Responses to Public Comments on
CMS-10185 – CY 2008 Part D Reporting Requirements
6/8/07- 8/7/07

Background:

Draft 2008 Part D reporting requirements were posted to the Federal Registry beginning on June 8, 2007 for a 60-day public comment period. This document summarizes the comments and questions received by CMS postmarked by August 7, 2007, and our responses to these questions and concerns. A revised draft 2008 Part D reporting requirements will be posted to the Federal Registry for a final 30-day public comment period. Following this, a final 2008 Part D reporting requirements document will be released once OMB approval has been received.

General

1) 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.
2) 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) It was suggested that CMS require reporting of pharmacy capacity, pharmacy contracts with nursing facilities, and pharmacy coverage, in addition to the current elements listed in Section B. The commenter stated this additional information is essential to accurately evaluate if adequate LTC access is available to Medicare beneficiaries.
   - Response: At this time these additional elements would significantly increase burden of reporting for Part D Sponsors without providing information needed to determine if access standards continue to be met. CMS will continue to evaluate this suggestion for future requirements.
2) Comments were received regarding the reporting burden associated with this section. One commenter stated that Part D Sponsors already provide attestation of the adequacy of their network, and because pharmacy networks are required to accept any willing provider, this reporting requirement may be burdensome and redundant. It was asked if data for Section A may be submitted at the Contract level, instead of the Plan (PBP) level. Another commenter suggested that Part D Sponsors only submit data when changes have been made to pharmacy networks, and that CMS allow PBMs to submit data on behalf of Part D Sponsors.

- Response: Current attestations are insufficient for ensuring pharmacy access is maintained through a contract year. CMS expects collection of these data may be used in lieu of audits related to these requirements. Regulations specifically state retail must be reviewed at the Plan level (home infusion and LTC networks are measured at the contract level). CMS has reduced the frequency of reporting from biannual to annual, thereby reducing the burden to Sponsors.

3) A commenter noted that the reporting deadlines occur simultaneously with deadlines for Plan Sponsors making significant changes to their pharmacy network, and suggested that CMS consider alternative reporting deadlines.
   - Response: CMS has changed the frequency of this data collection from biannual to annual. Additionally, it should be noted that CMS provides a 60-day window from the end date of the reporting period to the annual reporting deadline.
4) A commenter asked when the geo-access reports will be released to plans.
   - Response: CMS plans on the reports being available around June 1, 2008 and December 1, 2008.
5) It was asked if saving the report generated for reporting of these data satisfies the 10 year requirement for Part D documentation.
   - Response: It is acceptable for a Plan to save the report to meet this requirement.

Vaccines

1) A question was received about data element D, the number of vaccine processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access.
   - Response: This data element reflects one of the out of network approaches to improve vaccine access, as described in the CMS memo released on May 8, 2006.
2) Clarification was requested for data elements A, B, and C.
   - Response: CMS has clarified these 3 data elements.
3) CMS received comments regarding data element F. It was asked if there was an error in the description of data element F. Additionally, clarification was requested for vaccine claims that would not already be captured in data elements B through E.
   - Response: This data element has been corrected in the revised reporting requirements document. It is now listed as, "the number of vaccines processed during the time period specified above through a process not described in data elements B through E." As stated in the vaccine access memo released by CMS on May 8, 2006, other possible means to coordinate the billing of vaccines in the real-time environment of the Part D benefit with the current batch billing processes used by physicians may exist. Data element F allows reporting of vaccines billed through such methods not already listed.

Reversals

1) One commenter suggested that CMS require Sponsors to report the reason for claim reversals in addition to the total number of claim reversals.
   - Response: The number of reversed claims is collected quarterly for a cursory evaluation of potentially unusual patterns in claims processing. Reporting reasons for each claim reversal would be burdensome for Part D Sponsors. Additionally, CMS may not utilize this level of detailed information, due to the availability of other sources of information such as complaint, PDE and audit data. CMS appreciates this suggestion, and will continue to evaluate its need as a future reporting requirement.
2) CMS received two questions clarifying reporting. Specifically, a definition for final disposition was requested, and CMS was asked if retroLICS reversals should be included in this dataset, although these reversals were not generated by pharmacies.
   - Response: This section is currently being considered for deletion from the CY2008 reporting requirements, in which case, responses to these questions would not be necessary. If this reporting section is not deleted, CMS will add clarifications to the final CY2008 reporting requirements document.

