CY2007 PART D REPORTING REQUIREMENTS:
TECHNICAL SPECIFICATIONS

Revised: 12/31/2007

Table of Contents

Introduction

This information pertains to CY2007 Reporting Requirements; however, responses from previously released CY2006 FAQs that remain relevant are included in this document.

Updates made to this document since the third release in October 2007 are highlighted.

General Questions

1) Where is the reporting requirements document posted?
   A: CY2007 Part D Plan Reporting Requirements are posted at http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage.

2) How are data for CY2007 Reporting Requirements submitted to CMS?
   A: For the majority of the reporting requirements sections, Part D Sponsors will enter data directly into the Health Plan Management System (HPMS). Data will be uploaded in the Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions, and Long-term Care Rebates sections. For the Licensure and Solvency section, Part D Sponsors will mail hard-copies of various documents for subsections 1 and 2, and enter data into HPMS for subsections 3 and 4; please refer to the Licensure and Solvency section for specific limitations of organization types required to comply to each subsection.

3) At which level are these data reported?
   A: The level of reporting for each section is specified in the reporting requirements document and within each section in HPMS. Sponsor - level reporting indicates data may be submitted from an organization that is associated with more than one Part D Sponsor. Contract - level reporting indicates data should be entered at the H#, S#, R#, or E#. Plan - level reporting indicates data should be entered at the PBP - level, (e.g. Plan 001 for contract H#, R#, S#, or E#). CMS has determined that Plan - level reporting of some areas is necessary to conduct appropriate oversight and monitoring. Below is a summary of the reporting level required for each section:

REPORTING REQUIREMENT SECTION	LEVEL OF REPORTING
Reversals	Contract
Medication Therapy Management Programs (MTMP)	Contract
Generic Dispensing Rate	Plan
Grievances	Plan
Pharmacy & Therapeutics (P&T) Committees	Contract
Transition	Plan
Exceptions	Plan
Appeals	Plan
Call center measures: Beneficiary Service line and Pharmacy Support line	This reporting section is suspended.
Overpayment	Contract
Pharmaceutical Manufacturer Rebates, Discounts, and Other price concessions	Sponsor or Contract
Long-term Care (LTC) Rebates	Sponsor or Contract
Licensure and Solvency, Business Transactions, and Financial requirements	Contract
Drug Benefit Analyses	Plan

4) Does CMS expect Part D Sponsors to update previously submitted data?
   A: If previously submitted data are incorrect, Part D Sponsors should request the opportunity to correct and resubmit data as described above. Part D Sponsors are not responsible for updating previously submitted sections such as pharmaceutical manufacturer rebates or LTC rebates in which CMS expects Part D Sponsors to receive reconciled data. Part D Sponsors are, however, responsible for correcting previously submitted data if it is determined the data were erroneous.

5) If it is discovered that data already submitted are erroneous, can Part D Sponsors resubmit corrected data after the reporting deadline?
   A: Once a reporting deadline has passed, CMS requires the Part D Sponsor to submit a formal request to resubmit data. HPMS designates this request as a due date extension. Due date extension requests will only be approved for 7 days from the date the request is reviewed by CMS. Sponsors should not submit due date extension requests until they have data available to submit. Data submitted after the given reporting period deadline shall be considered late, and may not be incorporated within CMS data analyses and reporting.
   For CY2007, the following steps must be followed by a Part D Sponsor:
   a) At the Part D Plan Reporting Start Page, click the Due Date Extension link.
   b) Select/complete the following:
      - Reporting section (e.g. Appeals)
      - Time period (e.g., 1st quarter 2007)
      - Parent organization/contracts
      - The date of this request
      - The reason for the due date extension
   c) CMS will review the information provided and either accept or reject the request for resubmission.

6) Must these data be submitted by Part D Sponsors themselves, or can data submissions be delegated to a PBM or other third-party entity?
   A: Submission of reporting requirements is up to the discretion of the contracted Part D Sponsor, and is limited to entities with HPMS access. CMS contracts with the Part D Sponsor, as such CMS, will hold the Part D Sponsor responsible for timely and accurate submission of reporting requirements data.

7) For CY2007, where is the Enrollment/ Disenrollment reporting section?
   A: CMS suspended enrollment/disenrollment reporting in November 2006 for the remainder of CY2006. This section was also removed from the CY2007 reporting requirements.

8) Are MA-PD organizations required to comply with all reporting requirements?
   A: All reporting requirements apply to MA-PD organizations with the exception of subsections 1, 2 and 3 of Section XIII. Licensure and Solvency, Business Transactions and Financial Requirements.

9) Are these reporting requirements applicable to MA - only Plans?
A: The Part D reporting requirements apply to Part D Sponsors offering the Part D benefit, including PDPs and MA-PDs. They do not apply to MA only plans.

10) Which reporting sections apply to Program for All Inclusive Care for the Elderly (PACE) organizations? How should these organizations document when a specific section is not applicable to them?
A: For CY2007, PACE Organizations offering Part D coverage, reporting requirements will be limited to:

- Section III. Generic Dispensing Rate;
- Section V. Pharmacy & Therapeutics (P&T) Committees (for PACE Organizations utilizing formularies);
- Section VI. Transition (for PACE Organizations utilizing formularies);
- Section VII. Exceptions (for PACE Organizations utilizing formularies);
- Section X. Overpayment;
- Section XI. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions; and
- Section XII. Long-term Care (LTC) Rebates. HPMS will only display the relevant reporting sections for these organizations.

11) Should Part B drug claims always be excluded from these reports?
A: Yes, data relating to Part B claims should be excluded from these Part D reports.

12) Should enhanced alternative and OTC drug claims be included?
A: No, these claims are not paid as Part D claims, and should not be included in these data.

13) What are the implications for Part D Sponsors who are non-compliant with the reporting requirements?
A**:** Compliance with these reporting requirements is a contractual obligation of all Part D Sponsors. Late or inaccurate submission of data, as well as submitting data at incorrect reporting levels, may be considered non-compliant. According to Subpart O, sanctions may be imposed on Part D Sponsors that fail to comply with these reporting requirements. Part D Sponsors who fail to submit data may also face corrective action plans. Under no circumstances are Part D Sponsors relieved of these obligations if data are supplied or collected by subcontractors or third-party entities.

14) Where can Sponsors send questions about Part D reporting requirements?
A: Questions may be sent via email to partd-planreporting@cms.hhs.gov.

