome.
- Response: These data are necessary as CMS will be comparing reversal rates across Plans to ensure that reversals are being performed appropriately. For example, CMS needs to ensure that prescriptions not picked up by beneficiaries are reversed out of the system rather than being restocked and resold to another patient.

3. CMS was asked if reversal records were requested, which specific data elements would be required, and in what format, or would the entire claim be required.
- Response: In the event CMS would require reversal records, Sponsors may be asked at a minimum for the number of elements equivalent to those of the prescription drug event record.

4. A suggestion was made to clarify that these data elements are for pharmacy transactions which were adjudicated during the reporting periods.
- Response: CMS agrees to use adjudicated date for reversed claims, and has added this detail to the section.

5. Questions were asked about how to accurately capture adjustments, which may be submitted as partial reversals.
- Response: Any prescriptions with reversal as the final disposition should be included. If a prescription's final disposition was a partial reversal, it should be included in these data.

6. CMS was asked to clarify if "pharmacy transactions reversal as final disposition" means that the last transaction that comes for that particular claim should be a reversal. For example:
    a. Case 1: claim is billed and then reversed
    b. Case 2: claim is billed, then reversed and again billed
    c. Case 3: claim is billed, and then partially reversed
    d. Case 4: claim is billed, then reversed and billed partially
- Response: Cases 1 and 3 would be considered reversals and should be captured in these data.

Section III. Medication Therapy Management Programs

1. CMS received questions regarding how to define patients who are eligible for a MTMP, who are actively enrolled in a MTMP, who have declined to participate in a MTMP, and who have disenrolled from a MTMP. Other questions received were how to accurately count beneficiaries enrolling or disenrolling during the reporting period, and if CMS will request supporting documentation of beneficiaries declining to participate in a MTMP.
- Response: Plans will define criteria for eligibility into a MTMP. Once a beneficiary is targeted as eligible for a MTMP, the Plan may have different methods for enrollment; these could be enrollment by opt-in or opt-out. A Plan's disenrollment would then reflect the Plan's enrollment design. Any enrollees meeting the Plan's definitions for enrolling, disenrolling, or declining to participate in a MTMP at any point during the reporting time period should be counted. CMS will not request supporting documentation of those enrollees who declined to participate in a MTMP, however Plans must maintain this documentation if it is needed during CMS audit.

2. In regards to reporting the prescription cost for all MTMP beneficiaries per MTMP beneficiary per month, CMS was asked to clarify how to calculate this cost, if it should exclude TROOP, and if it should only include costs of prescriptions targeted by the MTMP.
- Response: Additional clarification was added around calculating prescription cost for all MTMP participating beneficiaries on a per MTMP beneficiary per month basis. This data element should include costs of all prescription drugs for beneficiaries enrolled in MTMP.

3. A suggestion was made to have these data submitted annually instead of semi-annually.
- Response: CMS will need to have this data reported semi-annually and annually. Reporting deadlines for these data were not changed.

4. CMS was asked if reporting period 2 was incorrectly listed as dates of service from January 1 through December 31.
- Response: Reporting period 2 is listed correctly as a 12 month period in order to capture all beneficiaries identified, targeted, and/or participating in a MTMP during 2006.

5. In general, commenters asked CMS the intended use for these data. Some stated concerns that the proposed data requirements would be inconsistent with the Plan's currently offered disease management (DM) programs.
- Response: These data will be considered preliminary for Contract Year 2006, and will not be used to evaluate the effectiveness of MTMPs at this time. CMS intends to bring Plans together to discuss MTMP, including additional methods for evaluation.

Section IV. Generic Dispensing Rate

1. CMS received requests to clarify the definition of generic drugs, and whether utilization of Plan-defined generics (e.g. multi-source brand drugs) should be included in this data element.
- Response: While CMS recognizes that some Part D Sponsors are able to increase generic utilization through the use of multi-source brands in the generic tier, generic dispensing data for this regular reporting requirement will be limited to prescriptions classified by First DataBank or Medispan as generic equivalents of brand medications.

