

August 14, 2006

CMS, Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development – A  
Attention: Melissa Musotto, Room C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: 2007 Part D Reporting Requirements

Dear Ms. Musotto:

Families USA is pleased to submit these comments on CMS's proposed 2007 Part D Reporting Requirements. Families USA is the national, non-profit, non-partisan organization for health care consumers. Our mission is to ensure that all Americans have access to high-quality, affordable health care. Families USA strongly supports comprehensive, affordable health insurance for all residents of this nation.

Overall, we commend CMS for proposing more detailed data collection from Part D plans. This should be helpful in assessing which plans are best serving beneficiaries. We have several remaining concerns:

1) We urge CMS to ensure that the data reported is made available to the public in a timely matter, so that beneficiaries may assess which plans offer the best service. The policy for public dissemination could be included in these requirements. In particular, key information about generic dispensing rate, enrollment and disenrollment, grievances and appeals and their resolution, and the quality of service in telephone call centers should be made public. We suggest such information should be available on a quarterly basis, no more than one or two months after it is submitted. As much data as possible should also be available prior to beneficiaries making enrollment decisions during the open enrollment period this fall.

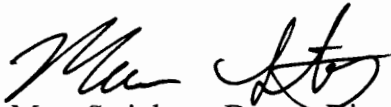
2) We urge CMS to emphasize that erroneous reporting or failure to report will have adverse consequences. For P&T Committees, for example, because conflicts of interest can be difficult to identify, Part D plan sponsors must be expected to investigate aggressively.

3) CMS should also consider now or in the near future collection of non-numerical data, including what drugs most frequently trigger utilization management rules or transition requirements. This can be very helpful in assessing which beneficiaries and conditions are most commonly affected by these policies.

4) We also urge CMS to develop methods of assessing whether the information provided to beneficiaries is accurate and complete. Section X, for example, is quite thorough in reporting the basic quantitative aspects of call center performance, but it does not capture occasions where a caller may receive incomplete or inaccurate information.

Thank you for the opportunity to submit these comments. If you have questions, please do not hesitate to contact Marc Steinberg at (202) 628-3030 or [msteinberg@familiesusa.org](mailto:msteinberg@familiesusa.org).

Very truly yours,

A handwritten signature in black ink, appearing to read 'Marc Steinberg', written in a cursive style.

Marc Steinberg, Deputy Director, Health Policy  
On behalf of Families USA

**America's Health  
Insurance Plans**

601 Pennsylvania Avenue, NW  
South Building  
Suite Five Hundred  
Washington, DC 20004

202.778.3200  
www.ahip.net



#3

August 14, 2006

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development—A  
Attention: Melissa Musotto, Room C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Re: CMS 10185 [OMB#: 0938-0992]**

Dear Ms. Musotto:

I am writing on behalf of America's Health Insurance Plans (AHIP) to submit comments on the proposed CY 2007 Part D Reporting Requirements in response to the notice published on June 16, 2006 in the Federal Register (71 FR 34938) by the Centers for Medicare & Medicaid Services (CMS) under the Paperwork Reduction Act of 1995 (PRA). AHIP is the national trade association representing nearly 1,300 member companies providing health insurance coverage to more than 200 million Americans. These requirements are of significant interest to AHIP's member organizations, many of which participate in the Part D program as stand-alone prescription drug plans (PDPs) or Medicare Advantage organizations or Medicare cost plans that offer Part D prescription drug benefits (MA-PD plans and Cost-PD plans, respectively).

AHIP recognizes the need for CMS to continue to collect reliable data to meet Part D program management objectives and appreciates CMS' efforts to do so in a way that makes efficient use of Part D plan and Medicare program resources. Consistent with these goals, we have a number of concerns and recommendations for improving the reporting requirements that are discussed in our comments below. AHIP will first offer its general comments followed by its specific comments related to the proposed reporting requirements. [Note: The term Part D plan sponsor is used in these comments to refer to all types of participating organizations (PDPs, MA-PD plans, and Cost-PD plans.)

**General Comments**

- **Plan level v. contract level reporting.** Under the proposed CY 2007 Part D Reporting Requirements, Part D sponsors must report most of the data elements at the "Plan level." In general, plan level reporting is highly resource intensive, and

we believe that CMS should retain reporting at this level only when the value of the data for program oversight and management justify the investment of Part D sponsor resources. More specifically:

- + In some cases, plan level reporting may yield such small numbers on a plan by plan basis that the data are unlikely to provide meaningful insight into Part D sponsor performance (i.e., Section III. Medication Therapy Management.)
- + In other cases, contract level reporting can provide complete information about Part D sponsor performance because sponsors establish a single mechanism that addresses their program responsibilities across all plans. [i.e., processes for resolving grievances (Section V.) and appeals (Section VII.) and for making determinations on requests for prior authorization, step edits and non-formulary exceptions (Section VI.) are established at the contract level rather than differing by plan.]
- + Further, pharmaceutical manufacturer rebates, discounts and other price concessions (Section IX.) are commonly negotiated at the contract level (and for organizations with multiple contracts may be negotiated at the organization level) so that the requirement for plan-level reporting is inconsistent with the basis on which the arrangements are established.

In addition, the proposed CY 2007 requirements are likely to heighten the concerns described above and in the comment immediately below, because they contain four new sections and add approximately 35 new metrics in six existing sections. In total, the proposed CY 2007 requirements have the potential to double the number of metrics reported.

AHIP strongly recommends that CMS reevaluate the level of reporting required under each Section of the requirements and revise plan-level reporting to contract level reporting, as needed to address the concerns discussed above.

- **Duplicative reporting.** In several instances the reporting requirements call for submission of data that are available to CMS from other sources. For example, Maximus collects appeals data that are readily accessible to CMS. Particularly in light of the significant increase in the number of metrics for CY 2007, as noted above, we strongly recommend that CMS review the reporting requirements and eliminate metrics for which CMS can obtain data from internal CMS sources or CMS contractors.
- **Timely issuance of final CY 2007 Part D Reporting Requirements.** To permit Part D sponsors to complete systems modifications and testing that may be needed to comply with changes from the CY 2006 requirements, we strongly recommend that CMS issue the final CY 2007 Part D Reporting Requirements as soon as possible. We also recommend that CMS issue a redline comparison of the CY 2006 requirements and the final CY 2007 requirements to assist Part D plan sponsors in quickly identifying new or modified requirements.

## **Specific Comments**

### **Introduction**

- **Part D Sponsor Reporting Requirements.** The last paragraph of this section states that MA Organizations will be required to comply with all reporting requirements with the exception of those found in Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements. It is our understanding that the same exception applies to Medicare cost plans that choose to offer Part D benefits. If this is correct, for accuracy, we recommend that CMS revise the Introduction to reference both MA Organizations and Medicare Cost Plans.

### **Section I – Enrollment/Disenrollment.**

- **General Comments.** In this version of the proposed CY 2007 Part D reporting requirements, CMS signals that Part D plan sponsors will be required to report both low-income subsidy (LIS) and non-low-income subsidy (non-LIS) data for all metrics in this section. We recognize that CMS is engaged in ongoing systems work to ensure the accuracy of LIS status information, and we recommend that CMS ensure that Part D plan sponsors will be able to make use of CMS data in CY 2007 for the purpose of this reporting requirement. In addition, we note that in some cases, LIS status may change during the reporting period or may change retroactively after the close of the reporting period (i.e., due to retroactive eligibility determinations). Accordingly, we recommend that CMS clarify that Part D plan sponsors are required to report on the data elements in this section based upon the LIS status that is available at the close of the reporting period for each beneficiary who is enrolled in the plan at that time (e.g., for the first quarter, as of March 31).
- **Data Elements K. and L.** These data elements require plans to report the number of all LIS (full and partial) and non-LIS beneficiaries who were disenrolled from the Plan because of death during the reporting period. It is our understanding that Part D plan sponsors commonly receive initial notification from CMS that a beneficiary has been disenrolled due to death. If we are correct that CMS is the principal source of this information, we recommend that CMS obtain this data from the Agency's systems and eliminate these data elements from the reporting requirements.

### **Section III - Medication Therapy Management.**

- **General Comments.** This section proposes a significant expansion of the data elements on which Part D plan sponsors must report regarding their Medication Therapy Management programs. We are concerned that these requirements are

likely to require significant additional resources, particularly in light of the requirement for plan-level reporting. We believe that reporting at this level is likely to produce small numbers that are unlikely to reliably reflect plan performance. AHIP recommends that CMS reconsider expansion of these reporting requirements and strongly recommends that all requirements in this section call for contract level reporting.

- **Data Element A.** This data element states that the method of enrollment “may be opt-in, opt-out, a combination of opt-in and opt-out, or other.” We believe that the reference to combination of opt-in and opt-out” is likely to be confusing because the circumstances in which such a combination would occur are unclear. We recommend that CMS revise this metric to include an example or explanation of the circumstances in which enrollment in an MTM program would include both opt-in or opt-out.
- **Data Element E.** This data element requires Part D plans to report the number of beneficiaries that have discontinued participation in the MTMP due to death. As also noted above, it is our understanding that Part D plan sponsors commonly receive initial notification from CMS that a beneficiary has been disenrolled due to death. The lag in receipt of this notice by the Part D plan sponsor and time required to incorporate the information into the MTM data is likely to undermine the utility of this information. We recommend that CMS rely on internal data sources for this information and eliminate the reporting requirement for Part D plan sponsors.

#### **Section V – Grievances.**

- **General Comments.** It is our understanding that the information Part D plan sponsors would be required to report for data elements N, O, and P may already be available through Maximus or the Qualified Independent Contractors (QICs). If this is the case, to avoid duplicative reporting requirements, AHIP recommends that CMS remove N, O, and P from this section and obtain this information from CMS’ contractors.
- **Data Element A.** This data element calls for Part D plans to report the number of fraud and abuse grievances received related to Part D. We believe that categorizing such grievances based upon the information available upon receipt rather than information available after investigation to confirm whether they relate to potential fraud and abuse is likely to miscategorize grievances and make the information collected an inaccurate indicator of the prevalence of fraud and abuse grievances. For accuracy, AHIP recommends that CMS revise this data element to require Part D plan sponsors to report the number of grievances determined to relate to fraud and abuse after investigation by the Part D sponsor.

- **Data Element I.** This data element requires Part D plan sponsors to provide the number of transition grievances received related to Part D and provides several examples, including situations involving pharmacies not in the Part D plan's network. It is unclear what transition issues are related to pharmacies not in a plan's network. To promote consistent understanding of the requirement, AHIP recommends that CMS revise this data element to clarify this example.
- **Data Element P.** This data element indicates that Part D plan sponsors must "...provide the average number of hours for the Plan to complete disposition..." It is our understanding that CMS intends that Part D sponsors will provide a specific number of hours. For clarity, we recommend that CMS include a parenthetical that illustrates the nature of the required reporting, including confirming that CMS intends for the data to reflect rounding to the nearest hour (i.e., an average of 12 hours).

#### **Section VII – Transition.**

- **Data Element C.** This data element requires Part D plan sponsors to report the number of *enrollees* "receiving one or more prescriptions via transition policy during the reporting time period." The preceding data element requires reporting of the number of *prescriptions* "authorized via transition policy during the reporting period." For clarity and consistency, we recommend that the language of data element C. be revised to reference the number of *enrollees* "receiving one of more prescriptions authorized via transition policy."

