Responses to Public Comments on
CMS-10185 – CY 2008 Part D Reporting Requirements
10/12/07-11/13/07

Background:

Draft 2008 Part D reporting requirements were posted to the Federal Registry beginning on October 12, 2007 for a final 30-day public comment period. This document summarizes the comments and questions received by CMS and our responses to these questions and concerns. Final 2008 Part D reporting requirements document will be released pending OMB approval.

General

1) A commenter asked if all data elements listed in the 2008 Reporting Requirements are necessary to ensure proper oversight of Part D.
   - Response: Yes, all 2008 Reporting Requirements data elements have been reviewed to ensure burden of reporting is justified by the need for data for oversight and monitoring. CMS has made revisions to previous contract years' reporting requirements, and drafts of 2008 reporting requirements that decrease burden, including decreasing the frequency of reporting, raising the level of reporting to contract versus individual PBP, and in some cases, deletion of a reporting section when other sources of information are available.
2) One commenter asked if enhanced alternative and OTC drug claims continue to be excluded from reporting.
   - Response: Yes, these exclusions continue to apply. Only Part D covered drugs should be included for these reporting requirements.
3) A commenter expressed concern to the statement, 'these requirements will be in effect for Contract Year 2008 and are subject to change at the discretion of CMS'. The commenter stated language added to the CY2007 Part D long-term care (LTC) rebate reporting requirement of CMS reserving the right to require NDC level data had not been included for public comment.
   - Response: Following CMS' release of final Part D reporting requirements, it is possible that operational changes become necessary. In some cases, these changes reduce, not increase, the burden associated with reporting these data. Two examples have been CMS' suspension of Enrollment reporting for 4th quarter 2006, and Call center reporting in CY2007. These suspensions followed the release of the respective contract years' requirements. It should be noted that the change to the CY2007 LTC rebate reporting section cited by the commenter was only a clarification of CMS' implicit right to request additional information from their contracted entities.
4) It was requested that future clarifications or additional information important for Part D Sponsors' compliance are included in upcoming releases of Reporting Requirements, and in HPMS.
   - Response: Prior to the final publication of Reporting Requirements, CMS incorporates all clarifications necessary for Part D Sponsors. Once published, additional information to clarify these requirements may be provided via memos and FAQs. Changes cannot be made to the Reporting Requirements documents unless errors are identified in the data collection. To improve distribution of any updates related to Reporting Requirements, CMS will announce memos and FAQs on Part D User Group calls and through HPMS announcements. All documents related to Part D Reporting Requirements are posted on the CMS website. They are not posted in HPMS as it is a secure system that may not be available to all parties needing the information.

Retail, Home Infusion, and Long-Term Care Pharmacy Access

1) A commenter asked if employer groups are exempt from this reporting section.
   - Response: Employer groups are not exempt from this reporting section. The following clarifications regarding definitions of service area for employer groups have been added to the revised reporting requirements document.
     - Part D Sponsors that offer both individual plans and "800 series" plans need only to demonstrate pharmacy access (retail, home infusion, long term care) for their individual service area. There are no separate requirements for their EGWP-Only service area.
     - Part D Sponsors that offer plans to employer groups only (i.e., "800 Series Only" contracts) need to demonstrate pharmacy access (retail, home infusion, long term care) for their entire service area.
     - Employer/Union Direct contracts need to demonstrate pharmacy access (retail, home infusion, long term care) for their entire service area.
2) Commenters suggested section A's data elements to be reported at the contract level, instead of at the plan (PBP) level as proposed.
   - Response: This recommendation has been accepted and has been incorporated in the revised Reporting Requirements document. Plans (PBP) level data may be requested by CMS if it is determined more detailed data are necessary.
3) It was recommended that section A's data elements are reported as of the last day of the reporting period for the period January – March 2008.
   - Response: This recommendation has been accepted and is reflected in the revised Reporting Requirements document.
4) Questions were received regarding the reference file for GEO access reports. It was asked which month the file would be made available, if a link to the file could be provided, how often the file was updated, and if the file was a national file.
   - Response: The reference file is a national file that is used for PDP and MA-PD sponsors, and is updated annually. The file will be posted on the Prescription Drug Contracting section of CMS' website in January 2008. (http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage). This information has been added to the revised Reporting Requirements document.
5) It was asked if CMS will request GEO Access reports supporting section A's data elements.
   - Response: As stated in the introduction of this reporting section, CMS will only require the submission of Geo Access reports upon request and not as an initial part of these reporting requirements.
6) A commenter asked if data elements A1-A3 are to be reported similarly as the initial Pharmacy Access Analysis (ex. Urban= 2 miles, Suburban = 3 miles, Rural = 15 miles).
   - Response: Yes, this is the same standard as the initial pharmacy access analysis submission.
7) It was asked plans that have received a waiver of convenience access standards for retail pharmacies are required to complete section A.
   - Response: The revised Reporting Requirements document clarifies plans completing sections C and D are not required to complete section A.
8) Clarification was requested for section A to whether the term Medicare beneficiaries includes plan enrollees, or all Medicare beneficiaries residing within the pharmacy network.
   - Response: Per the regulatory requirements, the reference file used for section A contains all beneficiaries, and is not limited to only plan enrollees. This clarification has been added to the revised Reporting Requirements document.