Medication Therapy Management Programs (MTMP)

1) A commenter requested CMS collect information on MTMPs directed towards LTC residents, in order to determine the extent Part D Sponsors have outreached to this population, and the impact of MTMP services.
   - Response: CMS has added this data element to be collected within the file uploaded to CMS annually.
2) Several questions were received regarding data element J, the number of beneficiaries whose participation status in the MTMP is pending. CMS was asked to clarify the term "pending", and if a Plan can report a beneficiary as pending if the Plan attempted to contact a beneficiary, but the beneficiary did not respond. Lastly, it was asked if a Plan may report beneficiaries as pending in the second reporting period.
   - Response: CMS added data element J in order to account for MTMP-eligible beneficiaries whose participation status was unknown as of the reporting deadlines. This data element may be more applicable with MTMPs utilizing an opt-in program design for enrollment. For a MTMP using an opt-in enrollment design, a beneficiary identified to be eligible for MTMP must actively choose to participate. It is possible that not all beneficiaries would have responded by a reporting deadline. A Plan may therefore have three different groups of MTMP-eligible beneficiaries to report to CMS: those beneficiaries participating in MTMP, those beneficiaries declining to participate, and those beneficiaries whose MTMP status remain pending. For a MTMP using an opt-out enrollment design, a beneficiary that meets the eligibility criteria is auto-enrolled and is considered to be participating unless s/he opts-out of the program. Therefore, the pending status may not be applicable and should be reported as zero. CMS anticipates Plans would only need to report beneficiaries in a pending status for Period 1 (January 1- June 30). The second reporting period is the full program year (January 1- December 31) and the participation statuses should be resolved.
3) A few comments were received regarding the MTMP data file. One commenter asked if the reporting requirements document incorrectly listed the MTMP data file to be uploaded in HPMS only for the January-December period, or will Sponsors be required to submit a data file for Period 1 (January-June). CMS was asked to clarify the statement, "Data file to be uploaded through the HPMS at the Contract level", and if this indicated the CMS contract number. Another commenter questioned the need for this level of data.
   - Response: Part D Sponsors will only submit this data file to CMS once a year. The reporting requirements document has been revised to clarify this reporting period as YTD, from January 1-December 31. Uploading of data files will be performed in HPMS by CMS Contract ID. Beneficiary level data are necessary to help identify and evolve MTM best practices, and are not available through other sources. CMS has attempted to diminish the burden of reporting associated with this section by only requiring annual submission of the file.

Home Infusion Utilization

1) CMS received a comment that these data are already available through PDE data, and is therefore unnecessarily burdensome. The commenter also cited tracking home infusion drugs is difficult, and questioned the need for this report.
   - Response: CMS has revised this reporting section by deleting two of the proposed four data elements, and revising one of the remaining data elements. The aggregate information reported in this section is not duplicative of PDE data.
2) A commenter requested CMS clarify if the term "home infusion drug" is dependant on drug classifications or the type of pharmacy from which a drug is dispensed (e.g. all drugs dispensed by a pharmacy classified as a home infusion pharmacy)

- Response: Home infusion drugs are products administered by IV in settings for which these products are not covered by Part B.

Grievances

1) 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 has been clarified to state: Plans should not dismiss or exclude any Part D grievances from this reporting section. Previously, CMS stated that Plans should not dismiss or exclude any grievances file by beneficiaries from this reporting section.
2) CMS was asked if data element L, the total number of grievances received related to Part D should contain those reported in data element M, the total number of LIS grievances received related to Part D.
   - Response: Data element L should be the sum of data elements A-K. Data element M is the number of grievances filed by LIS enrollees, and therefore these grievances would already have reported in data elements A-K, based on the types of the grievances filed by LIS enrollees.
3) Clarification was requested for data element M, the total number of LIS grievances received related to Part D. It was asked if a beneficiary retroactively obtained LIS status, should their grievance be included in data element M.
   - Response: As stated in the description of data element M, this number should be based on the beneficiary's status at the time of filing the grievance. In the example given, the beneficiary's status was non-LIS, therefore their grievance should not be included in data element M.