#### **Section IX – Appeals.**

- **Data Element G.** This data element requires Part D plan sponsors to report the number of redeterminations resulting in partial reversal of the original decision. For clarity, we recommend that CMS include an example of a partial reversal.
- **Data Element Q.** This data element requires Part D plan sponsors to report the average number of hours for the plan to complete standard redeterminations. However, the time frame for standard determinations is stated in days (i.e., 7 days). Therefore, it appears that the reference to reporting the number of hours is a typographical error. If this is the case, we recommend that CMS revise the draft to state that Part D plan sponsors must report the average number of days to complete standard redeterminations.
- **Data Element R.** This data element states that Part D plan sponsors must report the average number of hours to complete expedited redeterminations. For clarity, we recommend that CMS include a parenthetical that illustrates the nature of the required reporting, including confirming whether CMS intends for the data to reflect rounding to the nearest hour or to reflect hours/minutes (i.e., an average of 36 hours).

## **Section X – Call Center Measures.**

- **General Comments.** The last sentence of the first paragraph states: “Also, while call centers may track other metrics such as calls related to medical care, calls related in any other matter to Part D should be tracked separately for inclusion in this reporting requirement.” While we recognize CMS’ interest in collecting data specifically related to Part D, the integration of medical and prescription drug benefits offered by MA-PD plans makes separate reporting of Part D beneficiary call center data highly problematic.

Options available to MA-PD plans that have the potential to improve their ability to separate data on beneficiary medical and Part D inquiries also are likely to both confuse beneficiaries and significantly increase administrative costs. For example, different telephone numbers for medical and Part D issues and interactive voice response (IVR) prompts designed to direct these two categories of calls to different beneficiary customer service representatives have the potential to result in a significant number of misrouted calls due to confusion about benefit type (e.g., Part B v. Part D drugs) and to make it more challenging for plans to enhance the availability and effectiveness of assistance for their members. In addition, beneficiaries who have been MA plan members for several years are likely to find such options particularly confusing. An underlying reason for these difficulties is that inquiries may frequently mix medical and Part D issues (i.e., EOC, ANOC, ID card, change of address, billing, etc.). In addition, to beneficiary confusion, beneficiary customer service representatives are likely to have similar difficulty correctly categorizing inquiries whether a single beneficiary call center or separate lines/call centers are maintained. For all of these reasons, despite their best efforts, beneficiary call center data generated by MA-PD plans may not reflect a clear picture of their Part D performance.

AHIP strongly recommends that CMS reconsider requiring MA-PD plans to report separately on medical and Part D beneficiary call center inquiries. We believe that beneficiary call center data that does not distinguish between medical and Part D inquiries will provide a more reliable indicator of MA organization beneficiary call center performance. We would welcome the opportunity to discuss these issues with CMS.

- **Data Elements A. and B.** These data elements require Part D plan sponsors to provide the total number of Part D inbound connections abandoned on the Beneficiary Customer Service and Pharmacy Support lines respectively. However, the data element does not define “abandoned” connection. To promote consistent reporting of this metric, AHIP recommends that CMS revise these elements to provide an explanation of the term “abandoned.”



- **Data Elements E and F.** These data elements require Part D plan sponsors to report the “average speed of answer for Part D calls” to the Beneficiary Service and Pharmacy Support lines, respectively. Average speed of answer is defined as “the time it takes to get an inbound call connected to a customer service representative, excluding time navigating an IVR.” It is our understanding that welcome time on an automated call distribution (ACD) system would also be excluded. If this is correct, we recommend that CMS revise this data element to explicitly state that this is the case.
- **Data Elements I & J.** Data elements I and J require Part D plan sponsors to report the number of calls to the Beneficiary Service Line and Pharmacy Support lines, respectively, that were resolved and did not require a call back. It is our understanding that the language, “did not require a call back,” means that the customer service representative did not need to call the beneficiary back, since it would be generally infeasible for sponsors to report a beneficiary call back that would link a subsequent call by the beneficiary to the initial inquiry. AHIP recommends CMS revise these data elements to clarify that “did not require a call back” means “did not require the customer service representative to call the beneficiary back.”
- **Data Elements K. and L.** These data elements require Part D plan sponsors to provide the average length of calls to the Beneficiary Support and Pharmacy Support lines, respectively. It appears that CMS intends for Part D plan sponsors to report the average length of time from the point that a beneficiary or pharmacist is connected to a customer service representative until the call is terminated. If this is the case, the time would not include the welcome message in an automated call distribution system, the time to navigate an IVR system, or hold time prior to being connected to a customer service representative. For clarity, AHIP recommends that CMS revise these data reporting elements to include details such as these concerning the information that must be reported.

### **Section XIII - Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies.**

- **General Comments.**
  - + **Disclosure requirement.** This section requires that Part D plan sponsors must require network long-term care (LTC) pharmacies to disclose access/performance rebates or “other price concessions.” We believe that it will be very difficult for Part D plan sponsors to require such disclosure. Arms-length business relationships exist between Part D plan sponsors and these pharmacies, and we anticipate that the pharmacies will be reluctant to disclose proprietary information about the rebates they receive. Further, AHIP believes that Part D plan sponsor benefit management strategies, such as monitoring the trends in the dispensing of

specific drugs by LTC pharmacies, provide effective safeguards against prescribing or dispensing practices that have the potential to interfere with successful implementation of these strategies. These benefit management strategies are designed and implemented to achieve the same goal as CMS' proposed LTC rebate reporting requirement. To the extent that fraudulent or abusive conduct is identified, Part D plan sponsors are responsible for referring such conduct to the appropriate enforcement agency for investigation consistent with CMS' Part D Fraud, Waste, and Abuse Guidance. Under these circumstances, we believe that CMS' focus on LTC pharmacy rebate reporting is not well-founded. Pending reevaluation of the practicality and value of this requirement, AHIP recommends that CMS remove it from the Part D reporting requirements.

- + **Access/performance rebates and "other price concessions."** In the event that Part D plan sponsors succeed in obtaining the agreement of LTC pharmacies to disclose rebates they receive, it is unclear what rebates must be reported under the CMS requirements. While we understand that the term "access/performance" rebates is generally understood among LTC pharmacies, in the context of the Part D reporting requirements, its scope may not be clear. For example, it is our understanding that, under some rebate arrangements, LTC pharmacies receive rebates based upon prescription drugs purchased by the pharmacies rather than on utilization. In such cases, the rebates would not be linked to drugs dispensed to the Part D plan sponsors enrollees. It is unclear whether such arrangements constitute "access/performance" rebates that must be disclosed. Further, the term "other price concessions," may not have a well-established meaning for LTC pharmacies. If CMS retains these reporting requirements, AHIP recommends that CMS clarify the meaning of both "access/performance" rebates and "other price concessions" as they relate to LTC pharmacies and the Part D program.

#### **Section XV - Drug Benefit Analyses.**

- **Data Elements A, B, and C.** This section requires Part D plan sponsors to report the number of beneficiaries in different phases of the Part D benefit. We believe that CMS has established requirements to collect more detailed information more frequently through the Prescription Drug Event (PDE) reporting requirements. Therefore, we believe that CMS should obtain this information from these records and, to avoid duplicative reporting, we recommend that CMS eliminate this section. In the event that CMS does not accept this recommendation, we recommend that CMS revise the section to clarify that Part D sponsors will report based upon the specific benefit design offered under each plan (e.g., standard, enhanced, etc.).

Ms. Musotto  
August 14, 2006  
Page 9

We appreciate the opportunity to comment on the proposed CY 2007 Medicare Part D Reporting Requirements. If you have questions or would like additional information, please contact me at (202) 778-3209 or [cschaller@ahip.org](mailto:cschaller@ahip.org).

Sincerely,

A handwritten signature in cursive script that reads "Candace Schaller". The signature is written in black ink and is positioned above the printed name and title.

Candace Schaller  
Senior Vice President, Regulatory Affairs



#4

1300 WASHINGTON STREET  
KANSAS CITY, MISSOURI  
64105-1433

WWW.ARGUSHEALTH.COM

Date:  
August 14, 2006

CMS, Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development – A  
Attention: Melissa Musotto, Room C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: 60 Day Public Comment Period for 2007 Part D Reporting Requirements

Dear Ms. Musotto,

Argus Health Systems provides Medicare Part D Claims processing to several Health Plans nationwide.

We are submitting our feedback as requested in your June 21, 2006 memo to All Part D Plan Sponsors. We appreciate your consideration of our recommendations.

Sincerely,

Argus Health Systems

Attachment



# 60 Day Public Comment Period for 2007 Part D Reporting Requirements

---

## All Sections:

- Reporting is being requested at the contract level for some reports and at the plan level for others. A consistent reporting method would provide better reconciliation and comparison detail.

## Section I. Enrollment/Disenrollment

- No comment

## Section II. Reversals

- No comment

## Section III. Medication Therapy Management Programs

- Medication Therapy Management Programs be reported at Plan level (PDP ID) or Contract level (as noted in MEMO\_MTM\_073106.pdf)?
- What is the value of data element 'I' of Section III. Medication Therapy Management Programs (calculation below)? Why use a denominator of all member Part D months rather than MTMP member months?
  - I. For each beneficiary participating in the MTMP as of the last day of the reporting period specified, provide the total prescription cost of all medications on a per MTMP beneficiary per month basis. This should be a currency field. The total prescription cost should include MTMP beneficiary cost sharing and Part D Sponsor costs paid, exclusive of premiums or rebates, and should be calculated as follows: (AWP – network discounts + tax + dispensing fee). This amount should be summed for all prescriptions that were dispensed within the reporting period specified for each beneficiary enrolling in the MTMP as of the last day of the reporting period specified. Finally, this sum should be divided by the total number of member months for the included beneficiaries. These member months should include all months enrolled in the Part D Plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

## Section IV. Generic Dispensing Rates

- No comment

## Section V. Grievances

- No comment

## Section VI. Pharmacy & Therapeutics (P&T) Committee

- No comment

## Section VII. Transition

- No comment

## Section IX. Appeals

- No comment

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

- Argus would like to address the Call Center reporting changes for 2007, specifically regarding the necessity to provide separate Medicare Part D pharmacy support line statistics (Calls Abandoned, Total Calls, ASA etc.). Our understanding is that prescription claims processors, like Argus, typically have a primary pharmacy help desk phone number accessed by all pharmacies filling prescriptions on behalf of their customers' members. In Argus' case, this main number has been in use since 1986 and is currently being provided to over 60,000 pharmacies on behalf of our customers from whom we provide Medicare Part D pharmacy support. As such, it is widely recognized by the pharmacy community and the one they routinely call for support regardless of line of business (commercial, Part D, Medicaid, etc.) As such, Argus routinely provides pharmacy support line statistics to our customers that reflect performance for the entire customer base.
- Our understanding of the new 2007 requirement is that reporting needs to occur on a per plan basis and will therefore require a unique pharmacy support phone number per plan in order to ensure accurate capturing and reporting of statistics. In addition to potential cost increases and other burdens to customers (e.g., needing to provide existing beneficiaries with new Medicare Part D cards due to a change in phone number), we anticipate confusion as pharmacies will have to update their records to incorporate a multitude of new phone numbers, over 50 for Argus alone.

- Given this, Argus recommends that such calls not be required to be split out by plan and requests that CMS allow reporting across the entire customer base for such statistics.