2. CMS was asked to clarify if these data should include only prescriptions that have been approved and paid, or also include claims that were later reversed.
- Response: These data should include only prescriptions that have been approved and paid. CMS has added this clarification to the final reporting requirements.

3. CMS received questions about how to accurately report late claims or late reversals, after a reporting period had been completed.
- Response: Part D Sponsors will have the opportunity to correct previously submitted data to HPMS, and should take all actions necessary to submit the most accurate data possible. There, however, may still be instances beyond a Sponsor's control in which some claims are not included.

4. A suggestion was made to evaluate generic dispensing rate for drugs for which a generic equivalent is available.
- Response: This type of analysis will be performed as part of CMS' independent analysis of prescription drug event (PDE) data.

5. A question was asked regarding how partial fills and /or partial adjustment prescriptions should be incorporated to these data elements.
- Response: These types of prescriptions will already be included in these data elements, as these data include all paid claims.

Section V. Grievances

1. CMS received requests to provide definitions for various terms, specifically complaint and grievance.

- Response: CMS added definitions for pertinent terms to the final reporting requirements document. CMS removed the term complaint, and instead used the term grievance consistently through this section.

2. Commenters recommended these data requirements be incorporated into the Appeals section.

- Response: CMS, and its designated contractors, will be responsible for working fraud and abuse complaints. It is vital to have statistics on the number of fraud and abuse complaints so that CMS can allocate resources accordingly. In addition, this is a new program, and it is important for CMS to have an idea, as early as possible, of any perceived fraud and abuse indicators. Therefore, the requirement for fraud and abuse complaint reporting cannot be eliminated.

3. Commenters recommended these data requirements are removed, due to potential inconsistency in Part D Sponsor tracking, and possible duplication to the Appeals section.

- Response: For purposes of CMS reporting, the Plans shall use the definition listed in the reporting requirements document for the definition of a fraud and abuse complaint. The definition of a fraud and abuse complaint is very specific. Therefore, inconsistency should be less of a concern for this reporting element. Tracking of appeals is not sufficient, because as mentioned above, CMS, and its designated contractors, will be responsible for working fraud and abuse complaints. Therefore it is necessary to have a tracking of the number of such complaints.

4. CMS was asked to clarify that all complaints may be oral or written, and if complaints may be both a grievance and an appeal/exception.

- Response: CMS added a statement at any grievance or complaint may be oral or written. Per Final Rule, a grievance is not an appeal, and therefore must be reported as a separate data element. CMS added this clarification to the final reporting requirements document.

5. Commenters stated there are potential variations in the level of tracking by Part D Sponsors of grievances received. Other commenters asked if CMS will request turnaround times or outcomes of the grievance process.

- Response: Final Rule stated that all Part D Sponsors track and maintain records of all grievances received orally or in writing. CMS added this clarification to the final reporting requirements. CMS may request additional information if necessary.

6. CMS received comments regarding the number of grievance categories increasing the potential for inaccurate reporting. One commenter asked how to accurately report grievances for combined Part D and non-Part D issues. Another commenter asked how to accurately report grievances for combined grievance categories.

- Response: CMS has reduced the number of grievance categories to be reported, as well as further defined example grievances within each category. The following categories have been incorporated into other categories – formulary (into benefit package), quality (into other), appeal (into other) grievances. The category of pricing grievances was eliminated. A grievance which is related to both Part D and non-Part D issues should be included in a Part D Sponsor's report, and categorized by the Part D issue. Multiple grievances by a single complainant should be tracked and followed as separate grievances.

7. CMS was asked to define an abuse complaint or abuse grievance. CMS was also asked to consider eliminating this data element.

- Response: CMS would define an abuse complaint to be one in which a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Part D Plan, or beneficiary

engaged in behavior that the individual should have known to be false, and the individual should have known that the deception could result in some unauthorized benefit to himself/herself or some other person. As described above, CMS cannot eliminate this data element.

