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November 12, 2007

CMS-10185
Cover letter #4

VIA OVERNIGHT MAIL

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
725 17th Street, NW
Washington, DC 20503

Dear Ms. Lovett,

As a Medicare Part D Plan Sponsor, Medco appreciates the opportunity to review and provide comments regarding the Centers for Medicare and Medicaid Services' 2008 Reporting Requirements for Medicare Part D.

Section I. Retail, Home Infusion and Long-Term Care Pharmacy Access
To prepare for network access reporting, Medco requests the timeframe within which the necessary reference file will be released by CMS for the reporting time period January 1 – March 31st.

Section III. Vaccine, Data Elements A-F
This section requires submission of the total number of vaccines for a given period (Data Element A), as well as the reporting of the number of vaccine claims processed through each listed method (Data Elements B-F). Since a vaccine claim can include up to three components, ingredient cost, dispensing fee and administration fee, and the administration fee may be billed separately from the ingredient cost, we are requesting clarification regarding what claims should be counted as a "vaccine" claims. Should only claims that include the ingredient cost be counted?

The focus of Data Elements D and E appears to be to provider paper claims vs. electronic internet claims. It would be helpful for CMS to elaborate on what types of claims fall into each category. Does Data Element E include claims processed via third party web tools?

Section V. MTMP, Subsection I and Subsection II
CMS requires reporting of the number of beneficiaries whose participation status in the MTMP is pending during the specified time period above. We respectfully request clarification of the term "pending status." Does this refer to members who are eligible to participate in the program but did not contact the Part D Sponsor to opt in or opt out of the program?

Section VIII. Grievances, Data Element M

In regards to the required submission of LIS grievances, please clarify the types of grievances that should be considered an LIS grievance. Does this include situations where a member has a grievance regarding their LIS status, or does it apply to all situations where a grievance is filed by a member with LIS? Should a grievance concerning LIS status, which is filed by a member who does not have LIS, be included in this category?

Section XVII. Drug Benefit Analyses, Data Elements B-E

For data elements B – E, please clarify the difference between the pre-initial coverage phase and the deductible phase of coverage. Is the pre-initial coverage phase considered the period between the deductible phase and the coverage gap?

Thank you for this opportunity. If your office needs any follow-up information I may be contacted at 201.269.4347.

Sincerely,

Maureen Dempsey

Maureen Dempsey
Medicare Compliance Officer

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CVS CAREMARK

CMS-10185

November 12, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attn: CMS-10137
7500 Security Boulevard
Mail Stop: C4-26-05
Baltimore, MD 21244-1850

Re: Comments in Response to CMS' Draft 2008 Part D Reporting Requirements

Dear Mr. Weems:

CVS Caremark is the largest provider of prescriptions and related healthcare services in the nation. The Company fills or manages more than one billion prescriptions annually. It operates 6,200 CVS/pharmacy stores; a pharmacy benefit management, mail pharmacy and specialty pharmacy division, Caremark Pharmacy Services; its retail-based health clinic subsidiary, MinuteClinic; and its online pharmacy, CVS.com. SilverScript Insurance Company, a national Part D Sponsor, and SilverScript, Inc., a Part D pharmacy benefit management company (PBM), are both affiliates of Caremark. SilverScript Insurance Company (SSIC) is one of only 10 national PDPs servicing the Part D market. We have united with distribution partners, including health plans and Medicare Supplement providers, in the sales of our products nationwide. We bring substantial prescription drug benefit management experience through operating our own PDP (SSIC) as well as through our affiliate SilverScript, Inc. (SSI), a PBM offering prescription drug management services to Part D plans. SSI supports over 30 of our health plan clients, which have a combined membership of 2 million lives in Medicare Advantage and PDP programs.

We appreciate the opportunity to provide comments on the 2008 Reporting Requirements (as updated on 09/17/2007), and, in particular, to offer ways to reduce the administrative burden of this information collection. We have limited our comments to issues on which we have not previously commented, except in those instances where we believe the reporting requirement imposes a significant administrative burden, and therefore, cost to the program, that could be avoided. As such, it is our hope that CMS will reconsider our comments in these instances.