## Section XI. Overpayment

- No comment

## Section XII. Pharmaceutical Manufacturers, Discounts and Other Price Concessions

- No comment

## Section XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies

- The Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies reporting requirement as specified by CMS creates significant challenges for LTC pharmacies and Part D Plans Sponsors. Because this requirement impacts all LTC participating pharmacies and all Part D plans, NCPDP created a task group to establish a standard reporting template for all LTC pharmacies to use to report rebates to the Part D plans in which the LTC pharmacy participates.
- The CMS reporting requirements require all Part D participating LTC pharmacies that receive any form of “access/performance” rebate or “other price concessions” to report the information on a quarterly basis to any Part D plans in which the LTC pharmacy participates. Each LTC pharmacy and Part D plan must determine what “access/performance” information must be reported and allocate the information into two categories for reporting purposes, “rebates” and “other pricing concessions”. While the term “rebates” is generally understood within the industry, there is less consensus on the definition of “other price concessions”. Furthermore, while the linkage between “access/performance “ and “rebates” may be strong, the linkage between “other price concessions” and “access/performance” may be in the eye of the beholder.
- Part D plans are at risk of running afoul of CMS requirements if they fail to police the submitted reports to ensure that all applicable “other price concessions” are included in the reported information. As a result of the different interpretations, disclosure by LTC pharmacies may not be uniform and may open some LTC pharmacies to audit by Part D plans and CMS.
- Additional issues raised by the NCPDP task group include:
  - CMS requires that only access/performance rebates applicable to Medicare Part D be reported:
  - Manufacturer rebates paid to LTC pharmacies do not distinguish between lines of business or products. Unlike Part D Plans that have CMS requirements for separate rebate agreements for Part D products, LTC pharmacy rebate agreements don't distinguish “rebates” and “other price concessions” earned for drugs purchased for commercial,

Medicaid or Medicare product lines, or LTC and retail lines of business. Rebates and “other pricing concessions” are earned based on consolidated purchasing by the pharmacy. Therefore, the requirement to report only information directly related to Medicare Part D drugs places a significant burden on the LTC pharmacies as well as the Part D plans to allocate rebates to Part D drugs.

- The CMS template assumes that rebates applicable to Medicare Part D reported on a utilization basis:
  - Rebates earned by LTC pharmacies are based on product purchasing, not dispensing the drug product. The rebate earned/accrued/paid in any quarter may not represent the applicable rebates per dispensed products because of use of stock from prior quarter purchases. For example, if a LTC pharmacy purchased a six (6) month supply of a product, the rebate would accrue in the quarter when the drug was purchased, not dispensed and paid in a subsequent quarter. Furthermore, unlike rebates earned by Part D plans for paid claims, LTC pharmacies may return products to the wholesaler or manufacturer, thus debiting their rebates after accrual or payment.
- To facilitate utilization reporting by the Part D Plans, the NCPDP task group “unanimously” agreed that the most productive reporting format for LTC pharmacies to report rebates and “other price concessions” is by units (pills, ml, etc.):
  - The “unit method” allows LTC pharmacies to report the same information in the same format to all Part D plans. Upon receipt, each Part D plan would allocate the reported dollars per unit by the quantity of units of drug reimbursed by the Part D plan for the quarter, by CMS contract (LTC pharmacies do not know which CMS contract the member is covered under). This method would place a burden on the LTC pharmacies to create a per unit fee and for the Part D plans to allocate to utilization each quarter and for prior quarters.
  - Although the “unit method” is the preferred approach, the NCPDP task group has identified several issues.
    - LTC pharmacies are paid rebates by brand product, e.g., Lipitor, not necessarily by the brand’s particular strength or method of administration. Rebates are not reported by the NDC of the product purchased. Without the NDC, Part D plans will be challenged with accurately allocating rebates to dispensed products because a manufacturer arrangement may exclude certain NDC’s from rebates, such as those for vials (the Part D plan will not have sufficient detail without the NDC to exclude vials because rebate agreements may differ by manufacturer and pharmacy) in the allocation of the rebates per unit to the number of units dispensed. Therefore, the reporting will be inaccurate and overstated because the Part D plan must allocate the rebates based on the more general “brand name”. Despite the significant burden to many LTC pharmacies to allocate their earned rebates to the original NDC



purchased, Part D plans must receive rebate and “other pricing concession” unit prices at the NDC level.

- Formulary status of the drug will drive utilization, thus the amounts of rebate dollars reported to CMS. Part D plans will only report on those drugs that the Part D plan paid for and in the quantity that they paid for, i.e., formulary, transition/emergency supply drugs, and exception drugs. Therefore, each Part D plan will report data skewed toward their own formulary drugs and may report few rebates earned for drugs that are not on the Part D plan’s formulary or placed on a non-preferred tier.
- While CMS recognizes the highly sensitive and confidential nature of the rebate information that will be reported to them, the rebate information (at the unit level) is shared with Part D plans that may or may not have comparable rebates agreements for those drugs with the manufacturers. LTC pharmacies have expressed concern about violating the manufacturer rebate agreement confidentiality clauses by sharing rebate information with a Part D plan, such as a PBM, (not with CMS directly)
- An alternative to the “unit method” is for LTC pharmacies to report all rebates and “other price concession” at the aggregate level, i.e., the total dollar amount earned within a quarter for each brand product:
  - The “aggregate method” is problematic because LTC pharmacies earn rebates regardless of product lines (commercial, Medicaid, and Medicare etc) and lines of business (retail and LTC lines of business). Also, chains that own multiple LTC pharmacies may be unable to allocate rebate amounts to the NCPDP level as required by the CMS reporting requirement because purchasing is handled centrally (other than straight line division). Because LTC rebates don’t distinguish by lines of business or product, the “aggregate method” reports information beyond the scope of the CMS requirements (limit to Part D drugs).
  - Part D plans question their contractual right to require disclosure of aggregate rebate information that incorporates all lines of products and business given that the contracts with the LTC pharmacies are specific to Medicare Part D covered services, not all product lines. LTC pharmacies may dispute disclosing aggregate rebate amounts to the Part D plans for lines of business and products or drugs not reimbursed by the Part D plan.
  - Part D plans are not able to allocate aggregate rebate information to the appropriate contract as required by CMS. LTC pharmacies are unable to report rebates by Part D contract with CMS. For those Part D plans with a national network attached to each contract, the Part D plans will submit all the rebate information even if no claims were processed by that pharmacy under the contract. The “aggregate method” significantly overstates the rebates earned for a Part D contract.

- LTC pharmacies are concerned about potential manufacturer confidentiality clause violations by disclosing rebates information to Part D plans rather than CMS directly. In some situations, LTC pharmacies will be reporting rebates earned on drugs not reimbursed by the Part D plan.
- Termination from the LTC network is the only remedy for non-compliance.
  - All LTC pharmacies participating in the network must report the access/performance “rebates” and “other pricing concessions”, at the NCPDP level by manufacturer and drug product, on a quarterly basis, as a condition for participation in the Part D LTC network. Part D plans interpret the regulations to require that any LTC pharmacy that fails to provide the information quarterly (and certify accuracy) may not participate in the network.
    - Termination of network participation may cause potential member disruption. While overall potential member disruption may be limited because all Part D plans will have generally similar requirements for network participation, differing interpretations and requirements by Part D plans and differing abilities by LTC pharmacies to comply with the requirements may lead to non-participation by a LTC pharmacy in a Part D plans network – thus member disruption.
    - CMS does not specify what happens if a Part D plan fails to report the required information for an individual pharmacy and whether any cure period exists for the Part D plan to report delayed LTC pharmacy information to CMS. Also, to what extent does a Part D plan have to accommodate those LTC pharmacies that fail to meet reasonable timeframes for data submission without being in violation of CMS requirements?
    - The only remedy that Part D plans have for non-compliance, termination of network participation, conflicts with CMS’s goal of access to a network pharmacy for all LTC patients.
- The task group also had questions for CMS:
  - Purpose (s) CMS will use the LTC pharmacy rebate information provided by the PDPs?
  - Will CMS only be using this information in order to gauge “best pricing” in the market place?
  - Will CMS use the reported rebate amounts to lower reimbursement to the PDPs?
  - Will CMS use the reported rebate amounts for risk-corridor adjustments to the PDPs?
  - Why is not reporting required for all pharmacies dispensing (retail, chains, combo, mail service)

## Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements

- No comment

## Section XV. Drug Benefit Analyses

- No comment

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



**CENTER FOR BENEFICIARY CHOICES**

---

*Red 8/4 on Monday*

**Date:** June 21, 2006  
**To:** All Part D Plan Sponsors  
**Fm:** Gary Bailey, Deputy Director  
**Subject:** 60 Day Public Comment Period for 2007 Part D Reporting Requirements

In compliance with the Paperwork Reduction Act of 1995, CMS has published the current 2007 Reporting requirements document for a 60 day public comment period. This current version already reflects changes made to the initial draft in response to comments received during the first 30 day comment period this Spring. The document may be downloaded at <http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/list.asp> under CMS document #CMS-10185, Medicare Part D Reporting Requirements.

To be assured consideration, comments and recommendations must be received no later than 5 p.m. on **August 15, 2006**. Comments and recommendations should be sent to:

CMS, Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development—A  
Attention: Melissa Musotto, Room C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

# **MEDICARE PART D REPORTING REQUIREMENTS Contract Year 2007**

Updated: 04/14/06

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-00992. The time required to complete this information collection is estimated to average 32 hours annually per respondent, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

## Table of Contents

Introduction .....	1
Section I. Enrollment/Disenrollment .....	3
Section II. Reversals.....	4
Section III. Medication Therapy Management Programs .....	5
Section IV. Generic Dispensing Rate.....	6
Section V. Grievances .....	7
Section VI. Pharmacy & Therapeutics (P&T) Committees.....	9
Section VII. Transition.....	10
Section VIII. Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions.....	11
Section IX. Appeals.....	12
Section X. Call Center Measures: Beneficiary Service line and Pharmacy Support line .....	14
Section XI. Overpayment.....	15
Section XII. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions.....	16
Section XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies.....	18
Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements .....	20
Section XV. Drug benefit analyses.....	23
Appendix .....	24
Table 1. Summary of Reporting Elements .....	24

## **Introduction**

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the new Medicare Part D benefit. In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D Sponsor to have an effective procedure to provide statistics indicating:

- 1) the cost of its operations
- 2) the patterns of utilization of its services
- 3) the availability, accessibility, and acceptability of its services
- 4) information demonstrating it has a fiscally sound operation
- 5) other matters as required by CMS

The purpose of this document is to assure a common understanding of reporting requirements and how these data will be used to monitor the prescription drug benefit provided to Medicare beneficiaries. This document represents current expectations of data elements to be reported by Part D Sponsors at the distinct Plan level (i.e., data will be reported for each Plan offered under each Part D Contract) unless otherwise specified, reporting timeframes, and monitoring of Part D sponsors. These requirements will be in effect for Contract Year 2007 and are subject to change at the discretion of CMS. According to Subpart O, sanctions may be imposed on Part D Sponsors who fail to comply with these reporting requirements.

The following criteria were used in selecting reporting requirements:

- 1) Minimal administrative burden on Part D Sponsors
- 2) Legislative and regulatory authority
- 3) Validity, reliability, and utility of data elements requested
- 4) Wide acceptance and current utilization within the Industry

Reporting requirements are described in this document for the following areas: Enrollment and Disenrollment, Reversals, Medication Therapy Management Programs, Generic Dispensing Rate, Grievances, Pharmacy & Therapeutics (P&T) Committees, Transition, Prior Authorization/Step Edits/Non-Formulary Exceptions, Appeals, Call Center Measures – Beneficiary Service line and Pharmacy Support line, Overpayment, Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions, Licensure and Solvency, Business Transactions and Financial Requirements, and Drug Benefit Analyses.

Each Part D Sponsor shall provide necessary data to CMS to support payment, program integrity, program management, and quality improvement activities. Specifically, additional reporting requirements are identified in separate guidance documents for the following areas: formulary, TrOOP, coordination of benefits, payment and 1/3 audit, Direct Contract Employer Group Waiver Plans (Direct EGWPs), Employer Group Waiver Plans (EGWPs), and low income subsidy.

Part D Sponsors may also be required to submit other information as defined by requirements in the application, guidances, or other documents (e.g. pharmacy access and formularies) during the annual contract bidding, application, or renewal process. Information is also required to be submitted throughout the contract year as allowable changes are made (e.g. formulary changes).