9) A commenter asked if zero values are acceptable for data element A1, percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area.
   - Response: If a Part D sponsor's service area has no urban counties then a zero value should be reported.
10) It was suggested that CMS require Part D sponsors to provide access reports only if there has been a significant reduction in their retail network, given the burden associated with generating new reports.
   - Response: CMS determines a plan meets access requirements at the time of initial application. This new reporting section applies for all Part D sponsors in order to ensure continued compliance with the pharmacy access requirements.
11) CMS was asked if processes are available to allow Part D sponsors' PBM subcontractors to submit data.
   - Response: At this time, this option is not available, as PBMs cannot report data in HPMS.
12) A commenter asked if data and formulas used by CMS to evaluate compliance with LTC and HI pharmacy access standards are available to plans. Another commenter asked what threshold will be used to determine if LTC pharmacy access requirements are met.
   - Response: The elements used to calculate access are discussed in the introductory language in Section I as well as in Chapter 5 of the Prescription Drug Benefit Manual. The reference files for long-term care nursing home beds will be posted at the same time as the beneficiary file. Formulas used to evaluate applicants are not available to Plans.
13) It was suggested that in cases where Plans have received a waiver of any willing pharmacy requirements and a waiver of the convenient access standards report, Part D sponsors are allowed to report data at the contract level.
   - Response: Consistent with section 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual, this waiver is granted at the plan, not at the sponsor level, and therefore data must be reported for sections C and D at the plan (PBP) level.
14) It was asked if Part D sponsors should cross-reference the CMS reference files to enrollee data.
   - Response: Part D sponsors do not need to cross-reference the CMS reference files to enrollee data for this reporting.

Access to Extended Day Supplies at Retail Pharmacies

1) Recommendations were received that these data be reported as of the last day of the reporting period, and reported at the Contract level, instead of at the plan (PBP) level as proposed.
   - Response: These recommendations have been accepted and are reflected in the revised Reporting Requirements document.
2) It was asked why these data are collected biannually while Section I's access measures are collected annually.
   - Response: For consistency with the Retail, Home Infusion, and Long-Term Care Pharmacy Access reporting section, CMS has reduced the reporting frequency of this section's from biannual to annual. This change is reflected in the revised Reporting Requirements document.
3) Verification was requested that this section requires reporting the number of retail pharmacies that offer mail order rates for extended days supply only.
   - Response: Yes, this is correct.
4) A commenter asked how CMS will evaluate the data reported, and if other factors such as enrollment will be considered. Another commenter asked what criteria would be used to determine adequate access.
   - Response: This new reporting section will provide data previously unavailable for CMS oversight. Analyses will consider other factors in addition to the information reported by plans. Criteria used to evaluate data are not available to Plans.