Section I. Reversals

1) How does CMS define “out - of - cycle” pharmacy transactions?
A: The term "out-of-cycle" refers to the individual billing/processing cycle of each organization. Each organization determines its own payment cycle. An out-of-cycle reversal occurs if a prescription is filled and adjudicated, and then, outside the Part D Sponsor’s billing cycle, the pharmacy reverses the claim. Part D Sponsors must also report those claims with a partial reversal as the final disposition to CMS the total number of (electronic, paper and manual) pharmacy claims ending with a reversed status.

Out – of - cycle does not refer to the CMS quarterly reporting periods. The intent of this reporting section is to gain a cursory view of pharmacy's claim adjudication and to obtain baseline reversal patterns to protect against fraudulent cash flow activities. At the same time, CMS is accommodating for the various billing cycles utilized by Part D Sponsors at the contract level.

Example: A Sponsor’s billing cycles are the 1st – 15th of the month and the 16th-end of month. The following transactions are examples when reporting out-of-cycle reversals:

Claim transaction	Out-of-cycle reversal or not?
1) Original claim processed on the 2nd, reversed on the 5th.	**Not a reversal**
2) Original claim processed on the 2nd, reversed on the 17th. No other transaction received before the end of the reporting quarter.	**Reversal**
3) Original claim processed on the 14th, reversed on the 16th. No other transaction received before the end of the reporting quarter.	**Reversal**
4) Original claim processed on the 2nd, reversed on the 17th. Resubmitted on 18th.	**Not a reversal**

2) The reporting requirements document states the reversal records must be maintained and must contain elements equivalent to the PDE record. Is there a specific field in mind for record keeping or nomenclature that is preferred?
A: At a minimum, the data elements required for the PDE should be kept for all reversed claims.

Section II. Medication Therapy Management Programs (MTMP)

1) For data element C, please clarify what is meant by "longitudinally cumulative total"?
   A: Data element C is the number of beneficiaries who participated in the MTMP at any point during the time period, and should be a longitudinally cumulative total. This means that a Part D Sponsor should report at the contract level the number of beneficiaries who participated at any time over the specific reporting period. If a beneficiary began to participate in MTMP, discontinued their MTMP participation, and then participated again during a reporting period, the Part D Sponsor should count this beneficiary only once.

2) Is it CMS' intention that the sum of data element C (the total number of beneficiaries who participated in the MTMP) and data element H (the number of beneficiaries who declined to participate in the MTMP) be equal to data element B (the number of beneficiaries who met the eligibility criteria for the MTMP)?
   A: Yes, for data reported for the 2nd reporting period of the full 12 month contract year, CMS would expect that the sum of these two data elements would be approximately equal to the number of beneficiaries eligible for MTM.

3) How is discontinued participation in MTM reported to CMS?
   A: There are four data elements related to beneficiaries who discontinued participation in MTM.
   - Data element D is the total number of beneficiaries who discontinued participation from the MTMP at any time during the specified time period above.
   - Data elements E, F and G represent subsets of data element D. Specifically, data element E is the number of beneficiaries who discontinued participation from the MTMP due to death; data element F is the number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Part D Sponsor; and data element G is the number of beneficiaries who discontinued participation from the MTMP at their request.

4) Please clarify how Part D Sponsors should calculate the value for data element I at the contract level, the prescription cost of all covered Part D medications on a per MTMP beneficiary per month basis.
   A: The prescription cost of all covered Part D medications per MTMP beneficiary per month basis should be calculated in the following manner:
   - For the numerator, calculate total prescription drug costs using gross drug cost as follows: (Ingredient Cost Paid + Dispensing Fee + Sales Tax). This is based on the sum of the gross drug cost of all Part D covered prescriptions that were dispensed within the reporting period specified for each beneficiary participating in the MTMP as of the last day of the reporting period. This includes both MTMP beneficiary cost sharing and Part D costs paid.
   - For the denominator, calculate the total number of member months for MTMP participating beneficiaries. These member months should include all months

in which the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

5) For data element I, should Part D Sponsors report total drug costs per MTMP beneficiary per month or only Part D covered drug costs?
   A: Part D Sponsors should include only Part D covered drugs in this calculation.

6) Data element I requests the prescription cost of all covered Part D medications on a per MTMP beneficiary per month basis. Should this currency amount be rounded to the nearest dollar?
   A: Dollar figures should be rounded to the nearest whole dollar. HPMS will not accept the entry of decimals in this data field.

7) Please clarify how Part D Sponsors should calculate the value for data element J, the number of covered Part D 30-day equivalent prescriptions per MTMP beneficiary per month basis.
   A: The number of covered Part D 30-day equivalent prescriptions per MTMP beneficiary per month basis should be calculated in the following manner:
   - For the numerator; first, sum days supply of all covered Part D prescriptions dispensed for beneficiaries participating in MTMP as of the last day of the reporting period. Divide this sum by 30 to determine the number of 30 - day equivalent prescriptions dispensed.
   - For the denominator, calculate the total number of member months for the MTMP participating beneficiaries. These member months should include all months in which the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

8) Please clarify the appropriate method to report beneficiaries that began participation in MTM during CY2006, and remain eligible for participation in CY2007.
   A: The period of MTMP eligibility and enrollment is for a contract year. At the start of each contract year, beneficiaries who continue to meet the eligibility criteria should be invited to participate (per each Part D Sponsor's MTM program's enrollment method) and may re-enroll into the MTMP. In this case, enrollment into the MTMP may begin on the first of the new contract year to avoid gaps in MTMP services. Beneficiaries who no longer meet the eligibility criteria at the start of the new MTM program year would not be asked to participate. Eligibility, participation, etc. should be counted distinctly for each program year.

9) Should Part D Sponsors choosing to provide MTMP services to members outside of the CMS approved MTM criteria exclude those members' data from these reports?
   A: Yes, these members should be excluded from this report, as these services are not considered by CMS as reimbursed MTM services.

Section III. Generic Dispensing Rate (GDR)

1) Regarding the two data elements within this reporting section, please clarify the phrase, “regardless of days supply”.
    - Data element A: Number of paid claims for generic drugs (regardless of days supply) with dates of service during the specified reporting period identified above.
    - Data element B: Total number of paid claims (regardless of days supply) with dates of service during the specified reporting period identified above.