### **Part D Sponsor Reporting Requirements**

In each of the sections that follow, the method of submission (e.g. entered into or uploaded via the Health Plan Management System (HPMS)) and the level of reporting are specified following the reporting timeline. Sections that refer to prescriptions should encompass all drugs, including compounded drugs.

For PACE Organizations offering Part D coverage, reporting requirements will be limited to: Section I. Enrollment/Disenrollment; Section IV. Generic Dispensing Rate; Section VI. Pharmacy & Therapeutics (P&T) Committees (for PACE Organizations utilizing formularies); Section VII. Transition (for PACE Organizations utilizing formularies); Section VIII. Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions (for PACE Organizations utilizing formularies); Section XI. Overpayment; Section XII. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions; and Section XIII. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions for Long Term Pharmacies.

MA-PD Organizations will be required to comply with all reporting requirements contained herein, with the exception of those found in Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements.



## Section I. Enrollment/Disenrollment

Title I, Part 423, Subpart B includes regulations regarding beneficiary eligibility and enrollment. CMS will request enrollment data as part of the monitoring of a Plan's availability, accessibility, and acceptability of its services. Part D Sponsors will be responsible for reporting multiple data elements related to beneficiary enrollment at the Plan level.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Number of non-LIS beneficiaries enrolled in the Plan as of the end date of the reporting period identified above. This should be a numeric field.
- B. Number of all LIS (full and partial) beneficiaries enrolled in the Plan as of the end date of the reporting period identified above. This should be a numeric field.
- C. Number of non-LIS beneficiaries who disenrolled for any reason from the Plan any time during the reporting period identified above. This should be a numeric field.
- D. Number of all LIS (full and partial) beneficiaries who disenrolled for any reason from the Plan any time during the reporting period identified above. This should be a numeric field.
- E. Number of non-LIS beneficiaries who were involuntarily disenrolled from the Plan for failure to pay their premium during the reporting period identified above. Please refer to 423.44 (d) (1) for exact definitions and requirements. This should be a numeric field.
- F. Number of all LIS (full and partial) beneficiaries who were involuntarily disenrolled from the Plan for failure to pay their premium during the reporting period identified above. Please refer to 423.44 (d) (1) for exact definitions and requirements. This should be a numeric field.
- G. Number of non-LIS beneficiaries who were involuntarily disenrolled from the Plan for disruptive behavior during the reporting period identified above. Please refer to 423.44 (d) (2) for exact definitions and requirements. This should be a numeric field.
- H. Number of all LIS (full and partial) beneficiaries who were involuntarily disenrolled from the Plan for disruptive behavior during the reporting period identified above. Please refer to 423.44 (d) (2) for exact definitions and requirements. This should be a numeric field.
- I. Number of non-LIS beneficiaries who were disenrolled from the Plan for providing false or incomplete information regarding other coverage. This should be a numeric field.
- J. Number of all LIS (full and partial) beneficiaries who were disenrolled from the Plan for providing false or incomplete information regarding other coverage. This should be a numeric field.
- K. Number of non-LIS beneficiaries who were disenrolled from the Plan because of death during the reporting period identified above. This should be a numeric field.
- L. Number of all LIS (full and partial) beneficiaries who were disenrolled from the Plan because of death during the reporting period identified above. This should be a numeric field.
- M. Number of non-LIS beneficiaries who were disenrolled from the Plan because of moving from the service area during the reporting period identified above. This should be a numeric field.
- N. Number of all LIS (full and partial) beneficiaries who were disenrolled from the Plan because of moving from the service area during the reporting period identified above. This should be a numeric field.
- O. Number of non-LIS beneficiaries who were disenrolled from the Plan because of a reason other than those listed above during the reported time period identified above. This should be a numeric field.
- P. Number of all LIS (full and partial) beneficiaries who were disenrolled from the Plan because of a reason other than those listed above during the reported time period identified above. This should be a numeric field.

**Section II. Reversals**

Part D Sponsors will be responsible for reporting data elements related to claim reversals. Information on claim reversals will serve as a component in the monitoring of operational functions of Part D programs.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Provide the total number of out-of-cycle pharmacy transactions with reversal as the final disposition, which were adjudicated during the time period specified above. This should be a numeric field.

Note: Reversed claim records must be maintained (the number of elements retained per record should at a minimum be equivalent to those of the prescription drug event record), and upon request, submitted to CMS.

**Section III. Medication Therapy Management Programs**

The requirements stipulating that Part D Sponsors provide Medication Therapy Management Programs (MTMP) are described in Title I, Part 423, Subpart D, § 423.153. For monitoring purposes, Part D Sponsors will be responsible for reporting several data elements related to their MTMP.

Data related to the identification and participation in the MTMP will be submitted according to the following timeline (note: Period 2 encompasses one full year):

	<b>Period 1</b>	<b>Period 2</b>
<b>Reporting Period</b>	January 1 - June 30	January 1 - December 31
<b>Data due to CMS/HPMS</b>	August 31	February 29

Data elements to be entered into the HPMS at the Part D Contract level or Plan level whenever available:

- A. The method used to enroll beneficiaries into the MTMP. Method of enrollment may be opt-in, opt-out, a combination of opt-in and opt-out, or other. This should be a text field.
- B. The number of beneficiaries who met the eligibility criteria for the MTMP in the specified time period above. This should be a numeric field.
- C. The total number of beneficiaries who participated in the MTMP at any point during the time period specified above. This should be a longitudinally cumulative total. This should be a numeric field.
- D. The total number of beneficiaries who discontinued participation from the MTMP at any time during the specified time period above. This should be a numeric field.
- E. The number of beneficiaries who discontinued participation from the MTMP due to death at any time during the specified time period above. This should be a numeric field.
- F. The number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Plan at any time during the specified time period above. This should be a numeric field.
- G. The number of beneficiaries who discontinued participation from the MTMP at their request at any time during the specified time period above. This should be a numeric field.
- H. The number of beneficiaries who declined to participate in the MTMP during the specified time period above. This should be a numeric field.
- I. For each beneficiary participating in the MTMP as of the last day of the reporting period specified, provide the total prescription cost of all medications on a per MTMP beneficiary per month basis. This should be a currency field. The total prescription cost should include MTMP beneficiary cost sharing and Part D Sponsor costs paid, exclusive of premiums or rebates, and should be calculated as follows: (AWP – network discounts + tax + dispensing fee). This amount should be summed for all prescriptions that were dispensed within the reporting period specified for each beneficiary enrolling in the MTMP as of the last day of the reporting period specified. Finally, this sum should be divided by the total number of member months for the included beneficiaries. These member months should include all months enrolled in the Part D Plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation

$$\left[ \begin{array}{l} \text{Total prescription cost} \\ \text{per MTMP beneficiary} \\ \text{per month} \end{array} \right] = \frac{\sum_i^n \left( \sum_j^m (\text{AWP} - \text{network discounts} + \text{tax} + \text{dispensing fee}) \right)}{\sum_i^n (\text{Member Months in Reporting Period})}$$

{For beneficiaries  $i$  to  $n$ , and prescriptions  $j$  to  $m$  from the  $i^{\text{th}}$  beneficiary}

- J. For beneficiaries participating in the MTMP as of the last day of the reporting period specified, provide the average number of covered Part D 30-day equivalent prescriptions per beneficiary per month. This should be a numeric field.

**Section IV. Generic Dispensing Rate**

Cost control requirements for Part D Sponsors are presented in Title I, Part 423, Subpart D. Accordingly, Part D Sponsors will be responsible for reporting data elements needed to monitor utilization of generic drugs (defined by Title I, Part 423, Sub-Part A, § 423.4).

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Number of paid claims for generic drugs (regardless of days supply) with dates of service during the specified reporting period identified above. First DataBank or Medispan generic drug classifications will be used to identify generic drugs. This should be a numeric field.
- B. Total number of paid claims (regardless of days supply) with dates of service during the specified reporting period identified above. This should be a numeric field.

**Section V. Grievances**

Title I, Part 423, Subpart M of the regulation includes regulations that require Part D Sponsors to maintain grievance information. Plans will be responsible for reporting data related to grievances received.

A grievance is defined as any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D Sponsor, regardless of whether remedial action is requested. Examples of subjects of a grievance provided in the solicitation for applications include, but are not limited to, timeliness, appropriateness, access to, and/or setting of services provided by the PDP sponsor, concerns about waiting times, demeanor of pharmacy or customer service staff, a dispute concerning the timeliness of filling a prescription or the accuracy of filling the prescription.

Part D Plans are required by the regulations to track and maintain records on all grievances received orally and in writing. Grievance data, requested herein by CMS, should be reported based on the date the grievance was received by the Part D Plan, not the date the event or incident that precipitated the grievance occurred. Multiple grievances by a single complainant should be tracked and followed as separate grievances.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. For the time period identified above, provide the number of fraud and abuse grievances received related to Part D. A fraud grievance is a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Part D Plan, or beneficiary engaged in the intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or some other person. An abuse grievance is 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. This should be a numeric field.
- B. For the time period identified above, provide the number of enrollment/disenrollment grievances received related to Part D. Examples include, but are not limited to, discrimination in the enrollment process, enrollment information and/or identification cards not being received by beneficiaries in a timely manner, and disenrollment requests not being processed in a timely manner. This should be a numeric field.
- C. For the time period identified above, provide the number of benefit package grievances received related to Part D. Examples include, but are not limited to, beneficiary cost sharing, pricing co-insurance issues and issues related to coverage during the coverage gap period. This should be a numeric field.
- D. For the time period identified above, provide the number of pharmacy access/network grievances received related to Part D. Examples include, but are not limited to, network pharmacy refusing to accept a beneficiary's card and network/non-network pharmacy concerns. This should be a numeric field.
- E. For the time period identified above, provide the number of marketing grievances received related to Part D. Examples include, but are not limited to, marketing materials or promotional messages by sales representatives that include misrepresentations or false/misleading information about

- plans and benefits, and discriminatory practices identified in marketing materials or through oral/written promotional messages. This should be a numeric field.
- F. For the time period identified above, provide the number of customer service grievances received related to Part D. Examples include, but are not limited to, grievances regarding services provided by the pharmacist/pharmacy staff, plan or subcontractor representatives, or customer service representatives. This should be a numeric field.
  - G. For the time period identified above, provide the number of confidentiality/privacy grievances received related to Part D. Examples include, but are not limited to, potential violations of medical information privacy standards by the plan or pharmacy. This should be a numeric field.
  - H. For the time period identified above, provide the number of quality of care grievances received related to Part D. Examples include, but are not limited to, grievances received from beneficiaries or Quality Improvement Organizations (QIOs) regarding quality of care. This should be a numeric field.
  - I. For the time period identified above, provide the number of transition grievances received related to Part D. Examples include, but are not limited to, issues related to pharmacies not included in network, and formulary issues not related to exceptions or appeals. This should be a numeric field.
  - J. For the time period identified above, provide the number of exception grievances received related to Part D. An example of an exception grievance is one which is filed because an enrollee's request to have their coverage determination expedited was denied. This should be a numeric field.
  - K. For the time period identified above, provide the number of appeal grievances received related to Part D. An example of an appeal grievance is one which is filed because an enrollee's request to have a redetermination expedited was denied. This should be a numeric field.
  - L. For the time period identified above, provide the number of other grievances received related to Part D not falling into one of the categories described above. This should be a numeric field.
  - M. For the time period identified above, provide the total number of grievances received related to Part D. This should be a numeric field.
  - N. For the time period identified above, provide the number of grievances related to Part D that received a response by the Plan in accordance to the MMA defined timeframe (including those granted extensions). Response by the Plan includes notification to the enrollee of the Plan's disposition. This should be a numeric field.
  - O. For the time period identified above, provide the average number of days for the Plan to complete disposition and notification of all standard grievances. This should be a numeric field.
  - P. For the time period identified above, provide the average number of hours for the Plan to complete disposition and notification of all expedited grievances. This should be a numeric field.