8. CMS received suggestions to capture data based upon the date grievances were received, as opposed to date of service.
- Response: CMS changed this section to state grievance data should be reported based on the date the grievance was received by the Part D Plan, not the date of the event or incident that precipitated the occurred grievance.

Section VI. Prior Authorization, Step Edits, and Non-Formulary Exceptions

1. It was asked that the term "denied" is substituted with "rejected" to more accurately reflect pharmacy transactions that do not constitute coverage determinations.
- Response: CMS agrees, and has substituted the term rejected in the final reporting requirements.

2. Commenters requested that data for Formulary prior authorizations and Non-formulary prior authorizations are reported as one combined data element.
- Response: CMS will need these data separately in order to accurately evaluate prior authorization programs.

3. Commenters asked to clarify the statements, "not including first pass step edits and/or early refills"
- Response: CMS does not want these data elements to include prescriptions initially rejected because either a 1st line step therapy edit was not documented as being fulfilled, or because the beneficiary has requested an early refill due to vacation or a lost prescription. This notation was therefore inserted.

4. CMS was asked to verify that these data elements refer to claim submissions that are rejected upon adjudication.
- Response: CMS verifies these data elements refer to claim submissions that are rejected upon adjudication.

5. It was asked why data regarding the use of other utilization management tools were not requested.
- Response: CMS acknowledges that Part D Sponsors may be utilizing other UM tools. Final rule, however, does not require the use of Part D tools such as prior authorization or step therapy. Part D Sponsors may have the opportunity to submit additional data to CMS in the future.

6. One commenter requested clarification in prior authorizations and non-formulary exception processes.-
- Response: Under the broad definition of exception processes, Part D Sponsors will make coverage determinations for non-formulary products. It is expected that for those non-formulary products to be approved for formulary payment (via Part D), a Part D Sponsor has to process and grant prior authorization. Prior authorizations are not limited to formulary drugs.

7. CMS received a suggestion to have the title of this section reflect Non-formulary and Tier Exceptions
- Response: This change has been made in the final reporting requirements document.

8. CMS received comments around potential causes for inaccurate data collection in this section, including claims being resubmitted multiple times after an initial rejection in an effort

to obtain approval, a step therapy edit requiring prior authorization, and prior authorization requests that are solely submitted for the purpose of determining whether a drug is covered under Part D.

- Response: CMS recognizes these potential causes for inaccurate data collection, and the potential difficulty in resolving these issues efficiently. CMS will use these data elements to measure trends in PA and Step therapy utilization, and acknowledges adjustments may be necessary.

9. CMS was asked to confirm that organizations not using prior authorization or step therapy will be able to document as such in HPMS.
- Response: CMS will structure the HPMS to allow documentation of this.

Section VII. Appeals

1. CMS was asked to change reporting of appeals data to semi-annually.
- Response: Quarterly reporting is necessary so that early detection and resolution can occur if a particular Plan has an excessive number of appeals.

2. CMS was asked if the IREs will be defined by CMS.
- Response: CMS will be releasing additional information regarding IREs in the near future.

3. CMS received suggestions to capture data based upon the date appeals were received, as opposed to date of service.
- Response: CMS changed this section to state appeal data should be reported based on the date the appeal was received by the Part D Plan, not the date of the event or incident that precipitated the occurred appeal.

Section VIII. Call Center Measures

1. CMS received questions of the level to report this data – Plan, Contract, or Sponsor level.
- Response: These reporting requirements were designed to provide flexibility around each Part D Sponsor's call center structure. CMS requests data is submitted at the most detailed level available, e.g. Plan level would be the most detailed, and preferred whenever available. Part D Sponsors must note in HPMS the level of reporting provided. Sponsors which have more than 1 call center that potentially receives these calls should make every effort to track and combine any Part D related calls for reporting.