   A: This statement indicates that each prescription fill should be counted as one fill, regardless of the prescription’s days supply. This would mean a 30-day prescription counts as one prescription, as would a 60-day prescription, and a 90-day prescription.

2) Should these data match Part D Sponsor’s PDE data submitted to CMS? If so, should Part D Sponsors delay their reporting until they have received the PDE submission results?
   A: No, Part D Sponsors should report summary pharmacy claims information for this reporting section, e.g. number of generic claims, and total number of claims. This should not be affected by a Part D Sponsor’s submission of PDE data.

3) Should Part D Sponsors report all claims, regardless of reversal status at the PBP-level?
   A: Part D Sponsors should not include any claims with a final disposition of reversal in data elements A (number of paid claims for generic drugs) or B (total number of paid claims), at the PBP-level.

Section IV. Grievances

1) Are Part D Sponsors expected to report grievance data at the PBP - level?
   A: Grievances under the Part D reporting requirements need to be reported at the PBP - level. According to MMA, Sponsors must maintain grievance records containing at the minimum: date of receipt, final disposition of grievance, and date the enrollee was notified of the disposition. Because PBPs must record the date the enrollee was notified and collect identifying information for beneficiaries, they will therefore be able to report grievance data by PBP.

2) Should complaints received by 1-800 Medicare be included in these grievance data? What is the distinction between CTM complaints and grievances?
   A: No. Part D Sponsors should not include 1-800 Medicare complaints or CTM complaints when reporting grievance data. Data for this grievance reporting section should be limited to grievances received directly by the Sponsors from beneficiaries. The difference between grievances and complaints lies in the entity which receives the complaint. Grievances are received by the Sponsor from the beneficiaries. Conversely, CTM complaints are received by CMS (through 1-800-Medicare call centers, phone calls to the CMS regional offices, etc.) and then entered in the CTM for resolution by either the Sponsor or by CMS. CMS does not require Sponsors to report CTM complaints because CMS has direct access to the complaint data.

3) Should Part D Sponsors categorize grievances based on the subject as stated by the beneficiary, or based on the subject determined by the Part D Sponsors during resolution? For example, a beneficiary may file a grievance alleging provider/pharmacy fraud. Upon investigation the Sponsor determines the beneficiary's grievance is related to privacy/confidentiality issues, and is not related to fraud.
   A: Part D Sponsors may report grievances in the categories as determined by the Part D Sponsors after initial investigation. In the example above, the Part D Sponsors should report the grievance as a privacy/confidentiality grievance. Part D Sponsors should not, however, dismiss or exclude any grievances filed by its enrollees from this report.

4) How should a Part D Sponsor handle a grievance that was received during a time period that the Sponsor was not active? One example would be a grievance related to a broker that occurred during the open enrollment period.
   A: In this case since the Sponsor cannot report the grievance in the time period for which it was received, the Sponsor must count this grievance in their first available report to CMS.

5) Should grievances filed by parties other than the beneficiary be included in the Part D reporting?
A: Grievances filed with a Part D Sponsor by enrollees or their appointed representatives should be included in this reporting. Grievances which are filed by other persons/entities should be directed by the Part D Sponsor to 1-800 Medicare or to the respective Regional Office, and are not included in this reporting. For further guidance about the Part D grievance process, please reference Subpart M section 423.564 of the Voluntary Medicare Prescription Drug Benefit.

5) Please clarify if coverage determinations should be included in this reporting.
A: No, as stated in the introduction of this reporting section, coverage determinations should not be included in this reporting. A request by a beneficiary for a prescription should be considered by a Plan as a coverage determination or exception, and processed following the required timeframes for review and decision.

Section V. Pharmacy & Therapeutics (P&T) Committees

1) If a Part D Sponsor has a confidentiality agreement for their P&T Committee with their PBM, how should the member change information be sent to CMS?
   A: CMS understands that some Sponsors may operate under a confidentiality agreement with a third party representative with respect to their P&T Committee. The following steps must be followed when submitting changes to the Pharmaceutical and Therapeutic (P&T) Committees that fall under a confidentiality agreement.

   1. Complete the "Pharmacy and Therapeutics Committee Disclosure Form" and "Certification for P&T" MS Word documents. When completing the Disclosure form, additional rows may be added to Tables B and C; no other format changes may be made to these documents. Both documents must be submitted to CMS for notification of P&T Committee changes.
   2. The completed "Pharmacy and Therapeutics Committee Disclosure Form" should be renamed as, "P&T Committee_(Contract Number) _ (Date)". The date should be in the following format: mo_day_year. An example filename is P&T Committee_H1234_03112007.doc.
   3. The completed "Certification for P&T" document should be renamed as, "P&T Certification_(Contract Number)_(Date)" The date should be in the following format: mo_day_year. An example filename is P&T Certification_H1234_03_11_2007.doc.
   4. Submit both documents via email to partd-planreporting@cms.hhs.gov. The subject line must read "P&T Committee Changes – Confidential Submission". Sponsors may encrypt the email or password protect the documents. If the documents are password protected, Sponsors must provide the password to CMS in a follow-up email and clearly indicate the files to which the passwords applies.

   Comments or questions should be sent via email to partd-planreporting@cms.hhs.gov about these directions, and include "P&T Committee Changes – Confidential Submission" in the subject line.

2) If a single contract number has multiple P&T Committees for its PBPs, how should a Part D Sponsor input these separate P&T Committee members into the HPMS Contract Management module?
   A: A Part D Sponsor, at the contract level, should input all P&T Committee member names in this section. CMS understands that the entire list of names may represent multiple P&T Committees serving different PBPs within one contract.

3) How should P&T Committee Confidentiality documents be named if they apply to more than one contract number?

A: The naming convention used for these documents should be file name and date. It should be indicated in the email to partd-planreporting@cms.hhs.gov that the submission is for multiple contracts,

4) If a Part D Sponsor operates under a confidentiality agreement, should the third party submit the Certification form or does the form need to come from the Part D Sponsor?
   A: The Certification can be sent by either the third party organization or directly from the Part D Sponsor via email to partd-planreporting@cms.hhs.gov

5) Should the Certification document contain an electronic signature or an original hard copy signed and scanned?
   A: The Certification document should contain an electronic signature.