## Section VI. Pharmacy & Therapeutics (P&T) Committees

In addition to satisfying and maintaining P&T committee requirements described in §423.120, Part D Sponsors will be responsible for providing information to CMS relating to changes made during a contract year to their P&T committees on a periodic basis.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Contract level:

- A. For each new P&T committee member added since the previous reporting period, provide the following:
  - a. First name. This should be a text field.
  - b. Middle name. This should be a text field.
  - c. Last name. This should be a text field.
  - d. Name suffix (e.g. Sr, Jr). This should be a text field.
  - e. Date of birth. This should be a date field.
  - f. Credential (e.g. MD, PharmD, RN, etc). This should be a text field.
  - g. Effective start date of P&T membership. This should be a date field.
  - h. If applicable, effective termination date of P&T membership. This should be a date field.
  - i. Indication if this individual is a practicing physician or pharmacist. This should be a text field.
  - j. Indication if this individual is independent and free of conflict from the Part D Sponsor, Part D plan, and Pharmaceutical manufacturers. This should be a text field.
  - k. Indication if this individual is an expert in the care of elderly or disabled individuals. This should be a text field.
- B. For each P&T committee member terminating P&T membership since the previous reporting period, provide the following:
  - a. First name. This should be a text field.
  - b. Middle name. This should be a text field.
  - c. Last name. This should be a text field.
  - d. Name suffix (e.g. Sr, Jr) . This should be a text field.
  - e. Date of birth. This should be a date field.
  - f. Credential (e.g. MD, PharmD, RN, etc). This should be a text field.
  - g. Effective termination date of P&T membership. This should be a date field.

## Section VII. Transition

As described in §423.120 and other guidance issued by CMS, Part D Sponsors must maintain and implement an effective transition process to ensure that beneficiaries transitioning into a Plan are provided a smooth transition to drugs on the formulary. Part D Sponsors will be responsible for reporting various data elements related to their transition process for CMS oversight.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Contract level:

- A. Total number of newly enrolled beneficiaries during the reporting time period. This should be a numeric field.
- B. Number of prescriptions authorized via transition policy during the reporting time period. This should be a numeric field.
- C. Number of enrollees receiving one or more prescriptions via transition policy during the reporting time period. This should be a numeric field.



**Section VIII. Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions**

Title I, Part 423, Subpart D includes regulations regarding drug utilization management programs. Part D Plans that utilize prior authorization or step therapy edits as utilization management tools (including for non-formulary exceptions) will be responsible for reporting several data elements related to these activities.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Number of pharmacy transactions rejected due to failure to complete step therapy edit requirements in the time period specified above. This should be a numeric field.
- B. Number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills) in the time period specified above. This should be a numeric field.
- C. Number of prior authorizations requested for formulary medications in the time period specified above (not including first pass step therapy edits or early refills). This should be a numeric field.
- D. Number of prior authorizations approved for formulary medications in the time period specified above (not including first pass step therapy edits or early refills). This should be a numeric field.
- E. Number of exceptions requested for non-formulary medications in the time period specified above (not including early refills). This should be a numeric field.
- F. Number of exceptions approved for non-formulary medications in the time period specified above (not including early refills). This should be a numeric field.
- G. Number of exceptions requested for tier exceptions in the time period specified above (not including first pass step therapy edits or early refills). This should be a numeric field.
- H. Number of exceptions approved for tier exceptions in the time period specified above (not including first pass step therapy edits or early refills). This should be a numeric field.

**Section IX. Appeals**

Title I, Part 423, Subpart M includes regulations regarding coverage determinations and appeals under Part D. As defined in §423.560, an appeal is any of the procedures that deal with the review of adverse coverage determinations made by the Part D Sponsor on the benefits under a Part D Plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage. These procedures include redeterminations by the Plan and reconsiderations by the independent review entity (IRE). Redeterminations or reconsiderations may result in reversal or partial reversal of the original decision.

- Example of a reversal of an original decision: Non-formulary exception request approved upon redetermination for drug and quantity prescribed.
- Example of a partial reversal of an original decision: Non-formulary exception request approved upon redetermination for drug, but full quantity prescribed is not approved.

CMS will request appeal data as part of the monitoring of a Plan's availability, accessibility, and acceptability of its services.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Number of appeals submitted for **standard** redetermination in the time period specified above. This should be a numeric field.
- B. Number of appeals submitted for **expedited** redetermination in the time period specified above. This should be a numeric field.
- C. Number of appeals submitted for **expedited** redetermination that were granted **expedited status**. This should be a numeric field.
- D. Number of appeals submitted for **standard** redetermination withdrawn by the enrollee. This should be a numeric field.
- E. Number of appeals submitted for **expedited** redetermination withdrawn by the enrollee. This should be a numeric field.
- F. Number of redeterminations resulting in reversal of original decision. This should be a numeric field.
- G. Number of redeterminations resulting in partial reversal of original decision. This should be a numeric field.
- H. Number of adverse redeterminations due to insufficient evidence of medical necessity from enrollee's prescribing physician. This should be a numeric field.
- I. Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **coverage determination**. This should be a numeric field.
- J. Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **redetermination**. This should be a numeric field.
- K. Number of IRE decisions for **standard** reconsideration resulting in reversal of original coverage determination or redetermination. This should be a numeric field.
- L. Number of IRE decisions for **standard** reconsideration resulting in partial reversal of original coverage determination or redetermination. This should be a numeric field.
- M. Number of IRE decisions for **expedited** reconsideration resulting in reversal of original coverage determination or redetermination. This should be a numeric field.
- N. Number of IRE decisions for **expedited** reconsideration resulting in partial reversal of original coverage determination or redetermination. This should be a numeric field.

- O. Number of IRE decisions for **standard** reconsideration resulting in upholding of original coverage determination or redetermination. This should be a numeric field.
- P. Number of IRE decisions for **expedited** reconsideration resulting in upholding of original coverage determination or redetermination. This should be a numeric field.
- Q. Average number of hours for the Plan to complete **standard** redeterminations (excluding those redeterminations forwarded to the IRE due to failure to meet the 7 day timeframe). This should be a numeric field.
- R. Average number of hours for the Plan to complete **expedited** redeterminations (excluding those redeterminations forwarded to the IRE due to failure to meet the 72 hour timeframe). This should be a numeric field.

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

Part D Sponsors will report several data elements related to customer service center calls related to Part D. This information will be utilized to monitor plan performance. 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) and Part D Sponsors must note in HPMS the level of reporting provided. Also, while call centers may track other metrics such as calls related to medical care, calls related in any matter to Part D should be tracked separately for inclusion in this reporting requirement.

Reporting timeline: Part D Sponsors will provide monthly data on a quarterly basis to CMS.

	Quarter 1			Quarter 2			Quarter 3			Quarter 4		
<b>Reporting Period</b>	1/1 – 1/31	2/1 – 2/28	3/1 – 3/31	4/1 – 4/30	5/1 – 5/31	6/1 – 6/30	7/1 – 7/31	8/1 – 8/31	9/1 – 9/30	10/1 – 10/31	11/1 – 11/30	12/1 – 12/31
<b>Data due to CMS/HPMS</b>	May 31			August 31			November 30			February 29		

Data elements to be entered into the HPMS at the Part D Contract level or Plan level whenever available:

- A. For the time period specified above, provide the total number of inbound Part D connections abandoned to the Beneficiary Service line. This should be a numeric field. For Part D Sponsors that cannot separate abandoned Part D calls from other calls, the total number of inbound connections abandoned will be reported and also the total number of inbound calls for the customer service center, during the reporting period specified.
- B. For the time period specified above, provide the total number of inbound Part D connections abandoned to the Pharmacy Support line. This should be a numeric field. For Part D Sponsors that cannot separate abandoned Part D calls from other calls, the total number of inbound connections abandoned will be reported and also the total number of inbound calls for the customer service center, during the reporting period specified.
- C. For the time period specified above, provide the total number of inbound Part D calls to the Beneficiary Service line. This should be a numeric field.
- D. For the time period specified above, provide the total number of inbound Part D calls to the Pharmacy Support line. This should be a numeric field.
- E. For the time period specified above, provide the average speed of answer for Part D calls to the Beneficiary Service line. This is defined as the time it takes to get an inbound call connected to a customer service representative, excluding time navigating an IVR. This should be a numeric field (mm:ss).
- F. For the time period specified above, provide the average speed of answer for Part D calls to the Pharmacy Support line. This is defined as the time it takes to get an inbound call connected to a customer service representative, excluding time navigating an IVR. This should be a numeric field (mm:ss).
- G. For the time period specified above, provide the number of Part D calls to the Beneficiary Service line answered in ≤30 seconds. This should be a numeric field.
- H. For the time period specified above, provide the number of Part D calls to the Pharmacy Support line answered in ≤30 seconds. This should be a numeric field.
- I. For the time period specified above, provide the number of calls to the Beneficiary Service line completed with issue resolved and not requiring a call back. This should be a numeric field.
- J. For the time period specified above, provide the number of calls to the Pharmacy Support line completed with issue resolved and not requiring a call back. This should be a numeric field.
- K. For the time period specified above, provide the average length of calls to the Beneficiary Support line. This should be a numeric field (mm:ss).
- L. For the time period specified above, provide the average length of calls to the Pharmacy Support line. This should be a numeric field (mm:ss).

## Section XI. Overpayment

Part D Sponsors will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Sponsor erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit. Examples would include overpayments a plan makes to pharmacies, sub-contractors, or PBMs for claims payment. This information is necessary to ensure that overpayments are being identified and recouped appropriately.

Reporting timeline:

	Period 1	Period 2
<b>Reporting Period</b>	January 1 - June 30	July 1 – December 31
<b>Data due to CMS/HPMS</b>	August 31	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. For the time period identified above, provide the total overpayment dollars identified to be recouped by the Plan (i.e., any funds the Plan recovers from any entity it has overpaid, including, pharmacies, providers, Pharmaceutical Benefit Managers, etc.) This should be a currency field.
- B. For the time period identified above, provide the total overpayment dollars recouped by the Plan. This should be a currency field.

**Section XII. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions**

Part D Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D Sponsor's operational costs. 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 and will track those who have accessed these records.

Rebates, discounts, and other price concessions will be reported at the CMS Part D Sponsor level. Reporting will not be combined by the subcontractor PBM to include multiple Part D Sponsor data. For example: (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. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations. The quarterly reported totals are not cumulative YTD totals.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	September 30	December 31	March 31	June 30

Data files to be uploaded through the HPMS at the CMS Part D Sponsor level as specified above:

A. Part D Sponsors will provide an Excel file (filename=REBATES\_(SPONSORNAME)\_(2007Q#).XLS, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(2007Q#)' with the year and quarter number) with the first row of data containing all included Contract IDs in separate columns and then include information related to actual rebate dollars starting in the second row using the following columns in the order as listed (i.e., column headings will be listed in row 2 and data starting in row 3):

1. **MFG\_NAME:** For each rebate, provide the contracting manufacturer name. This should be a character field.
2. **BRAND\_NAME:** For each rebate, provide the brand name. This should be a character field.
3. **REBATE\_REC:** For each unique manufacturer/brand name combination, provide the rebate amount requested and received in the reporting period specified. This should be a numeric (currency) field.
4. **PEND\_REBATE:** For each unique manufacturer/brand name combination, provide the rebate amount requested but not yet received for the reporting period specified (if applicable). This should be a numeric (currency) field; enter zero if none.
5. **PRIOR\_REBATE:** For each unique manufacturer/brand name combination, provide any rebate amount(s) posted as pending rebates in a prior reporting period, and received in the current reporting period (if applicable). This should be a numeric (currency) field; enter zero if none.