2. CMS was asked to clarify if these data elements are for claims processing calls only or any call received from a beneficiary. CMS was also asked to verify that CMS is anticipating a requirement to separate call statistics for non-Part D related calls from Part D calls.
- Response: These data elements are for any calls received which are related to Part D. Call centers may track other metrics, such as calls related to medical care, however whenever a call is related in any way to Part D, it should be tracked separately for inclusion in this reporting requirement.

3. CMS was asked to verify that these call center measures are for the health plan customer service call center and not the PBM provider call center.
- Response: CMS' priority is to ensure the data reported are for Part D related calls. If data are available from the PBM provider call center, this would be preferred, however health plan customer service call center data are acceptable as long as these data are separately tracked as Part D related calls.

4. Suggestions were given to retitle this section to reflect a few industry call centers.
- Response: This section's title sufficiently describes the type of data to be reported.

5. It was noted that call abandonment cannot be separately reported for Part D related calls versus overall calls abandoned.
- Response: CMS agrees that Part D Sponsors which do not utilize a separate phone line for Part D will not be able to identify Part D calls for the reporting of call abandonment. The final reporting requirements document has been updated to reflect Part D Sponsors will indicate if a separate phone line is available, if so what is the Part D call abandonment, and if not, what is the overall call abandonment, and additionally, what is the overall total number of inbound calls.

6. CMS was asked to clarify two data elements – hold time versus speed of answer for calls.
- Response: Definitions for these terms have been added to the final reporting requirements.

Section IX. Overpayment

1. CMS was asked to provide a definition of overpayment.
- Response: An overpayment occurs anytime Medicare directly, or through one of its contractors, erroneously makes a payment. The actual overpayment amount is the amount of money received in excess of the amount due and payable under the Part D drug benefit. Examples would include overpayments made to pharmacies, overpayments a Plan makes to a PBM for claims payment, and findings from pharmacy audits. This information is necessary to ensure that overpayments are being identified and recouped appropriately. This means any funds the plan recovers from any entity it has overpaid. This would include, pharmacies, providers, Pharmaceutical Benefit Managers, etc. The term overpayment does not include premium overpayments.

2. Commenters stated reporting of these data quarterly would be inappropriate for accurate reflection of recoupment of overpayments
- Response: In order to alleviate reporting burden, this reporting requirement has been changed to a semi-annual frequency.

Section X. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions (Formerly "Rebates")

1. CMS was asked to change the reporting timeline from quarterly to semi-annually.

- Response: CMS will need to have this information available quarterly. CMS is concerned about the timeliness of data. By receiving the data more timely at CMS, this will prevent CMS from having to make ad hoc requests for data if and when it is needed more frequently.

2. Commenters requested the data field of 'Rebate requested' changed, and that rebates not yet received, and received for previous quarters also be captured.

- Response: CMS will request the following data to be submitted: Rebate received, pending rebates, and prior rebates. Worksheet 2 was removed. Please refer to the Rebates section of the final reporting requirements for additional information.

3. Will CMS have a specific naming convention of these reports?

- Response: Instructions for creating, naming, and submitting these files are included in the final reporting requirements document.

4. CMS was asked to assure the information contained in these reports will be kept confidential and not readily available within CMS except to designated staff who have agreed to maintain confidentiality as to these data elements.
- Response: CMS recognizes the importance of maintaining confidentiality of these records. CMS will do everything within its authority to limit access to those who have appropriate use or oversight role. Additionally, CMS will track those who have accessed these records.

5. CMS was asked what types of items should be considered as non-rebate discounts, price concessions, or other value adds such as gift-in-kind or other programs.
- Response: Examples of these items include, but are not limited to, coupons or disease management programs specific to a Part D Sponsor.

6. CMS received comments questioning the authority of CMS to request this information.
- Response: 42CFR §423.322(a) states "Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law." 42 CFR §423.322(b) further states that the information disclosed can be used for payment, oversight and program integrity. CMS views this information necessary for program integrity activities and therefore is required to be reported.

7. CMS was asked if a Microsoft Excel file would be adequate to accommodate the volumes of rebate data.
- Response: CMS would like to reiterate that each Plan should submit one Excel file of rebate information listed by drug. An Excel file will be able to accommodate these data. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations.