Section VI. Transition

1) Does this section only pertain to members who have enrolled into a plan as a new enrollee under that specific quarter? Are Part D Sponsors expected to include data for members who received transition fills under the LTC portion of the Transition policy?
   A: Part D Sponsors should report data for any beneficiaries who are in transition during the reporting time periods. This is an important distinction from only reporting data for new enrollees in that reporting quarter, since a beneficiary's effective date may occur at the end of Q1 and the beneficiary is still in a transition period during Q2. That beneficiary should be reported in both Q1 and Q2 reports. Beneficiaries who receive fills under the LTC portion of the transition period should be included in these data.

2) Please define the term "authorized" as it is used in this reporting section; does it refer to paid claims only?
   A: Yes, the term "authorized" refers to paid claims only.

3) Should data element A include total number of LTC residents enrolled? For example, should any member residing in an institution at the time of enrollment count regardless of their condition?
   A: Element A should include all LTC beneficiaries due to the fact that they are eligible for emergency fills. Element C should include those LTC beneficiaries that received one or more prescriptions authorized during the transition period.

4) Data element B is the number of prescriptions authorized during transition periods. Should this be interpreted as the number of transition fills, or the total number of prescriptions filled by new members during their transition period?
   A: Sponsor should report the number of prescriptions filled per the Sponsors' transition policy. This is not equivalent to the total number of prescriptions filled by members in transition. This is also not limited to transition prescriptions filled by new members.

5) Please clarify if data element B, the number of prescriptions authorized is equivalent to the number of claims authorized?
   A: Yes, the terms prescriptions and claims are being used synonymously.

6) Please clarify data element D, the number of days per transition period?
   A: Part D Sponsors should report the length of their transition period per their CMS approved transition policy. For 2007, CMS has designated only one data element in which to report this information. Therefore, if a Sponsor has different transition periods for retail and LTC, they should report the retail number. Separate reporting of retail and LTC transition periods, is being proposed for 2008.

7) If a beneficiary receives a transition fill due to a level of care change, should this beneficiary be included in the Transition data that is associated with the reporting period?
   A: Yes, data included in the Transition Reporting Requirements should be based on the CMS-approved Transition policy.

8) If a new member in a transition period disenrolls from the plan and after a period of time rejoins the plan, should the end date of the transition period be extended to equal the number of days that the member was not enrolled? For example, if a member is not enrolled for 10 days should the end date of the transition period be extended 10 days?
   A: No, the end date of the original transition period is not extended. Rather, the member is entitled to a second transition period which is equivalent to the number of days in the Part D Sponsor's transition period.

9) In HMPS, there is a total column which adds the number of transition days for each PBP to a contract total. Is this the intent?
   A: The total calculation for data element D is ignored by CMS. The total is an artifact of the default total column setup. This row should be ignored.

Section VII. Exceptions

1) How will the exceptions data be released outside of CMS?
   A: Exceptions data are not currently used as part of the Part D performance metrics. However, these data could be used in the future. CMS does not intend to release any information at the beneficiary level.

2) For data element A (number of pharmacy transactions rejected due to failure to complete step therapy edit requirements) and data element B (number of pharmacy transactions rejected due to need for prior authorization) should Part D Sponsor report all transactions or only distinct drug claims?
   A: Part D Sponsors should report the total number of pharmacy transactions. CMS understands these numbers may include multiple transactions for the same prescription drug claim.

3) Are Part D Sponsor expected to report data regarding quantity limits or non-formulary rejections?
   A: For CY2007, data elements J and K have been added to collect information regarding quantity limit exceptions. Data elements F and G collect information regarding non-formulary exceptions.

4) Should Prior Authorizations that relate to Part B vs. Part D coverage be included in this reporting?
   A: For CY2007 reporting, PA requests/approvals that relate to Part B vs. Part D coverage should not be included in this reporting. Note that effective for CY2008 reporting, prior authorization requests/approvals that relate to Part B versus Part D coverage should be included in this reporting.

5) Should claim rejections due to quantity limits be limited to quantity vs. time rejects (e.g. a claim is submitted for 20 tablets/10 days, but is only approved for 10 tablets/5 days) or include all types of quantity limit rejects?
   A: Part D Sponsors should include all types of quantity limit rejects in these data.

6) Please clarify the definitions for each of the data elements in this reporting section, and how they are related.
   A: The exceptions data elements relate to various components of Plans' coverage determination processes. As some exception requests may apply to more than one type of exception, requests may be reported in several data elements, and therefore data elements are not mutually exclusive. Plans should not report exception requests for non-covered Part D drugs.
   - Data elements A, B and C relate to pharmacy transactions which reject due to the Plan's utilization management requirement.
   - Data elements D and E relate to enrollees' requests for prior authorization exceptions. E, the number of requests approved, is a subset of D.

- Data elements F and G relate to enrollees' requests for coverage of non-formulary medications. G, the number of requests approved, is a subset of F.
- Data elements H and I relate to enrollees' requests for tier exceptions. I, the number of requests approved, is a subset of H.
- Data elements J and K relate to quantity limit exceptions. K, the number of requests approved, is a subset of J.

Section VIII. Appeals

1) Please clarify the definitions for each of the data elements in this reporting section, and how they are related.
   A: The appeals data elements relate to the first two levels of the Part D appeals process, a plan's redetermination and the IRE's reconsideration. The specific data elements also relate to the appeal's priority and decision. Plans should not report appeal requests for non-covered Part D drugs.
   - Level 1 – Plan redetermination – data elements A-H
     - Data elements A, B, and C relate to the priority of redetermination requests (standard or expedited). C, the number of requests for expedited redetermination granted expedited status, is a subset of B.
     - Data elements D and E relate to enrollees' withdrawals of redetermination requests.
     - Data elements F and G relate to the disposition of the Plan's redeterminations.
     - Data element H is the number of adverse redeterminations due to insufficient evidence of medical necessity.
   - Level 2 – IRE reconsideration – data elements I-P
     - Data elements I and J relate to IRE reconsiderations that resulted because of the Plan's inability to meet Part D timeframes.
     - Data elements K, L, M, N, O, and P relate to the disposition of the IRE's reconsiderations. Each element represents a type of request (standard or expedited), as well as disposition (full reversal, partial reversal, or upholding of Plan decision).
       - Data element K, L, and O relate to standard reconsiderations
       - Data elements M, N, and P relate to expedited reconsiderations
       - Data elements K and M relate to full reversals of the Plan's decision
       - Data elements L and N relate to partial reversals of the Plan's decision
       - Data elements O and P relate to upholding of the Plan's decision

Section IX. Call Center Measures: Beneficiary Service line and Pharmacy Support line

CMS has suspended reporting by Part D Sponsors for the Call center reporting section for the entire 2007 contract year due to CMS' direct monitoring of Part D call centers. All Part D Sponsors are required to continue collection of these data, in the event CMS reinstitutes call center data submission.