Vaccines

1) One commenter requested more information about the various methodologies included in this reporting section for the types of vaccine claims reported under each data element. Clarifications and definitions were requested for terms listed in various data elements, including clinic setting, paper-enhanced, provider, and internet-based web tools.
   - Response: The introduction of this reporting section provides specific references for more information (section 60.2 of Chapter 5 of the prescription drug benefit manual) regarding the various terms, potential methods of administration and how they relate to the data elements. Information is also found in the CMS memorandum released in May 2006 on Part D vaccines (http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoVaccineAccess_05.08.06.pdf). Additional clarifying language has been added to the revised reporting requirements document.
2) It was requested that the term "vaccine" is defined to include only combination claims (vaccine and administration together on the same claim) and product–only claims to avoid duplicate reporting of the same vaccine event. Similarly, other commenters asked if data Elements B – F may exceed the total listed in data element A. One commenter stated a small number of beneficiaries may receive their vaccine at a pharmacy and then later will have the vaccine administered in a physician's office.
   - Response: This reporting section only speaks to the vaccine itself (or ingredient). While Part D will provide for the reimbursement of vaccine administration beginning 1/1/2008, the reporting requirements do not relate to this new administration benefit. Part D sponsors should only report information relevant to the vaccine itself; therefore CMS does not expect that claims could be reported more than once in data elements B-F. Data element A should be a sum of data elements B-F. This has been clarified in the revised reporting requirements. These clarifications have been added to the revised reporting requirements document.
3) For data element B, the number of Part D vaccines administered in a clinic setting (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine, it was stated that some Part D sponsors are unable to differentiate if a vaccine was administered in a clinic setting.
   - Response: This data element has been modified to clarify that a clinic setting is "any out-of-network setting where a state recognized immunizer dispenses a Part D vaccine". Additionally, this data element contains two requirements, the vaccine is provided by out-of-network immunizer and is submitted retrospectively submitted to the plan as paper claim. Part D sponsors must have a process to receive out-of-network paper claims and should be able to differentiate these types of claims from in-network claims.
4) For data element D, the number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access, a commenter stated some business processes do not process claims that providers submit, and therefore no data are captured. Another commenter asked if this data element considers any process in which the provider, other than a network pharmacy, submits the claim to a Part D Sponsor for payment.
   - Response: Per the referenced section 60.2 of Chapter 5 of the prescription drug benefit manual, CMS does not expect plans to implement every method of vaccine reimbursement; as a result, the number of vaccines processed for some methods may be reported as zero values. This information has been incorporated in the revised reporting requirements document. Element D is any reimbursement process where a Part D sponsor provides its members with a vaccine-specific notice that the enrollees could bring to their physicians (or other provider recognized by state law to provide immunization). This notice would provide information necessary for a physician to contact the enrollee's Part D plan to receive authorization of coverage for a particular vaccine, reimbursement rates, enrollee cost-sharing to be collected by the physician,

and billing instructions. If the Part D plan authorizes payment, the physician would then bill the Part D plan using the physician standard claim form or ASC X12 electronic format (which Part D plans must accept).

5) For data element E, the number of vaccines processed through an internet based web tool, it was asked if an organization contracts with a company that acts as an online vaccine clearinghouse between physicians and a PBM, are these considered a web based tool?
   - Response: An internet based web tool can constitute any internet based process that facilitates physician or other state recognized immunizer billing to the Part D plan without requiring a retrospective paper based claim for reimbursement.
6) A commenter requested CMS to specify which vaccines should be included in this reporting section.
   - Response: The Part D sponsor should report all vaccines that satisfy the definition of a Part D drug outlined in 42 CFR 423.100.
7) CMS was asked about the value of these data. It was suggested that CMS collect aggregate data, and require more detailed documentation for audit purposes.
   - Response: The reporting of these data will allow CMS to monitor the implementation of in and out-of-network vaccine access and assess compliance with CMS' guidance on furthering Part D vaccine access. Aggregate numbers will not allow for evaluation of the various methods to provide access to Part D vaccines.

Reversals

This reporting section has been deleted from the 2008 Part D Plan reporting requirements.

Medication Therapy Management Programs (MTMP)