8. CMS was asked to verify rebate information should be submitted at the Contract level.
- Response: CMS has revised it's requirements to require rebate reporting at the applicable level as shown by the following examples: (1) national Part D sponsors with multiple regional plans contracting independently or through a PBM will report rebates from the level of the national Part D sponsor; (2) regional or local Part D sponsor whether utilizing subcontractor PBM or not report at the Part D sponsor specific level; (3) PBM providing Part D coverage outside of a subcontractor role will report rebates at the PBM level.

Section XI. Licensure and Solvency, Business Transactions and Financial Requirements

1. Commenters asked if the entire Health Blank form needs to be submitted.
- Response: The final reporting requirements document has been revised to list the specific sections of the Health Blank Form which need to be submitted.

2. One commenter requested clarification if these requirements applied to both MA-PD and Part D stand-alone plans.
- Response: These requirements are specific to the Part D PDP sponsor level.

3. Several commenters suggested that the HPMS reporting requirements should be removed for licensed Plans which are monitored by State regulators.
- Response: If a PDP is state licensed, it must already be completing an entire Health Blank Form and submitting it to the state quarterly. The data elements to be entered into HPMS are minimal and can be taken directly from the Health Blank form. The data being collected will be utilized to compile a database enabling CMS to learn more about this new type of organization.

4. It was requested that these data elements be reported annually rather than quarterly. One commenter suggested that requiring submission of the audited financial statements within 120 days of the fiscal year end was aggressive and that a period of 150 was more reasonable.
- Response: CMS believes that the 90 day after the end of a quarter and 120 day after the end of the fiscal year reporting timeframes are appropriate. Those timeframes are consistent with those set by the NAIC.

5. A suggestion was made to revise the instructions data elements to specify that reporting should be "as of the end of the reporting period," instead of, "for the reporting period".
- Response: This change was made.

6. One commenter asked to clarify if item H should include total medical expenses or total expenses.
- Response: Item H is correctly identified as total expenses.

7. One commenter asked for clarification to item L.
- Response: Additional clarification has been added to specify that item L does not include administrative expenses.

8. For item M, it was asked which portion of the revenue/capitation information would need to be provided.
- Response: For item M, sponsors should report premiums, subsidies from CMS, rebates and other reinsurance comprising this amount.

9. One commenter asked if administrative expenses in K, L and M would apply to a PBM.
- Response: Administrative expenses would be overhead expenses and would include but not be limited to things like salaries and wages, marketing, advertising, rent, postage, printing and traveling expenses.

10. Several comments were received regarding whether GAAP or SAP should be utilized for reporting purposes.
- Response: Financial reporting may be under GAAP or SAP applicable to similar organizations of similar type within the state where the organization is based. However, if an organization chooses to report under GAAP it may not report under GAAP for a period longer than 36 months unless a state has chosen not to license such organizations.

11. CMS was asked to provide definitions of the terms drug benefit expenses and drug benefit revenues.
- Response: These definitions were added to the final reporting requirements document. Drug benefit expenses are paid claims costs which would be comprised of negotiated costs and dispensing fees less member share. Drug benefit revenues would include premiums, CMS subsidies, rebates and other reinsurance.

12. One commenter asked if CMS would provide a standard projected losses worksheet
- Response: PDP sponsors should develop their own worksheet.

13. A commenter asked if there is a specific methodology to be followed for the projected losses worksheet.
- Response: PDP plan sponsors should follow the instructions for calculating projected losses in Appendix X, B.2.(b) Calculation of projected losses.

14. One commenter asked if any supporting documentation is required when a sponsor indicates that they have the appropriate sources of funding to cover projected losses.

- Response: In Appendix X, allowable sources of funding and requirements for their use are identified in the Funding for Projected Losses section. A sponsor should indicate the amount, the allowable source of funding being utilized and then submit supporting documentation verifying that requirements have been met relative to the allowable source of funding.