1) What level is call center data to be reported?
   A: For CY2007, call center data may be reported at one of three levels: At the Part D Sponsor - level; at the Part D Contract - level; or Other. Please refer to page 2 of the reporting requirements document for definitions of Part D Sponsor and Contract - levels. The reporting level of "Other" reflects CMS' understanding that Part D call centers may be structured as entities that do not fall into Sponsor or Contract relationships, and it therefore may be appropriate in some cases for these call center operation entities to prepare aggregate data for their clients' reporting to CMS. Contracts reporting aggregate data from call center operation entities outside of a Sponsor relationship should record the level of reporting as "Other". It should be noted that call center data may be used for performance monitoring and reporting as submitted to CMS. Part D Sponsors, therefore, who submit aggregate data will be considered as providing the equivalent call center services across these sponsors.

2) What if beneficiaries call the same call center for Part D and non-Part D questions?
   A: CMS strongly encourages Part D Sponsors to separate Part D calls from other calls for monitoring purposes. Other than call abandonment, all data should be reported for Part D related calls only and should not include non-Part D related calls (e.g. medical benefit inquiries). For those call centers who are unable to separate Part D calls, HPMS will allow reporting of a combination of Part D and non-Part D calls.

3) Should calls from providers to the Beneficiary Service line be included in data reported?
   A: Yes, all calls received by the Beneficiary Service line should be included in the data reported.

4) How should Part D Sponsors using multiple customer service lines report Beneficiary Service call center data?
   A: All customer service lines, whether for existing or prospective beneficiaries, should be summarized and included in CMS reports.

5) For Sponsors utilizing one call center system for more than one Part D contract, can data be reported for each Part D contract number using the same exact data?
   A: Yes, these aggregate data may be reported for each Part D contract number associated with this Sponsor's call center system. Each Part D Sponsor should select the Sponsor - level of reporting in HPMS.

6) For Part D Sponsors that combine Beneficiary Service or Pharmacy Support lines into one call center system, how should data be reported?
   A: In this situation, the Part D Sponsors should report the same data for both the beneficiary line and pharmacy support line (e.g. data elements A and B, the number of inbound Part D connections abandoned would be equivalent.) The Part D Sponsor must also specify "Other" as the level of reporting in HPMS to indicate this combined call center system.

7) Should calls terminated within 5 seconds of being connected be included in data elements A and B, number of calls abandoned?
   A: No, calls terminated within 5 seconds of being connected should be excluded from these two elements.

8) Please specify which phone line is referenced in data element B; is the Pharmacy Support line considered the pharmacy technical line?
   A: The Pharmacy Support line refers to the technical help line that provides support to the pharmacies and other providers attempting to adjudicate Part D claims, and is the same as the pharmacy technical line.

9) Please provide the CMS definition of Average Hold Time (data element E) for Part D reporting requirements.
   A: As stated in the reporting requirements document, CMS defines Average Hold Time as time spent on hold following the IVR system and before reaching a customer service representative (CSR). All calls, including abandoned calls, should be included in this calculation. To clarify, this time is measured *after* the caller exits the ACD/IVR system and *until* reaching the live CSR. Thus, time spent navigating an IVR/ACD by a caller is not included in the hold time. For calls where a live CSR directly answers the phone line, the hold time for these calls is zero.

10) Can data element E, Average Hold Time, be considered equivalent to average time in queue?
   A: No, average time in queue is not equivalent as it excludes calls with a zero hold time. Average Hold Time is calculated for all calls made to the call center and calls with a zero hold time must be included.

11) Does the Average Hold Time include time on the phone with a CSR?
   A: No, CMS defines Average Hold Time as the time measured while on hold *until* reaching a live CSR. Therefore, time on the phone with a CSR should be excluded.

12) Which specific data elements are used to determine if calls are being answered in a timely manner?
   A: The standard in the Part D 2007 application was to have 80% of calls answered within 30 seconds. Data elements G and H are used to evaluate this standard.

13) How should Part D Sponsors report time spent navigating the IVR?

A: Part D Sponsors are not required to report separately the time spent navigating an IVR; however data elements I and J, average length of call, incorporate this measurement. Length of call is defined as the period of time between call connection and disconnection. All increments of the call should be included, such as time spent navigating the IVR.

Section X. Overpayment

1) What is the definition of an overpayment for purposes of Part D reporting?
   A: 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 may include overpayments made to pharmacies, overpayments a Part D Sponsor 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.

2) Regarding data element B, the total overpayment dollars recouped by the Part D Sponsor, should this be a running total of dollars recouped from one six month period to the next? For example: $1,000 has been recovered for the 1/1/06 - 6/30/06 pharmacy audit by the 8/31/06 report date. Another $500 is recovered from the same period is brought in after 8/31/06. Where should a Part D Sponsor report the additional $500?
   A: Data elements A and B are not rolling YTD amounts, but amounts that are specific to the reporting period. If funds identified in 1st period are recouped in the 2nd period, the Part D Contract should report these funds as data element B for the 2nd reporting period's report.

3) Could an incorrect administrative fee be considered one example of an overpayment that should be reported?
   A: Yes. If the Part D Sponsor feels there were payment errors made relating to any type of administrative fees, these amounts should be included in the Part D Sponsor's report to CMS.

4) Are claim reversals or adjustments considered overpayments?
   A: Part D Sponsors have already reported this information in the Reversals reporting section, and should not include these data in the Overpayments section.

5) How should a Part D Sponsor indicate that there were no overpayments identified during a reporting period?
   A: A zero should be entered in HPMS for each field of the overpayment reporting section to reflect no overpayments were identified.

Section XI. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

1) Does CMS require that a drug manufacturer offer a rebate in order for a Part D Sponsor to cover the manufacturer's drug?
   A: No, CMS does not require Part D Sponsors to operate under such restrictions when determining formulary inclusion of a drug.