1. Section I – Pharmacy Access

The primary area where we believe there is an opportunity to significantly reduce the administrative burden on plans while still allowing CMS to obtain the information it needs to monitor compliance is with respect to the retail pharmacy access reporting. Previously, Part D sponsors were only required to submit a geo-access report with their

Part D application, and to advise CMS of any significant changes in the network. The Reporting Requirements now require that access reports be submitted annually by every plan, based on the Medicare beneficiaries in the plan's service area, irrespective whether there are any significant reductions in coverage. Retail networks, once established, generally do not change significantly, and almost never decrease in size. Instead, the norm is for them to grow incrementally over time as new pharmacies are added. In light of that, it should be sufficient for plans to submit access reports only when there are significant negative changes in their retail networks. This is particularly the case in light of the fact that access reports are extremely large documents requiring significant man hours (approximately 400 man hours per report) and information systems resources to prepare. As such, they should be required only in exceptional situations when clearly necessary, and not as a routine matter on a periodic basis.

In addition, since many Part D plans use the same pharmacy networks of their PBM subcontractors, in many cases identical reports will be generated multiple times for multiple Part D sponsors by their PBM. In light of this, we strongly urge CMS to consider a more streamlined approach to submitting reports on behalf of multiple Part D sponsors. This would greatly reduce the administrative burden and the time and effort associated with this reporting requirement. Specifically, we recommend that a certification process be established such that a PBM may submit its access report to CMS only once on behalf of all its PBM clients. While we understand that the current reporting requirements are specific to a given plan's service area, a PBM could submit a national geo-access report or, at least, a geo-access report covering all the service areas of its various plans, broken down to the county level if need be to address local plans. Adopting this approach would satisfy the CMS concern that retail pharmacy access be monitored, but would make the information reporting and review process much more efficient by eliminating duplicative reports and redundant administrative work currently being done on behalf of plans, and would accomplish the same outcome, with far less cost and time for all concerned.

Recommendation: (i) Require plans to provide access reports only if there has been a significant reduction in their retail network that would warrant the generation of new reports and the enormous work their production entails; (ii) Develop a process to allow a PBM subcontractor to submit one set of pharmacy access reports for all Part D plans that use its retail pharmacy network. This report can cover all relevant service areas and be broken down to the county level where required.

2. Section III – Vaccine Administration

Data Element A requires reporting of the total number of "vaccines processed", and Data Elements B through F each refers to "vaccines" adjudicated or processed. However, there is no definition of the term "vaccine", and so it is unclear whether plans are required to report only combination claims (i.e. where product was dispensed and administered), or also claims involving either the product or the administration fee. If all claims, there would be some double-counting in that the single administration of a vaccine would generate two claims and so be reported twice. In addition, if all claims involving a vaccine product or administration fee must be included, for Data Elements B through F, it is not clear whether the reporting criterion applies to the product or the administration in those claims that include both. Also, for several of the data elements, terms are used that in this context could have more than one meeting, yet the terms are not defined. For example, in Data Element B, it is not clear whether "clinic setting"

means only a physician's office, or if it also includes a pharmacy counter, long-term care setting, or hospital. Similarly, in Data Element D, the term "paper-enhanced" is not defined, and so it is not clear how, if at all, such a process differs from a "paper" process. It is also not clear if "provider" here refers to pharmacies and physicians, or only physicians. Finally, for Data Element E, it is not clear whether "internet-based web tool" is limited to tools used by physicians only, or also includes internet based submission methods used by pharmacies and others. Indeed, it is not clear under which Data Element out-of-network pharmacy claims must be reported.

In addition to the above clarifications, it is not clear how the different data elements are linked, and so whether a claim reported under one element must be carved out of the others. To avoid this confusion, it would be extremely helpful if CMS could define each element in relation to the others. For example, if this is correct, CMS might explain that Data Element A is the sum total of Data Elements B through F.

Recommendations: **(i) Define the term "vaccine" to include only combination claims (i.e. vaccine and administration together on the same claim) and product-only claims so as to avoid duplicate reporting of the same vaccine event; (ii) Define the terms "paper-enhanced", "provider ", "clinical setting" so that they clearly indicate which types of vaccine claims must be reported under which element; (iii) Clarify how the different data elements interrelate, preferably by providing an equation that links each data element to the others (e.g. Date Element A is equal to the sum of Data Elements B through F, and no claim should be included more than once in Data Elements B through F).**

3. Section V -- MTMP

Data element H requires reporting of the number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G. Since Data Elements E-G cover death, disenrollment and beneficiary request, we are not aware of any other reasons a participant might discontinue participation, except perhaps something highly unusual, such as termination of the plan. As such, in the vast majority of cases this Data Element will be zero, and in the few cases it is not, it is not clear what value the information will provide. In light of this, we recommend that CMS delete Data element H.