Example:

H1234	H1235			
<b>MFG_NAME</b>	<b>BRAND_NAME</b>	<b>REBATE_REC</b>	<b>PEND_REBATE</b>	<b>PRIOR_REBATE</b>
<Data>	<Data>	\$X	\$X	\$X

B. It is expected that the file specified above will summarize most rebate information. However, for all non-rebate discounts, price concessions, or other value adds such as gift-in-kind or other programs (e.g., coupons or disease management programs specific to a Part D Sponsor), Part D Sponsors will

provide an additional Excel file (filename=DISCOUNTS\_(SPONSORNAME)\_(2007Q#).XLS, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(2007Q#)' with the year and quarter number) with the first row of data containing all included Contract IDs in separate columns and then include information related to the discounts, price concessions, or other value adds starting in the second row using following columns in the order as listed (i.e., column headings will be listed in row 2 and data starting in row 3):

1. **MFG\_NAME:** List the name of each manufacturer for whom there is an associated discount, price concession, or other value add. This should be a character field.
2. **DESCRIPTION:** Describe the discount, price concession, or other value add. This should be a character field.
3. **VALUE:** Provide the value of the discount, price concession, or other value add. This should be a currency field.
4. **JUSTIFICATION:** For each discount, price concession, or value add, provide a justification for receipt. This should be a character field.

Example:

H1234	H1235		
<b>MFG_NAME</b>	<b>DESCRIPTION</b>	<b>VALUE</b>	<b>JUSTIFICATION</b>
<Data>	<Data>	\$X	<Data>

**Section XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies**

As described in the CMS 2007 Call Letters, Part D Sponsors must require disclosure of access/performance rebates or other price concessions received by their LTC network pharmacies designed to or likely to influence or impact utilization of Part D drugs. The term "access/performance rebates" refers to rebates manufacturers provide to pharmacies that are designed to prefer, protect, or maintain that manufacturer's product selection by the pharmacy or to increase the volume of that manufacturer's products that are dispensed by the pharmacy under its formulary (referred to as "moving market share"). As evidence that they are managing and monitoring drug utilization, Part D Sponsors must report these data to CMS for oversight. 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 and will track those who have accessed these records.

Access/performance rebates received and reported by pharmacies will be reported at the CMS Part D Contract level. Data should only include rebates received for Part D covered drugs. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations. The quarterly reported totals are not cumulative YTD totals.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	September 30	December 31	March 31	June 30

Data files to be uploaded through the HPMS at the CMS Part D Contract level as specified above:

Part D Sponsors will provide an Excel file (filename=REBATES\_LTC PHARMACIES\_(SPONSORNAME)\_(2007Q#).XLS, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(2007Q#)' with the year and quarter number) with the first row of data containing all included Contract IDs in separate columns and then include information related to actual rebate dollars starting in the second row using the following columns in the order as listed (i.e., column headings will be listed in row 2 and data starting in row 3):

1. LTC PHARMACY NAME: Indicate the contracted LTC pharmacy name for which the listed rebate applies. This should be a character field.
2. LTC PHARMACY NCPDP Number: Indicate the contracted LTC pharmacy NCPDP number for which the listed rebates applies. This should be a numeric field.
3. MFG\_NAME: For each rebate, provide the contracting manufacturer name. This should be a character field.
4. BRAND\_NAME: For each rebate, provide the brand name. This should be a character field.
5. REBATE\_REC: For each unique manufacturer/brand name combination, provide the rebate amount requested and received in the reporting period specified. This should be a numeric (currency) field.
6. PEND\_REBATE: For each unique manufacturer/brand name combination, provide the rebate amount requested but not yet received for the reporting period specified (if applicable). This should be a numeric (currency) field; enter zero if none.
7. PRIOR\_REBATE: For each unique manufacturer/brand name combination, provide any rebate amount(s) posted as pending rebates in a prior reporting period, and received in the current reporting period (if applicable). This should be a numeric (currency) field; enter zero if none.

Example:

LTC Pharmacy,	1234567					
---------------	---------	--	--	--	--	--



USA						
LTC Pharmacy Name	LTC Pharmacy NCPDP # (or NPI # if available)	MFG_ NAME	BRAND_ NAME	REBATE_ REC	PEND_REBATE	PRIOR_REBATE
<Data>	<Number>	<Data>	<Data>	\$X	\$X	\$X

**Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements**

Title I, Part 423, Subpart I includes regulations regarding Licensure and Solvency. Part D PDP Sponsors will be responsible for reporting multiple data elements and documentation related to their licensure and solvency and other financial requirements. Some data will be entered into the HPMS and other information will be mailed directly to CMS. These data will be used to ensure Part D PDP Sponsors continue to be fiscally solvent entities. Additional requirements for Direct Contract Employer Group Waiver Plans (Direct EGWPs) are listed separately at the end of this section. Direct EGWPs are waived from reporting HPMS Data Element I, total administrative expenses.

Reporting timeline:

	<b>Quarter 1 YTD</b>	<b>Quarter 2 YTD</b>	<b>Quarter 3 YTD</b>	<b>Annual</b>
<b>Reporting Period</b>	January 1 - March 31	January 1 - June 30	January 1 - September 30	January 1 - December 31
<b>Data due to CMS/HPMS</b>	May 15	August 14	November 14	120 days after the end of the calendar year or within 10 days of the receipt of the Annual Audited F/S whichever is earlier

Financial and Solvency Requirements at the Part D PDP Sponsor Level:

- A. According to the quarterly time periods specified above, Part D PDP Sponsors that are licensed will mail the following completed Health Blank form pages directly to CMS:
    - Jurat
    - Assets
    - Liabilities, Capital and Surplus
    - Statement of Revenue and Expenses
    - Capital and Surplus Account
    - Cash Flow
- Note: CMS will accept a copy of the Health Blank form submitted to the state in its entirety.
- B. According to the quarterly time periods specified above, non-licensed Part D PDP Sponsors will mail un-audited financial statements, which convey the same information contained in the Health Blank form, directly to CMS. An alternative for non-licensed Part D PDP sponsors would be to complete the Health Blank pages as prescribed in A. above.
  - C. According to the quarterly time periods specified above, non-licensed Part D PDP Sponsors will mail documentation showing that an insolvency deposit of \$100,000 is being held in accordance with CMS requirements by a qualified financial institution.
  - D. According to the quarterly time periods specified above, non-licensed Part D PDP Sponsors in any state must submit a funding for projected losses worksheet demonstrating they possess the allowable sources of funding to cover projected losses for the greater of 7.5% of the aggregated projected target amount for a given year or resources to cover 100% of any projected losses in a given year. This documentation should also take into account modifications of previous projections and show how they arrived at the aggregated projected target amount. Guarantees, letters of credit and other documents essential to demonstrating that the funding for projected losses requirement has been met must also be included.

- E. All Part D PDP Sponsors will mail a copy of their independently audited financial statements (which are statutory based or GAAP based) with a management letter within one hundred twenty days following their fiscal year end or within 10 days of receipt of those statements, whichever is earlier directly to CMS.
- F. All Part D PDP Sponsors will mail a copy of an Actuarial Opinion by a qualified actuary within one hundred twenty days following their fiscal year end directly to CMS. The opinion should address the assumptions and methods used in determining loss revenues, actuarial liabilities, and related items.
- G. According to the quarterly time periods specified above, Part D PDP Sponsors with any state licensure waivers will mail documentation updating CMS on the status of obtaining licensure for each waived state.

Documentation being mailed to CMS should be sent to the following address\*:

Centers for Medicare & Medicaid Services  
 Attn: Part D Licensure & Solvency (C1-25-11)  
 7500 Security Boulevard  
 Windsor Mill, Maryland 21244

Additional Financial and Solvency Requirements for all Direct Contract Employer Group Waiver Plans (Direct EGWPs):

- A. All Direct EGWPs will mail a copy of their credit rating (or, if they have no credit rating, a Dun & Bradstreet report) on a quarterly basis directly to CMS as follows:
 

For Quarter 1:	May 15 <sup>th</sup>
For Quarter 2:	Aug. 14 <sup>th</sup>
For Quarter 3:	Nov. 14 <sup>th</sup>
For Quarter 4:	Feb. 15 <sup>th</sup>
- B. All Direct EGWPs will mail an ERISA Sec. 411(a) attestation directly to CMS by February 15<sup>th</sup>. See 2007 Solicitation for Application for Employer/Union Direct Contract PDPs, Appendix VI, Sec. E.4 for explanation of this attestation.

\*All Direct EGWPs related documentation being mailed to CMS should be sent to the following address:

Centers for Medicare & Medicaid Services  
 Attn: Financial Solvency Reporting (C1-22-06)  
 7500 Security Boulevard  
 Windsor Mill, Maryland 21244

Data elements to be entered into HPMS at the Part D Sponsor Level:

- A. Total assets as of the end of the quarterly reporting period identified above. This should be a currency field.
- B. Total liabilities as of the end of the quarterly reporting period identified above. This should be a currency field.
- C. Total cash as of the end of the quarterly reporting period identified above. This should be a currency field.
- D. Total cash equivalents as of the end of the reporting period identified above. This should be a currency field.
- E. Total current assets as of the end of the quarterly reporting period identified above. This should be a currency field.
- F. Total current liabilities as of the end of the quarterly reporting period identified above. This should be a currency field.
- G. Total revenue as of the end of the quarterly reporting period identified above. This should be a currency field.
- H. Total expenses as of the end of the quarterly reporting period identified above. This should be a currency field.

- I. Total administrative expense as of the end of the quarterly reporting period identified above. This should be a currency field.
- J. Total net income as of the end of the quarterly reporting period identified above. This should be a currency field.
- K. Drug benefit expenses (excluding administrative expenses) as of the end of the quarterly reporting time period. Drug benefit expenses are paid claims costs which would be comprised of negotiated costs and dispensing fees less member share. This should be a currency field.
- L. Drug benefit revenues as of the end of the quarterly reporting period. Drug benefit revenues would include premiums, CMS subsidies, rebates and other reinsurance. This should be a currency field.

**Section XV. Drug benefit analyses**

Part D sponsors must provide enrollees with coverage of benefits as described within §423.104. For the purposes of CMS review, sponsors will be required to report multiple data elements related to their provision of Part D benefits.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	May 31	August 31	November 30	February 29

Data elements to be entered into the HPMS at the Plan level:

- A. Provide the total number of enrollees in the pre-initial coverage limit phase as of the last day of the reporting period. This should be a numeric field.
- B. Provide the total number of enrollees in the coverage gap as of the last day of the reporting period. This should be a numeric field.
- C. Provide the total number of enrollees in the catastrophic coverage level as of the last day of the reporting period. This should be a numeric field.

## Appendix

**Table 1. Summary of Reporting Elements**

Note: this summary table is for quick reference use only. Please refer to the respective detailed sections for full definitions, timelines, reporting level, and submission procedures.