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 claims processed under transition policies.
   - Response: In order to minimize the burden of reporting, CMS eliminated the reporting of temporary fills from previous reporting requirements.
3) CMS was asked if the reporting timeline correctly listed that only data for Quarter 1 would be collected.
   - Response: The reporting timeline is correct. CMS will collect this information only once a year, at the beginning of the contract year. These data should not change quarterly, as the transition policy parameters apply for the entire contract year.

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.

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) A commenter described negative consequences from this reporting section, as well as alleging it violated the noninterference clause specifically prohibited by Section 1860D-11(i) of MMA. Comments were received regarding the purpose of this reporting section. Another commenter stated LTC pharmacies cannot influence prescribing due to Part D Sponsors' utilization management tools and state agencies' oversight.
   - Response: 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 market share in the context of a Part D plan 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. Given the critical role Part D plans play in allowing access to the most competitively priced drugs and moving market share on drugs for which they may receive rebates, it is unclear whether, and to what extent, LTC pharmacies play an appropriate role as independent agents in moving market share on behalf of manufacturers. Furthermore, rebates or discounts paid to LTC pharmacies to provide access or move market share in the context of Part D could create significant fraud and abuse concerns, including potential Federal anti-kickback concerns under section 1128B(b) of the Social Security Act [42 U.S.C. § 1320a-7b(b)]. 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, as part of this requirement, we expect Plan Sponsors to maintain policies and systems to prevent over-utilization and to protect beneficiaries and reduce costs when LTC pharmacies are subject to incentives for moving market share that are at odds with the plan's formulary. To ensure that Plan Sponsors are meeting this requirement, we require that sponsors include a provision in all LTC pharmacy contracts that requires pharmacies to fully disclose any and all discounts and rebate arrangements with or any other direct or indirect remuneration from, drug manufacturers or other parties when such remuneration is designed to or likely to directly or indirectly influence or impact utilization of Part D drugs. While it is true that Part D plans have significant power to enforce formularies with respect to LTC pharmacies, we continue to believe that there are significant incentives to influence drug product selection of non-formulary drugs in order to maximize LTCP rebates. Specifically, Part D plans are required to cover Part D drugs not on formulary during a new enrollee's transition period (which is generally a 90 day period) and to cover non-formulary Part Drugs provided outside of a transition period to a current enrollee when first dispensed under an emergency supply. Moreover, there is the opportunity to influence the selection of formulary drugs that are placed on higher tiers. Based on these incentives, we continue to believe our policy to require disclosure of LTCP rebates to Part D plans is appropriate.
3) It was suggested that these data are available from independent entities, other than Part D Contracts/Sponsors.
   a. Response: These data are not available from entities other than the Part D Contracts/Sponsors, and the LTC pharmacies which they are directly contracted.

Drug benefit analyses

1) Comments were received related to monthly reporting of these data. One comment supported reporting of these data monthly. Another commenter requested reporting is returned to a quarterly frequency.
   - Response: Part D Plans' reporting of these data at a higher frequency is necessary for CMS' monitoring of the Part D benefit. CMS believes the most significant burden of reporting is associated with the monthly collection of data, which has not been revised since 2007's reporting requirements. Part D Plans will only provide more frequent reports of these data to CMS.
2) A suggestion was made that Part D Plans use their benefit design, not the standard benefit, for reporting these data. CMS was asked to clarify how a Part D Plan should report these data if the standard benefit is absent, not that the benefit design is different. For example, Plans with coverage gaps that differ from the standard benefit or different deductible limits.
   - Response: The specific characteristics of each PBP's benefit design are not collected in this section. CMS is requesting simply the number of beneficiaries within each coverage level of the benefit offered by the PBP. CMS' analyses of the data will take into consideration deductible limits, initial coverage limits, etc.