2) What is the correct level of rebate reporting?
   A: HPMS will allow rebate reporting at either the Part D Sponsor or Contract - level. Please refer to page 2 of the reporting requirements document for definitions of each level.

3) In what format should these data be submitted?
   A: These data should be provided in a Microsoft Excel file, and uploaded into HPMS. The following file format should be used:

Pharmaceutical Manufacturer Rebate File Record Layout

NOTE: Uploaded rebate files must be in Microsoft Excel format and contain a header record.

Pharmaceutical Manufacturer Rebate File Record Layout				
Field Name	**Field Type**	**Field Length**	**Field Description**	**Sample Field Value(s)**
Manufacturer Name	CHAR REQUIRED	100	For each rebate, provide the contracting manufacturer name. This should be a character field.	
Drug Name	CHAR REQUIRED	100	For each rebate, provide the drug name.	
Rebates Received	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount received in the reporting period specified. • Limit to 999999999999, no decimals, can be a negative number • Zero should be entered in the fields if no data are available	999999999999

Pending Rebates	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount requested for the reporting period specified but not yet received (if applicable). • Limit to 999999999999, no decimals, can be a negative number • Zero should be entered in the fields if no data are available	999999999999
Prior Rebates	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount received that is associated with a prior reporting period (if applicable). • Limit to 999999999999, no decimals, can be a negative number • Zero should be entered in the fields if no data are available	999999999999

Discounts and Other Price Concessions File Record Layout

NOTE: Uploaded discount files must be in Microsoft Excel format and contain a header record.

Discounts and Other Price Concessions File Record Layout				
Field Name	**Field Type**	**Field Length**	**Field Description**	**Sample Field Value(s)**
Manufacturer/ Company Name	CHAR REQUIRED	100	List the name of each manufacturer for whom there is an associated discount, price concession, or other value add.	
Description	CHAR REQUIRED	250	Describe the discount, price concession, or other value add.	
Value	NUM REQUIRED	12	Provide the value of the discount, price concession, or other value add. • 0 is not an allowable value	999999999999
Justification	CHAR OPTIONAL	4000	For each discount, price concession, or value add, provide a justification for receipt.	

4) Are Part D Sponsors required to report the full amounts of rebates and administration fees received from the manufacturer, or the portion that is received by the Sponsor?
   A: Part D Sponsors must report 100% of Rebates, and may report 100% of Pharma Admin Fees. The determination of whether to include 100% of Pharma Admin Fees is at the discretion of the Sponsor per the conditions of the contracts between the Sponsor, PBM, and/or manufacturer.

5) Should Part D Sponsors include grant money received from a pharmaceutical manufacturer in the Discounts and other Price concessions file? Some grant money may be received by sections of an organization not directly administering the Part D benefit.
   A: Any grant monies that are related to Part D business should be reported, regardless of the formal recipient in the organization.

6) Should the rejection of a PDE affect an associated rebate from being reported?
   A: PDEs are data reported after the fact of point-of-sale processing. The rejection of a PDE should not affect the rebates that are being reported for these reporting requirements. Rebates should be based on paid valid claims.

7) Should various formulations of one drug be reported as separate rebate records? For example – Zocor 10 mg tablet, Zocor 20 mg tablet, Zocor 40 mg tablet.
   A: It is acceptable for formulations of the same drug to be rolled up to one record in the rebate file. In this example, Zocor may be inputted as the drug name, along with the total rebate amounts for all Zocor formulations.

8) In the Pending Rebate field, are Part D Sponsors to reflect the pending rebates for the specified reporting period only, or include all pending rebates YTD?
   A: Rebates are to be reported on a quarterly basis, not as a cumulative total. Therefore only those rebates identified to be pending during the specific quarter should be reported for that quarter, and should not be carried forward. For example, in Quarter 1 a Part D Sponsor identifies $100 in pending rebates. The Part D Sponsor reports this value in Q1 report. In Quarter 2, the Part D Sponsor determines that the $100 remains outstanding, but the Part D Sponsor should not carry the pending $100 to Q2's pending rebates report.

9) How should short paying by the manufacturer be accounted? Part D Sponsors may not ultimately be paid by the manufacturer for the full rebate amount. In the Pending Rebate field, should Part D Sponsors reflect the amount shorted as well as what has been billed but not paid?
   A: These reports are not cumulative, but quarterly snapshots. Part D Sponsors should account for short pays, as well as overpays. Here are 2 scenarios that demonstrate how data should be entered:

   Short pay: In this scenario, it is determined in Q2 that a Part D Sponsor has only received $50, and will not receive the remaining $50 as reported in Q1. To account

for this, the Part D Sponsor should enter the difference as a negative value in the pending rebate column: (-$50), and the amount received in the prior rebates column.

	Manufacturer Name	Drug Name	Rebates Received	Pending Rebates	Prior Rebates
Q1	Manuf A	Drug B	0	100	0
Q2	Manuf A	Drug B	0	-50	50

Overpay: In this scenario, it is determined in Q2 that a Part D Sponsor received more than the full pending amount reported in Q1, $200. To account for this, the Part D Sponsor should enter the difference as an additional value in the pending rebate column: ($50). The Part D Sponsor will also enter the total rebates received for the prior quarter Q1, $250.

	Manufacturer Name	Drug Name	Rebates Received	Pending Rebates	Prior Rebates
Q1	Manuf A	Drug B	0	200	0
Q2	Manuf A	Drug B	0	50	250

10) If the pending rebate amount can only be estimated initially, should this estimate be reported to CMS?
A: No, Part D Sponsors should not report estimates until an actual amount can be determined.

11) In the Pharmaceutical Manufacturer Rebate File Record Layout, the following description is given for the Prior Rebate field: For each unique manufacturer/drug name combination, provide the rebate amount received that is associated with a prior reporting period (if applicable). If 4th quarter 2006 rebates are received in 1st quarter 2007, should these rebates be reported in the 1st quarter 2007 report?
A: Yes, if the 4th quarter 2006 rebates are received during 1st quarter 2007, the rebates would be reported in the 1st quarter 2007 file as Prior Rebates.

12) How should rebates that apply to 1st quarter, but are received in 2nd quarter be reported? One example is when new contracts are signed with drug manufacturers that are backdated to the beginning of the year.
A: The Part D Sponsor should not resubmit 1st quarter's rebate report. Instead, in the 2nd quarter's rebate report, the rebate amount would be entered in both the Pending Rebates and the Prior Rebate column if the rebates were collected after 3/31/07.