Section	Element	Format	Frequency	HPMS
Enrollment and Disenrollment	Number of non-LIS beneficiaries enrolled	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries enrolled	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who disenrolled for any reason	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who disenrolled for any reason	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were involuntarily disenrolled for failure to pay their premium	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were involuntarily disenrolled for failure to pay their premium	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were involuntarily disenrolled from the Plan for disruptive behavior	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were involuntarily disenrolled from the Plan for disruptive behavior	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were disenrolled from the Plan for providing false or incomplete information regarding other coverage	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were disenrolled from the Plan for providing false or incomplete information regarding other coverage	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were disenrolled from the Plan because of death	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were disenrolled from the Plan because of death	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were disenrolled from the Plan because of moving from the service area	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were disenrolled from the Plan because of moving from the service area	Numeric	Quarterly	Yes
	Number of non-LIS beneficiaries who were disenrolled from the Plan because of a reason other than those listed above	Numeric	Quarterly	Yes
	Number of all LIS beneficiaries who were disenrolled from the Plan because of a reason other than those listed above	Numeric	Quarterly	Yes
Reversals	Total number of out-of-cycle pharmacy transactions with reversal as the final disposition	Numeric	Quarterly	Yes
Medication Therapy Management Programs	The method used to enroll beneficiaries into the MTMP	Text	Semi-annually	Yes
	Number of beneficiaries who met the eligibility criteria for the MTMP	Numeric	Semi-annually	Yes

Section	Element	Format	Frequency	HPMS
(MTMP)	Number of beneficiaries who participated in the MTMP at any point during the specified time period	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP at any time during the specified time period	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP due to death at any time during the specified time period	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Plan at any time during the specified time period	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP at their request at any time during the specified time period	Numeric	Semi-annually	Yes
	Number of beneficiaries who declined to participate in the MTMP	Numeric	Semi-annually	Yes
	Total prescription cost of all medications for all beneficiaries participating in the MTMP (as of the last day of the reporting period specified) on a per MTMP beneficiary per month basis	Currency	Semi-annually	Yes
	Average number of covered Part D 30-day equivalent prescriptions per month for all beneficiaries participating in the MTMP (as of the last day of the reporting period specified)	Numeric	Semi-annually	Yes
Generic Dispensing Rate	Number of paid claims for generic drugs (regardless of days supply)	Numeric	Quarterly	Yes
	Total number of paid claims (regardless of days supply)	Numeric	Quarterly	Yes
Grievances	Number of fraud and abuse grievances received	Numeric	Quarterly	Yes
	Number of enrollment/disenrollment grievances received	Numeric	Quarterly	Yes
	Number of benefit package grievances received	Numeric	Quarterly	Yes
	Number of pharmacy access/network grievances received	Numeric	Quarterly	Yes
	Number of marketing grievances received	Numeric	Quarterly	Yes
	Number of customer service grievances received	Numeric	Quarterly	Yes
	Number of confidentiality/privacy grievances received	Numeric	Quarterly	Yes
	Number of quality of care grievances received	Numeric	Quarterly	Yes
	Number of transition grievances received	Numeric	Quarterly	Yes
	Number of exception grievances received	Numeric	Quarterly	Yes
	Number of appeal grievances received	Numeric	Quarterly	Yes
	Number of other grievances received	Numeric	Quarterly	Yes
	Total number of grievances	Numeric	Quarterly	Yes
	Number of grievances related to Part D that received a response by the Plan in accordance to the MMA defined timeframe (including those granted extensions).	Numeric	Quarterly	Yes
Average number of days to complete disposition and notification of all standard grievances.	Numeric	Quarterly	Yes	
Average number of hours to complete disposition and notification of all expedited grievances.	Numeric	Quarterly	Yes	
Pharmacy & Therapeutics	First name of each new P&T committee member	Text	Quarterly	Yes
	Middle name of each new P&T committee member	Text	Quarterly	Yes

Section	Element	Format	Frequency	HPMS
Committees	Last name of each new P&T committee member	Text	Quarterly	Yes
	Name suffix (e.g. Sr, Jr) of each new P&T committee member	Text	Quarterly	Yes
	Date of birth of each new P&T committee member	Date	Quarterly	Yes
	Credential (e.g. MD, PharmD, RN, etc) of each new P&T committee member	Text	Quarterly	Yes
	Effective start date of each new P&T committee member	Date	Quarterly	Yes
	Effective termination date of each new P&T committee member (if applicable)	Date	Quarterly	Yes
	Indication if each new P&T committee member is a practicing physician or pharmacist	Text	Quarterly	Yes
	Indication if each new P&T committee member is independent and free of conflict from the Part D Sponsor, Part D plan, and Pharmaceutical manufacturers	Text	Quarterly	Yes
	Indication if each new P&T committee member is an expert in the care of elderly or disabled individuals	Text	Quarterly	Yes
	First name of each terminating P&T committee member	Text	Quarterly	Yes
	Middle name of each terminating P&T committee member	Text	Quarterly	Yes
	Last name of each terminating P&T committee member	Text	Quarterly	Yes
	Name suffix (e.g. Sr, Jr) of each terminating P&T committee member	Text	Quarterly	Yes
	Date of birth of each terminating P&T committee member	Date	Quarterly	Yes
	Credential (e.g. MD, PharmD, RN, etc) of each terminating P&T committee member	Text	Quarterly	Yes
Effective termination date of each terminating P&T committee member	Date	Quarterly	Yes	
Transition	Number of newly enrolled beneficiaries during the time period specified	Numeric	Quarterly	Yes
	Number of prescriptions authorized via transition policy during the time period specified	Numeric	Quarterly	Yes
	Number of enrollees receiving one or more prescriptions via transition policy during the time period specified	Numeric	Quarterly	Yes
Prior Authorization, Step Edits, and Non-Formulary Exceptions	Number of pharmacy transactions rejected due to failure to complete step edit requirements	Numeric	Quarterly	Yes
	Number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills)	Numeric	Quarterly	Yes
	Number of prior authorizations requested for formulary medications (not including first pass step therapy edits or early refills)	Numeric	Quarterly	Yes
	Number of prior authorizations approved for formulary medications (not including first pass step therapy edits or early refills)	Numeric	Quarterly	Yes
	Number of exceptions requested for non-formulary medications (not including early refills)	Numeric	Quarterly	Yes
	Number of exceptions approved for non-formulary medications (not including early refills)	Numeric	Quarterly	Yes



Section	Element	Format	Frequency	HPMS
	Number of exceptions requested for tier exceptions (not including first pass step therapy edits or early refills)	Numeric	Quarterly	Yes
	Number of exceptions approved for tier exceptions (not including first pass step therapy edits or early refills)	Numeric	Quarterly	Yes
Appeals	Number of appeals submitted for <b>standard</b> redetermination	Numeric	Quarterly	Yes
	Number of appeals submitted for <b>expedited</b> redetermination	Numeric	Quarterly	Yes
	Number of appeals submitted for <b>expedited</b> redetermination that were granted <b>expedited</b> status	Numeric	Quarterly	Yes
	Number of appeals submitted for <b>standard</b> redetermination withdrawn by the enrollee	Numeric	Quarterly	Yes
	Number of appeals submitted for <b>expedited</b> redetermination withdrawn by the enrollee	Numeric	Quarterly	Yes
	Number of redeterminations resulting in reversal of original decision	Numeric	Quarterly	Yes
	Number of redeterminations resulting in partial reversal of original decision	Numeric	Quarterly	Yes
	Number of adverse redeterminations due to insufficient evidence of medical necessity from enrollee's prescribing physician	Numeric	Quarterly	Yes
	Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for <b>coverage determination</b>	Numeric	Quarterly	Yes
	Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for <b>redetermination</b>	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>standard</b> reconsideration resulting in reversal of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>standard</b> reconsideration resulting in partial reversal of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>expedited</b> reconsideration resulting in reversal of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>expedited</b> reconsideration resulting in partial reversal of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>standard</b> reconsideration resulting in upholding of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Number of IRE decisions for <b>expedited</b> reconsideration resulting in upholding of original coverage determination or redetermination	Numeric	Quarterly	Yes
	Average number of hours for the Plan to complete <b>standard</b> redeterminations (excluding those redeterminations forwarded to the IRE due to failure to meet the 7 day timeframe)	Numeric	Quarterly	Yes
	Average number of hours for the Plan to complete <b>expedited</b> redeterminations (excluding those redeterminations forwarded to the IRE due to failure to meet the 72 hour timeframe)	Numeric	Quarterly	Yes

Section	Element	Format	Frequency	HPMS
Call Center Measures: Beneficiary Service line and Pharmacy Support line	Total number of inbound Part D connections abandoned to the Beneficiary Service line	Numeric	Quarterly	Yes
	Total number of inbound Part D connections abandoned to the Pharmacy Support line	Numeric	Quarterly	Yes
	Total number of inbound Part D calls to the Beneficiary Service line	Numeric	Quarterly	Yes
	Total number of inbound Part D calls to the Pharmacy Support line	Numeric	Quarterly	Yes
	Average speed of answer for Part D calls to the Beneficiary Service line	Numeric	Quarterly	Yes
	Average speed of answer for Part D calls to the Pharmacy Support line	Numeric	Quarterly	Yes
	Number of Part D calls to the Beneficiary Service line answered in ≤30 seconds	Numeric	Quarterly	Yes
	Number of Part D calls to the Pharmacy Support line answered in ≤30 seconds	Numeric	Quarterly	Yes
	Number of calls to the Beneficiary Service line completed with the issue resolved and not requiring a call back	Numeric	Quarterly	Yes
	Number of calls to the Pharmacy Support line completed with the issue resolved and not requiring a call back	Numeric	Quarterly	Yes
	Average length of calls to the Beneficiary Service line	Numeric	Quarterly	Yes
	Average length of calls to the Pharmacy Support line	Numeric	Quarterly	Yes
	Overpayment	Total overpayment dollars identified to be recouped by the Plan	Currency	Semi-Annually
Total overpayment dollars recouped by the Plan		Currency	Semi-Annually	Yes
Pharmaceutical Rebates, Discounts, and Other Price Concessions	REBATES_(SPONSORNAME)_(2007Q#).XLS	MS Excel	Quarterly	Yes
	DISCOUNTS_(SPONSORNAME)_(2007Q#).XLS	MS Excel	Quarterly	Yes
Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies	REBATES_LTCPHARMACIES_(SPONSORNAME)_(2007Q#).XLS	MS Excel	Quarterly	Yes
Licensure and Solvency, Business Transactions and Financial Requirements	Licensed Part D PDP Sponsors will submit Completed Health Blank form pages: Jurat, Assets, Liabilities, Capital and Surplus, Statement of Revenue and Expenses, Capital and Surplus Account, and Cash Flow OR Non-licensed Part D PDP Sponsors will submit un-audited financial statements	Mailed to CMS	Quarterly	No
	Documentation showing that an insolvency deposit of \$100,000 is being held (for non-licensed Part D PDP Sponsors only)	Mailed to CMS	Quarterly	No
	Funding for projected losses worksheet (for non-licensed Part D PDP Sponsors only)	Mailed to CMS	Quarterly	No

Section	Element	Format	Frequency	HPMS
	Independently audited financial statement with a management letter	Mailed to CMS	Yearly (fiscal)	No
	Copy of an Actuarial Opinion by a qualified actuary	Mailed to CMS	Yearly (fiscal)	No
	Documentation on the status of obtaining licensure for each waived state (for Part D PDP Sponsors with any state licensure waivers only)	Mailed to CMS	Quarterly	No
	Total assets	Currency	Quarterly	Yes
	Total liabilities	Currency	Quarterly	Yes
	Total cash	Currency	Quarterly	Yes
	Total cash equivalents	Currency	Quarterly	Yes
	Total current assets	Currency	Quarterly	Yes
	Total current liabilities	Currency	Quarterly	Yes
	Total revenue	Currency	Quarterly	Yes
	Total expenses	Currency	Quarterly	Yes
	Total administrative expense	Currency	Quarterly	Yes
	Total net income	Currency	Quarterly	Yes
	Drug benefit expenses (excluding administrative expenses)	Currency	Quarterly	Yes
	Drug benefit revenues	Currency	Quarterly	Yes
Part D Benefit Analyses	Number of enrollees in the pre-initial coverage limit phase as of the last day of the reporting period	Numeric	Quarterly	Yes
	Number of enrollees in the coverage gap as of the last day of the reporting period	Numeric	Quarterly	Yes
	Number of enrollees in the catastrophic coverage level as of the last day of the reporting period	Numeric	Quarterly	Yes



45

August 14, 2006

CMS, Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development-A  
Attention: Melissa Musotto, Room C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Thank you for the opportunity to comment on the 2007 Part D Reporting Requirements. UCare Minnesota (UCare) has the following five comments.

