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August 7, 2007

Bonnie L. Harkless
CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RECEIVED
8/13/07

no envelope attached

Dear Ms. Harkless:

**Re: PRA Comments on Medicare Part D Reporting Requirements for Contract Year 2008**
**Document Identifier: CMS-10185**

SilverScript[SM] Insurance Company (SSIC), a national Medicare Part D Sponsor, and SilverScript, Inc. (SSI), a Part D pharmacy benefit management company (PBM), both affiliates of Caremark Rx, Inc., a leading PBM company, appreciate the opportunity to provide comments on the draft 2008 Reporting Requirements.

SSIC is one of only 10 national PDPs servicing the Medicare 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 (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 two million lives in Medicare Advantage and PDP programs.

**General Comments**
We appreciate the opportunity to provide comments on the 2008 Reporting Requirements and, in particular, ways to reduce the administrative burden of this information collection. Given the significant amount of information being sought, any flexibility in the manner and/or frequency of data collection would be helpful.

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 these reports be submitted twice a year by every plan, based on the Medicare beneficiaries in the plan's service area. Geo-access reports are extremely large documents requiring significant man hours (approximately 400 man hours per report) and information systems resources to prepare. 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 ask CMS to reconsider the need for plans to submit these reports twice a year unless there have been significant network changes. Retail networks are generally very stable and change little from year to year. Certainly most major national networks easily meet the Part D retail access requirements and, if anything, these networks expand over time. As such, we believe it is excessive to require biannual submissions of the full geo-access reports. Instead, plans could be asked to certify that there have been no significant changes or reductions in their networks.

In addition, given that the current reporting requirements will result in substantially the same report being submitted multiple times by a PBM to CMS on behalf of multiple Part D sponsors, 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 once only (or once only at each of the reporting times established by CMS during the year) 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 will satisfy the CMS concern that retail pharmacy access be monitored, but will 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 will accomplish the same outcome, with far less cost and time for all concerned.

**Recommendations: (i) Require plans to provide Geo-Access reports for retail pharmacy access as part of their Part D applications, and thereafter only if there has been a significant change or reduction in their retail network; (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 F requires reporting of vaccines processed through a method other those outlined in Data Elements B through F. Since Data Elements B and C cover in-network and out-of network claims (and C and D merely addresses the method of submission), we do not believe there are any other types of vaccine claim. As such, we request that CMS either delete or clarify this Data Element.

**Recommendation: Clarify or delete Data Element F, since it seems duplicative of Data Elements B and C.**

3. Section V -- MTMP

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 that have been identified as qualified but not yet enrolled? Or invited to participate but not yet responded? Or those that 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 J is confusing and it should be deleted; alternately, CMS should clarify what is meant by the term "pending." (ii) Specific beneficiary-level detail should not be required.**

4. Section IX – Home Infusion Drugs

CMS requires plans to report certain data related to home infusion drugs, namely, the number of beneficiaries to whom such drugs are dispensed and the number of such drugs dispensed, during the specified time period. However, as mentioned previously, CMS provides no guidance on how the term "home infusion drug" should be defined. Since it would be difficult, burdensome, and lead to inconsistencies for plans' to develop their own lists for this purpose, we recommend that CMS clarify that the term "home infusion drug" is defined based on the classification of the pharmacy that dispensed the drug - i.e. if the drug is dispensed by a pharmacy that is classified as a home infusion pharmacy in the plan's network, then any drug dispensed by that pharmacy will be classified as a home infusion drug

Recommendation: CMS should define the term "home infusion drug" based on the classification of the pharmacy that dispensed the drug.

5. Section XVII – Drug Benefit Analyses

The number of data elements required to be reported for drug benefit analyses purposes has increased significantly, and CMS has changed the reporting frequency to monthly. Since in many cases it takes at least two weeks to collect this information, plans and their subcontractors will be in a constant cycle of collecting information for this purpose. In light of the significant number of elements, and the time and resources to gather and input the information, we request that CMS reconsider the need for these reports to be provided on a monthly basis. Instead, we recommend that they be provided on a quarterly basis, broken down by each month in the quarter.

**Recommendation: Require the drug analyses reporting to be provided on a quarterly basis only, but broken down for each month in the quarter.**

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 1-202-772-3501.

Sincerely,

Russell C. Ring
Sr. Vice President
Government Affairs