13) If a Part D Sponsor erroneously excluded small amounts billed and partially received for the reporting period in both the total and pending fields, should they resubmit the rebate report, or submit these amounts in the subsequent reporting period's report?
A: If an error has been identified in the data previously submitted, the Part D Sponsor should resubmit that reporting period's rebate report.

14) Please clarify if CMS requires year end reporting and reconciliations based on rebates paid versus rebates billed.
A: For the Part D reporting requirements, CMS does not require a year end report; however please refer to separate guidance on rebate reporting for reconciliation. CMS has not requested and does not expect that Part D Sponsors revise previously submitted quarter reports based on additional rebate dollars. Part D Sponsors should account for increases/decreases in expected or received amounts. See question #8 above for short pay/overpay scenarios.

15) Are PACE organizations required to report rebate data in 2007?
A: Yes, CMS requires this level of information from all Part D Sponsors, including PACE programs. This requirement was released to Part D Sponsors beginning in 2005, and continues for CY2007.

16) When uploading a revised rebate file, should the previously submitted file be deleted?
A: No. Prior submissions should not be deleted.

Section XII. Long-term Care (LTC) Rebates

1) What is the level of reporting for this section?
   A: Long-term Care Rebate data are reported at the Contract - level. Please refer to page 2 of the reporting requirements document for definitions of each level. These data do not have to be utilization based and LTC pharmacies are to report rebates to all contracts that they service.

2) CMS has only requested Long-term Care rebate information be supplied by drug name level. Will Part D Sponsors be responsible for supplying Long-term Care rebate information at a more detailed level?
   A: CMS reserves the right to request Long-term Care rebate information at the NDC level. The NDC level rebate information may be necessary to understand the dosage/route supplied to beneficiaries at the Long-term facilities.

3) In what format should these data be submitted in HPMS?
   A: Part D Sponsors will upload an Excel file (filename=REBATES_LTC PHARMACIES_(CONTRACTNAME)_(2007Q#).XLS, replacing '(CONTRACTNAME)' with the Part D Sponsor's name and '(2007Q#)' with the year and quarter number) containing a header record and the fields as described by the table below.

LTC Rebates File Record Layout

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
LTC Pharmacy Name	CHAR REQUIRED	100	For each rebate, provide the name of the LTC pharmacy. This should be a character field.	
NCPDP Number	NUM REQUIRED	7	Indicate the contracted LTC pharmacy NCPDP number. This should be a numeric field exactly 7 digits long.	
NPI Number	NUM OPTIONAL	10	Indicate the contracted LTC pharmacy NPI (National Provider Identifier) number. This should be a numeric field.	
Manufacturer Name	CHAR REQUIRED	100	For each rebate, provide the contracting manufacturer name. This should be a character field.	
Drug Name	CHAR REQUIRED	100	For each rebate, provide the drug name.	

LTC Rebates File Record Layout				
Rebate $ per unit received	NUM REQUIRED	17	Provide the contractual per unit rebates received during the reporting period (cash basis) associated with the listed drug. • Limit to 999999999999.9999, can also be a negative number	999999999999.9999
Technical Notes	CHAR OPTIONAL	4000	Provide any technical notes regarding the LTC pharmacy rebate calculations.	

4) Are all long-term care (LTC) pharmacies required to report rebates to Part D Sponsors?

A: In general, a plan is to require reporting for its entire network of LTC pharmacies. However, CMS will permit plans to exercise discretion about whether to collect rebate data from their LTC pharmacies that serve less than 5% of LTC beds in an area ("area" is defined as the state in which the LTC pharmacy is licensed.) For this reporting exemption, the term pharmacy represents a pharmacy organization at its highest level rather than the discrete NCPDP number or location. A pharmacy organization that includes multiple pharmacy locations should be considered in its entirety by a Plan to determine if that chain serves less than 5% of the LTC beds in the respective area. For reporting purposes, however, these LTC pharmacies must still be listed in the rebate report to CMS.

- For an individual pharmacy, that is not part of a pharmacy chain and serves less than 5% of the LTC beds in the area, the sponsor should list the LTC pharmacy NCPDP # in the report, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.
- For a pharmacy chain serving less than 5% of LTC beds of a state in which any of its pharmacies are licensed, the sponsor should list all pharmacies by NCPDP #, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.
- For a pharmacy chain with multiple pharmacies serving more than 5% of LTC beds in a state, a sponsor must list all of the chain's pharmacies licensed in that state and their rebates received. Any pharmacies that did not receive rebates should be reported by listing NCPDP #, leaving the Manufacturer, Drug name and Rebate unit fields blank, and entering "Not required to report" in the Technical Notes field.
- If a pharmacy is licensed in multiple states and meets the criteria of 5% of the LTC beds served in at least one state, the rebates received by that pharmacy must be reported.

5) If a Part D Sponsor's LTC pharmacy reports zero rebate dollars received, how should the Part D Sponsor report this to CMS?
A: For the 1st quarter 2007 LTC rebate reporting deadline CMS accepted, but did not require, Plans to report LTC pharmacies who received zero dollars. However, CMS recognizes this would have been inconsistent with the industry guidance established. Therefore, effective for the 2nd quarter 2007 LTC pharmacy rebate report, CMS will remain consistent with the previously issued guidance that Plans do not need to report zero rebate dollars for a given LTC pharmacy.

6) How should a Part D Sponsor indicate that a LTC pharmacy is noncompliant in reporting these data to the Part D Sponsor?
A: Part D Sponsors must adhere to the policies and guidance set forth by CMS, and submit data for Part D Plan Reporting Requirements based on those terms. CMS contracts with each Part D Sponsor, and in turn, a Part D Sponsor typically contracts with other providers. For cases in which a provider, such as a LTC pharmacy, is non-compliant, the Part D Sponsor should first consider initiating possible contractual remedies and other legal options to improve compliance. Meanwhile, the Sponsor should leave the NPI field blank, submit zeros for the Pharmacy Name, Manufacturer, Drug name and Rebate unit fields, and in the Technical Notes field enter "Noncompliant." If you have additional technical problems, send an email to the HPMS Help Desk at HPMS@cms.hhs.gov.