Data Element J requires reporting of the number of beneficiaries whose participation status in the MTMP is "pending" during the specified time period. CMS states that this is a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period, but it is not clear what CMS means by the term "pending". Is this beneficiaries who have been identified as qualified but not yet enrolled? Or invited to participate but not yet responded? Or those who have responded but not yet received any communications? This data element is likely to be interpreted differently by different plans and, depending what is required, could involve manual data collection. Unless there is a real need for and benefit to this information, we would recommend it be deleted. Alternately, if CMS believes it is necessary to retain it, it should clarify what it means by the term "pending."

We also note that for this Section, Part D plans are required to submit a file with up to 9 data elements on each beneficiary, including name, date of birth, HIC number, enrollment date and decline date, if applicable. It is not clear why this level of detail is

necessary, and in the interests of limiting the information collection to only that which is necessary, we recommend that this beneficiary level detail not be required.

Recommendations: (i) Data Element H appears to be unnecessary, since Data Elements E-G already cover most, if not all, reasons for discontinuation, and it is not clear what additional value will be derived from this catch-all category. Therefore, we recommend it be deleted. (ii) Data Element J is confusing since it is not clear what CMS means by "pending." We recommend that CMS either clarify what is meant by the term or delete it. (iii) Specific beneficiary-level detail should not be required.

4. Section XV – Long-Term Care (LTC) Rebates

CMS has provided two special reporting cases, one of which allows Sponsors to exercise their discretion for requiring rebate reporting from LTC pharmacies that "serve less than 5% of LTC beds in the area". We appreciate this discretionary exception, and believe that it will significantly reduce the administrative burden for Sponsors, since they will no longer have to pursue the many smaller LTC pharmacies that often do not respond to requests for reporting of their rebates. However, since Part D plans do not have access to information on the number of beds served by an LTC pharmacies, we recommend that CMS allow a substitute measure based on data that plan do collect. One such measure that could be used instead is the LTC pharmacy's claims as a percentage of the total LTC claims received by the Sponsor.

Recommendation: Use "LTC claims" rather than "bed served" as the measure of LTC pharmacies whose rebates need not be reported, since Sponsors have access to claims information, not bed information.

We appreciate the opportunity to provide these comments. If you have any questions or would like discuss our comments, please do not hesitate to contact me at 202-772-3501.

Sincerely,

Russell C. Ring
Sr. Vice President
Government Affairs

COVENTRY
Health Care

CMS-10145

November 12, 2007

Carolyn Lovett
OMB Human Resources and Housing Branch
New Executive Office Building, Room 10235
Washington, DC 20503

Dear Ms. Lovett:

I would like to thank the Centers for Medicare and Medicaid Services (CMS) for this opportunity to review and submit comments related to 2008 Part D reporting. We are requesting that CMS consider the following suggestions and provide additional clarification on the items listed below.

Section I; page 5
We suggest that CMS revise the reporting level for elements A, C and D to the contract level rather than the PBP level. This would make reporting level requirement consistent across all elements. We understand the value of the information requested. However, requiring reporting at the PBP level is burdensome and labor intensive, but likely would provide little additional value over reporting at the contract level.

Section II; page 7
We suggest that if the sponsor offers the mail order option for all PBPs, then the sponsor should have the option to report at the contract level rather than the PBP level for this element. This would eliminate unnecessary duplication of reporting.

Section V; page 10
Please clarify in what circumstances CMS would consider a beneficiary's participation status to be pending. We request that CMS define more clearly what it means by the term "pending." For example, if a sponsor is employing an opt-out option rather than an opt-in option, in what cases would beneficiaries be considered to be in pending status.

Section VII; page 14
We are requesting clarification from CMS whether or not it expects reporting on this element from those plans that did not choose to bundle Part D-covered home infusion drugs under a Part C supplemental benefit.

Again, thank you for the opportunity to provide input into the 2008 Part D reporting document. We appreciate all of the work that CMS put into these documents. And we look forward to our continued partnership with CMS.

Sincerely,

Cheryl A. Powell
Director, Policy and Compliance

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