**Section V. Grievances, page 8**

Data Element H: Number of quality of care grievances received related to Part D: This information is currently reported by the QIOs directly to CMS; therefore, requiring Part D Sponsors to report is duplicative. Reported in section F of the 8<sup>th</sup> Statement of work.

Data Element P: Reporting on average number of hours, instead of days, to complete disposition and notification of all expedited grievances, instead of days, will be burdensome and will add little value to reports. In addition, reporting days instead of hours fulfills the requirements of Federal Regulations because regulatory deadlines are in days.

**Section IX. Appeals, pages 12 and 13**

Data Element H: Number of adverse redeterminations due to insufficient evidence of medical necessity from an enrollee's prescribing physician. We assume this would be for Prior authorization or Tier or Formulary exceptions. Please clarify whether this reporting element is because the plan did not receive the information or that the information received did not support medical necessity.

Data Element Q: Reporting on average of hours, instead of days, for the plan to complete standard determinations, will be burdensome and will add little value to reports. IN addition, reporting days instead of hours fulfills the requirements of Federal Regulations because regulatory deadlines are in days.

**Section X. Call Center Measures, page 14**

Overall: We want to reiterate AHIP's comment that reporting at the contract level is extremely burdensome to plans. Developing a system to report at the plan level would be costly and would not add value to the current requirements. We believe that reporting at the contract level is appropriate because the contract level would detect the same problems/trends as reporting at the plan level.



THANK YOU AGAIN  
Thank you again for the opportunity to comment. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Keeley Kaziukewicz'.

Keeley Kaziukewicz  
Sr. Federal Programs Coordinator  
UCare Minnesota  
(612) 676-3367

#6



**EXPRESS SCRIPTS®**  
*Charting the Future of Pharmacy*

13900 Riverport Drive, STL105  
Maryland Heights, MO 63043

**Rebecca Rabbitt, MS, PharmD**  
Senior Director  
Product Management

314.702.7863  
800.332.5455 ext. 36.7863  
Fax: 314.702.7993

rebecca.rabbitt@express-scripts.com

www.express-scripts.com



**EXPRESS SCRIPTS®**  
*Charting the Future of Pharmacy*

www.express-scripts.com

Comments -  
Reporting -  
Send to CMS

#6

Report	Question
MTM Report	Is data element "E" a subset of "D"?
MTM Report	Does death result in disenrollment from the plan? Where is it counted (data element "F")?
MTM Report	Can this report be provided at the contract level since MTM programs were approved at the Contract Level?
MTM Report	How does P2P transfer affect this report? When targeting members for MTM, do we include TDS transferred from other plans?
MTM Report	Should D=E+F+G or are there "other" reasons not accounted for?
MTM Report	In reference to element J, how do we handle 10-day supplies (i.e. antibiotics)?
MTM Report	Should this report be limited to Part D only drugs?
Call Center	The requirements for 2007 require that the Pharmacy Help Desk calls be reported (they were not required in 2006). Does this mean that each client should have its own Pharmacy Help Line? Requiring a client specific number for the Pharmacy Help Desk may lead to Pharmacist dissatisfaction as they are accustomed to calling one line for several clients.
Call Center	When determining the Average Length of Call, what event indicates the call has begun and completed? Is this timed from the point when the representative answers?
Call Center	The guidelines for 2007 require that the Pharmacy Help Desk calls be reported (they were not required in 2006). Currently, the Pharmacy Help Desk calls are tracked at an overall program level. Do we now need to differentiate by client? Experience has shown that providers are likely to call the number they are familiar with instead of having to refer to multiple numbers for pharmacy benefits.
Call Center	Can you confirm that the definitions for each element are the same for the Beneficiary Service Line and the Pharmacy Support Line?
Appeals	What does partial reversal for an appeal mean?
Appeals	The last two bullets under the Appeal section is the Plan defined as the Client, ESI, or IRE? Also the turn around time part here they want in hours and that is a concern. We have time stamps on things but I do not believe there is anything out there currently that calculates TAT in hours.
Rebate Reporting	The CY 2007 Call Letter indicates that 100% of rebate and admin fee should be reported regardless of the share retained by the PBM or other entities. This is not indicated in the Reporting Requirements. Please clarify.
Call Center	What is the definition of a resolved call?
LTC Rebate Reporting	How will the data collected for LTC pharmacy rebates be used?
LTC Rebate Reporting	Will reported rebate amounts be used to lower reimbursement to plans? Risk-corridor adjustments?



#17

U S Steel Tower Floor 41 • 600 Grant Street • Pittsburgh, PA 15219-2704 • 412-255-4640

August 14, 2006

VIA FEDERAL EXPRESS

Ms. Melissa Musotto  
Centers for Medicare and Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development-A  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: 60 Day Public Comment Period for 2007 Part D Reporting Requirements

Dear Ms. Musotto:

Per CMS' memo dated June 21, 2006, please find attached Gateway Health Plan's comments and questions regarding the 2007 Part D reporting requirements.

Please contact me if you have any questions at (412) 255-4296.

Sincerely,

Angela Jackson  
Manager, Medicare Administration

Enclosure

cc: Ms. Ruth-lande Rogers, CMS Regional Office



## **Part D Reporting Requirements Comments/Questions**

### **Gateway Health Plan – H5932 & H8031(Pending)**

#### **III. MTM Programs.**

1. Regarding method used to enroll beneficiaries in the MTM program. Is CMS just looking for a one-word answer? We are giving our members the opportunity to "Opt-in" and not automatically enrolling eligible members and advising that they may "Opt-out" of the program. This is a text field. Please provide clarification.

#### **VI. Pharmacy & Therapeutics (P&T) Committees.**

1. Why is there a need to report the date of birth for members on the committee?

#### **VII. Transition**

1. Define newly enrolled members. Should this # include members who were once Gateway Health Plan (Gateway) members then moved to another plan and then may come back to Gateway?

#### **XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC.**

1. Does Long Term care include the following Nursing Home and Skilled Care Facilities?

#### **XIV. Licensure and Solvency, Business Transactions and Financial Requirements.**

1. Does this report still only apply to PDP's and not the MA-PD's?



#46

August 14, 2006

Centers for Medicare and Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development – A  
Attn: Melissa Musotto  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Ms. Musotto,

Please review the comments regarding the 2007 Part D Reporting Guidelines listed below:

***SECTION I. ENROLLMENT/DISENROLLMENT***

- No concerns. CMS has clarified the concerns about how to identify a LIS beneficiary with a more recent version of the 2007 requirements.

***SECTION II. REVERSALS***

- No concerns. This metric has remained unchanged from the 2006 reporting requirements

***SECTION III. MEDICATION THERAPY MANAGEMENT PROGRAMS***

- No concerns. This metric has remained unchanged from the 2006 reporting requirements

***SECTION IV. GENERIC DISPENSING RATE***

- No concerns. This metric has remained unchanged from the 2006 reporting requirements

***SECTION V. GRIEVANCES***

- Item H: CMS is indicating that grievances sent to the Quality Improvement Organizations (QIOs) must be included in the number of quality of care grievances received. Since members contact the QIO directly to initiate a grievance, IBC does not receive this data.
- Item I: This requirement requires sponsors to report on the number of transition grievances received. Appeals and grievances has no way to identify beneficiaries who are in the transition period versus regular beneficiaries. In addition, most members do not know if they are in the transition period to be able to self-identify themselves.
- Item J: Exception grievances are not tracked or recorded
- Items N, O, & P: Currently not reported at the PBP level in the appeals and grievances database.
- Item N: Clarification is needed. Is CMS looking for the total number of grievances in compliance with CMS guidance?

***SECTION VI. PHARMACY & THERAPEUTICS (P&T) COMMITTEES***

- This information is already included in the sponsor's bid. As recommended by the BCBSA, this information is already available upon request to CMS. A better option would be to have a field where each plan can indicate if there has been a change to the

P&T Committee. CMS would then be able to contact the plan for a copy of the committee members if it deems the information necessary.

#### ***SECTION VII. TRANSITION***

- Items B & C: Identification of these individuals will only be possible if the claim receives an edit or override code at the PBM indicating that the drug was issued as part of the transition policy.
- Item C: This level of detail will be difficult to obtain as the claims receiving an override code will then have to be analyzed to sort out multiple prescriptions for the same beneficiary. The benefit of this metric does not warrant the level of processing needed to obtain the results.

#### ***SECTION VIII. PRIOR AUTHORIZATION, STEP EDITS, NON-FORMULARY EXCEPTIONS, AND TIER EXCEPTIONS***

- No concerns.

#### ***SECTION IX. APPEALS***

- CMS is now requesting that appeals decisions now be reported as reversals and partial reversals for each measure. Need more clarification from CMS as to what they determine to be a partial reversal. Currently, IBC reports partial reversals as being upheld.
- Item H: IBC currently does not capture redeterminations due to insufficient evidence of medical necessity.
- Items Q & R: Turn around time is measured and reported in days, not hours.

#### ***SECTION X. CALL CENTER MEASURES: BENEFICIARY SERVICE LINE AND PHARMACY SUPPORT LINE***

- Clarification is needed by the reporting timeline comment above the grid of due dates. It reads "Part D Sponsors will provide monthly data on a quarterly basis to CMS." Currently, the data is a summary of a whole quarter. Is CMS looking for three fields (1 for each month of the quarter) to be entered into HPMS for every metric?
- Clarification is also needed as to whether presale and/or prospective calls are to be included in the call center metrics. Some plans are interpreting the requirements to read that these calls should be included. IBC only includes the calls received in the pharmacy services and member services call centers.
- Item I: IBC has no way to track the number of calls completed with the issue resolved and not requiring a call back to the member. Per the business area, the only way to extract this data would be to employ sophisticated software which is outside the scope of any currently tracking systems utilized.

#### ***SECTION XI. OVERPAYMENT***

- No concerns. This metric has remained unchanged from the 2006 reporting requirements

#### ***SECTION XII. PHARMACEUTICAL MANUFACTURER REBATES, DISCOUNTS, AND OTHER PRICE CONCESSIONS***

- No concerns. This metric has remained unchanged from the 2006 reporting requirements

#### ***SECTION XIII. PHARMACEUTICAL MANUFACTURER ACCESS/PERFORMANCE REBATES RECEIVED BY LTC PHARMACIES***

- This is an entirely new section of data for 2007. The information obtained is similar Section XI but must be specific to LTC pharmacies. These metrics will require another level of detailed analysis to obtain.

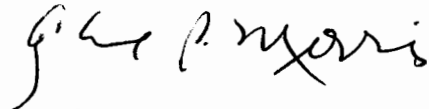
***SECTION XIV. LICENSURE AND SOLVENCY, BUSINESS TRANSACTIONS AND FINANCIAL REQUIREMENTS***

- Need clarification regarding the Direct EGWPs. Per the guidelines, it appears this section only applies to employer groups contracting directly with CMS, not through a plan that administers the group waiver.

***SECTION XV. DRUG BENEFIT ANALYSES***

- This section appears to only be applicable to standard Part D plans.
- How do we report these metrics for enhanced benefits? (i.e. if there is coverage through the gap, are we required to identify how many members would have been in the gap IF the plan were a standard Part D benefit?)
- Obtaining this information requires plans to review the utilization of every individual member every quarter to identify where each member falls in the program.

Sincerely,



Gail P. Morris  
Senior Compliance Coordinator  
IBC Medicare Compliance