1) CMS was asked to provide an example of data element H, the number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G.
   - Response: CMS incorporated this data element in response to a request from some plans to have the ability to report discontinuation for reasons not already listed (death, moving outside service area or at beneficiary's request). A value of zero may be reported.
2) For data element J, the number of beneficiaries whose participation status in the MTMP is pending, a definition of pending was requested. Additionally, it was asked if zero values may be reported.
   - Response: The pending status occurs when a beneficiary is eligible for MTMP, but the beneficiary has not participated, or declined participation as of the time of reporting. This may not apply to all MTMPs. A value of zero may be reported.
3) A commenter requested more information about the Gentran process for MTM beneficiary file upload.
   - The Gentran and Connect Direct translation processes are common vehicles used to transfer sensitive data between parties. Historically, these processes have been used by various Part D sponsors for other CMS data transfer processes. Further information will released as soon as possible, however it should be noted that the MTM beneficiary file will not be submitted to CMS until February 2009.
4) One commenter noted that some of the fields listed for the beneficiary file may not apply, and therefore should not be listed as required fields.
   - Response: CMS agrees and accepts this recommendation. These changes have been implemented in the revised final 2008 Part D Reporting Requirements document.
5) A comment was received indicating that PDPs may not be able to determine if a MTM participant is a LTC resident.
   - Response: CMS expects Part D Sponsors to use resources available to determine if a MTM participant is a LTC resident at any point of their MTM participation. CMS does not require the LTC resident to meet a minimum length of stay at a long term care facility in order to be

considered a LTC resident for this reporting requirement. CMS will allow Sponsors to indicate "U" to represent LTC status is unknown.

Home Infusion Utilization

1) Comments regarding this section largely related to requests for clarification of which Part D Sponsors were expected to report these data; requests for a definition or list of home infusion drugs; and suggestions to revise this section to collect different home infusion pharmacy data.
   - Response: As a result of public comments received for this proposed section, this section has been deleted from the revised reporting requirements document.

Grievances

1) For data element M, the total number of LIS grievances received related to Part D, it was asked if a grievance concerning a LIS status filed by a member who does not qualify for LIS should be reported.
   - Response: No, as stated in the reporting requirements document, the total number of LIS grievances received related to Part D should be based on the beneficiary's LIS status at the time of filing the grievance.
2) One commenter stated beneficiaries residing in LTC facilities may not be aware of, or able to communicate grievances, and therefore, caregivers should be allowed and encouraged to report grievances. The commenter stated these grievances should be reported by the Part D Plans and identified specifically as related to LTC.
   - Response: An appointed representative has the authority to file a grievance on behalf of an enrollee. The introductory paragraph to this reporting requirement section states: Plans should not dismiss or exclude any Part D grievances from this reporting section.

Transition

1) A comment was received indicating support of the proposed Transition reporting section.
   - Response: CMS appreciates this comment.
2) It was requested that CMS also collect data to evaluate denied claims processed under transition policies.
   - Response: CMS believes that this data collection would create an increased burden in reporting, but may consider inclusion of this data collection in the future.

Exceptions

1) A commenter requested CMS also collect exceptions data segregated for the ambulatory and LTC populations.
   - Response: This suggestion will be considered in the future. As this information is collected from claims data, Part D Sponsors may not be able to accurately map data to either the type of dispensing pharmacy (as retail pharmacies can provide prescriptions to long-term care facilities) or the long-term care status of a member. CMS will continue investigating if this type of information can be obtained from other sources.

Appeals

1) A commenter requested CMS also collect appeals data segregated for the ambulatory and LTC populations.
   - Response: This suggestion will be considered in the future. This information may not be available to Part D Sponsors readily without significantly increasing burden of reporting. CMS will continue investigating if this type of information can be obtained from other sources.

Pharmacy & Therapeutics (P&T) Committees/ Provision of Part D Functions

1) For Section B, it was requested that the term, "organizations providing Part D functions" is clarified. Additionally, it was asked which organizations should be included in this category.
   - Response: All Part D Sponsors are required to attest quarterly if changes have been made to the entities which perform Part D activities, and if so, if the Part D Sponsor reported these changes to CMS. The actual information regarding these entities is housed in a separate HPMS module called Contract Management. Sponsors should refer to the HPMS Contract management module for information regarding Part D Sponsor related functions.

Overpayment

1) A commenter requested additional clarification to the term overpayment to ensure accuracy in data collection and reporting.
   - Response: A definition for the term overpayment is provided in this reporting section. Sponsors questioning if specific transactions qualify as overpayments may request more information by sending an email to partd-planreporting@cms.hhs.gov.

Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

1) CMS received a comment asking if sponsors can incorporate prior rebates into the pending or received buckets if there are reinstatements due to reporting errors.
   - Response: Part D sponsors should incorporate prior rebates into the pending and prior rebates received fields. The 2007 Reporting Requirements Frequently Asked Questions (FAQ) provides detailed examples.