7) If a Part D Sponsor is in the process of possible contractual remedies and other legal options to improve compliance of LTC pharmacy reporting, will the Part D Sponsor be held responsible by CMS for meeting these reporting requirements?
A: Yes, these activities do not exempt a Part D Sponsor from compliance actions that may be taken by CMS.

8) Should a LTC pharmacy report rebate amounts to a plan if that plan did not have any prescriptions filled with that LTC pharmacy?
A: Yes. LTC pharmacies may receive rebates that are not contingent on prescription drug utilization, and therefore must report rebates to Part D Sponsors even if there is no prescription utilization by the plans' enrollees.

9) How should the NCPDP number be entered in the Excel file to retain the leading zeros?
A: In order to retain the leading zero(s) of the NCPDP numbers, this field must have a character field format. Previously, the format of this field had been listed as number, which would incorrectly truncate the NCPDP's leading zeros. This correction has also been made in the Draft 2008 Plan Reporting Requirements document.

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

1) For CY2007, this reporting section has been expanded to four subsections. Please clarify which organizations are required to submit data for these four subsections.
   A: The four subsections and the organizations required to report these data are as follows:
   - Subsection 1. Financial and Solvency Requirements Documentation - Part D PDPs
   - Subsection 2. Financial and Solvency Requirements Documentation – Direct EGWPs
   - Subsection 3. Financial and Solvency Requirements HPMS data– Part D PDPs and Direct EGWPs
   - Subsection 4. Performance of Part D Activities HPMS data – MA-PDs, PDPs, and Direct EGWPs

2) Will CMS accept the corresponding LAH (Life and A&H) Blank pages in lieu of Health Blank pages?
   A: Yes.

3) When reporting on claims paid, should Part D Sponsors report only those they have received Medicare payment, or also include those claims they are working through the reconciliation process?
   A: Part D Sponsors should report for both types of claims.

4) What is meant by licensed or non-licensed Part D Sponsor?
   A: A licensed PDP Sponsor refers to one that is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in at least one state. A non-licensed PDP Sponsor refers to one under which the Sponsor holds no state license (has licensure waivers in all states in the service area.)

5) What if an organization is licensed in some states, but not all states in which it operates?
   A: Contracting entities licensed in at least one state as a risk-bearing entity would be required to meet Part D reporting requirements for licensed PDP Sponsors.

6) Is there a contact name to put on L&S documents mailed to CMS?
   A: The L&S contact person is Robert Ahern. He can be reached via email at robert.ahern@cms.hhs.gov .

7) Would electronic filings (PDF files) meet filing requirements, or are only hard copies acceptable?
   A: The requirements indicate that hard copies should be mailed.

8) Are there any special requirements for the Actuarial Opinion to address specific to the Medicare Part D reporting requirements?

A: There is nothing specific to the Part D reporting requirements. Actuarial opinions should address the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

9) What constitutes a management letter?
A: A statement made by an organization's independent auditor addressing internal controls and other management issues discovered during the audit. It usually covers areas needing improvement and recommendations for addressing those areas.

10) Is a letter of deficiencies from the auditor required in all cases?
A: No

11) Should administrative expenses to be shown net of (offset by) Administrative Services Only (ASO) revenue as is statutory procedure?
A: Yes

12) Does CMS plan on making the financial information under Section XIII public information?
A: No, not at this time.

13) Are Part D Sponsors required to submit a Statutory and a GAAP audited financial statement?
A: Part D Sponsors are required to submit independently audited financial statements which are statutory based or GAAP based. Part D Sponsors do not have to submit both but if would like to send both, CMS will accept them.

14) According to Subsection I, data element G, PDP Sponsors with any state licensure waivers must submit an update on the status of obtaining licensure for each waived state. Should this update be submitted within 120 days of the end of the fiscal year along with the other annual financial and significant business transaction reporting or quarterly based on the time period specified in the requirements?
A: Updates on the status of obtaining licensure for each waived state are to be submitted quarterly.

15) Which data are collected by subsection IV – Performance of Part D Activities.
A: This subsection requires all Part D Sponsors to attest quarterly if changes have been made to the entities which perform Part D activities, and if so, if the Part D Sponsor reported these changes to CMS. The actual information regarding these entities is housed in a separate HPMS module called Contract Management.

16) Where should questions regarding Subsection IV be sent?
A: Questions regarding Subsection 4 should be emailed to partd-planreporting@cms.hhs.gov .

Section XIV. Drug benefit analyses

1) Should an enrollee be placed in only one data element for each monthly snapshot?
   A: Yes, beneficiaries should be reported in only one data element. Data reported should reflect each beneficiary's status as of the last day of the month.

2) Should members with no claims experience be reported in data element B, the number of non-LIS enrollees in the pre-initial coverage limit phase?
   A: This is correct.

3) If a Part D Sponsor at the PBP level offers partial coverage in the coverage gap (i.e. generics only), should anything be reported for data element C?
   A: Yes, the Part D Sponsor would still report beneficiaries in that phase, as only partial coverage is offered. Note, if a PBP covers all formulary drugs or all drugs through the coverage gap, the PBP should list the number of people who are pre-catastrophic in the data element B field, and then indicate zero in the data element C field.

4) Should a prior quarter's report be resubmitted after the original report submission deadline due to claims retroactivity?
   A: No, prior quarters' reports should not be resubmitted due to this reason. Reports should only be resubmitted if it is determined errors were made in the original dataset.

5) When identifying non-LIS members in the different phases of the benefit, should Sponsors include adjustments (e.g. N1 transactions)?
   A: These data should include adjustments that have been captured during each monthly snapshot. The data should be generated monthly, but should be reported quarterly. CMS does not expect Sponsors to go back and resubmit data from past quarters. Resubmission is only necessary when data errors occur in the submission.

6) Can CMS provide additional clarification regarding the timeframe in which data for the Drug Benefit Analyses Section of the reporting requirements should be generated?
   A: CMS requests that Sponsors run the reports necessary for this reporting on a monthly basis, at a point in time which captures as many adjustments as possible. This time period may differ for each Part D sponsor/PBM, but essentially this should be similar to the process for generation of monthly EOBs. CMS' priority is to capture monthly snapshots for trending, with the understanding that many transactions and adjustments may occur after the snapshots are provided.

7) Should Sponsors use the fill date or the claim submission date to determine where a beneficiary falls in the benefit as of the last day of the month?
   A: Sponsors should use the fill date to determine where a beneficiary falls in the benefit as of the last day of the month.