Long-Term Care (LTC) Rebates

1) CMS received comments regarding the burden associated with reporting these data, as well as the need to protect confidentiality of rebate data.
   - Response: CMS has provided estimates for the burden associated for the Part D sponsors which would complete these reporting requirements. As stated in the Reporting Requirements document, CMS recognizes the importance of maintaining confidentiality of these records. Systems are in place to ensure access to rebate data is restricted.
2) Comments were received that this reporting section violated the noninterference clause specifically prohibited by Section 1860D-11(i) of MMA, and that LTC pharmacies cannot influence prescribing due to Part D sponsors' utilization management tools and state agencies' oversight.
   - Response: We do not believe this requirement affects price negotiations between plans, pharmacies and manufacturers in violation of §1860D-11(i) of the MMA. We also disagree with the assertion that LTC pharmacies cannot influence prescribing in LTC settings. We are aware that certain long-term-care pharmacy business models involve incentives for moving market share through the activities of consultant pharmacists. Rebates and discounts paid to LTC pharmacies to move market share create significant concerns under Part D as the MMA clearly contemplates formularies are to be managed by Part D plans. To the extent that a LTC pharmacy is being paid by a manufacturer to move Part D market share without the knowledge or approval of a Plan, it may result in induced demand for higher-tiered or non-formulary drugs, which would increase the costs to the plan and the government. Under section 423.153(b) of our regulations, we require Plan Sponsors to establish a reasonable and appropriate drug utilization management program that (1) includes incentives to reduce cost when medically appropriate: (2) maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and (3) provides CMS with information concerning the procedures and performance of its drug utilization management program according to guidelines specified by CMS. Therefore, in implementing this requirement, we expect Plan Sponsors to maintain controls to prevent over-utilization and to protect beneficiaries and reduce costs when they become aware through this rebate reporting that LTC pharmacies are subject to incentives for

moving market share that are at odds with the plan's formulary and drug utilization management program.

3) It was suggested that these data are available from independent entities, other than Part D Contracts/Sponsors.
   - Response: These data are not available from entities other than the Part D Contracts/Sponsors, and the LTC pharmacies which they are directly contracted.
4) A commenter requested that the exemption from reporting for LTC pharmacies serving less than 5% of LTC beds be revised to be based on claims, instead of beds.
   - Response: CMS does not believe claims offer a reporting advantage to Sponsors, and that LTC beds are a measure more supported by the industry. Additionally, CMS has revised this exemption to include pharmacies and chains (pharmacy entities that have more than one NCPDP number associated with their organization). Sponsors who are unable to determine if pharmacies satisfy this threshold should report all LTC pharmacies' rebates received.
5) One commenter asked if CMS would allow LTC rebate reporting at the PBM level due to contracting arrangements.
   - Response: No, these data may not be reported by PBM, as there is no direct contractual relationship between CMS and PBM. As such, the PBM would not be granted access to HPMS. CMS has allowed these data to be reported at the Contract or Sponsor (parent organization) level.

Drug benefit analyses

1) One commenter asked if the term "pre-ICL" refers to the period in which a beneficiary is between the deductible and the coverage gap.
   - Response: Yes, the pre-ICL phase is the period of time in which a beneficiary is beyond the deductible phase, but has not reached the coverage gap.
2) CMS was asked if the source data for these reports should be plan enrollment data, as opposed to MMR data.
   - Response: Yes, the plan enrollment data should be used when reporting DBA data to CMS.
3) A commenter questioned how to complete data fields related to beneficiaries in the deductible phase if the PBP does not have a deductible.
   - Response: If a PBP does not have a deductible, HPMS will not display those respective fields for reporting.
4) It was stated that LIS data may be difficult for Plans and/or PBMs to extract.
   - Response: CMS appreciates this comment, however LIS data are extracted and utilized currently for correct claim adjudication. These data should therefore be available for these reporting.
5) CMS was asked how employer groups who are on a non-calendar year cycle should report these data, for example, will a group whose renewal data is September 1 consider the TrOOP threshold through August 31 or January 1.
   - Response: Regardless of renewal cycle, these data should be based on the enrollees' status within the given plan's benefit structure for each monthly reporting period.