

**CENTERS FOR MEDICARE & MEDICAID SERVICES
RETIREE DRUG SUBSIDY (RDS) PROGRAM GUIDANCE**

REBATES AND OTHER PRICE CONCESSIONS

Introduction

This document provides guidance for plan sponsors (sponsors) in the Retiree Drug Subsidy (RDS) program on how to submit cost data for purposes of receiving the RDS, including how to:

- Take into account manufacturer rebates and similar price concessions that are retained by a pharmacy benefit manager (PBM);
- Calculate manufacturer rebates and similar price concessions and allocate them among unique benefit options, by month, and;
- Arrange to make drug-specific data available to CMS in the event the sponsor does not have such data.

This updated document interprets the regulatory provisions in 42 CFR §423.888 dealing with the reporting of rebates and similar price concessions. This document incorporates existing guidance dated July 23, 2007 in a document titled “CMS Guidance on Calculating and Reporting Rebates and Similar Price Concessions under the Retiree Drug Subsidy Program,” but modifies that guidance by specifying that the requirement to report rebates retained by a Pharmacy Benefit Manager (PBM) applies only to RDS applications with plan years starting on or after January 1, 2007. (The previous version of this guidance specified that the requirement applied to RDS applications with plan years starting on or after July 1, 2006). This document also replaces two examples of how the requirement to report retained rebates operates, with more illustrative examples. This document, which also makes some technical, terminology-related corrections, supersedes the above-mentioned July 23, 2007 guidance document.

Manufacturer Rebates and Similar Price Concessions Retained by a Pharmacy Benefit Manager

Under 42 CFR §423.882, “allowable retiree costs” (ARC) means gross covered retiree plan-related prescription drug costs (gross costs) that are actually paid (net of any manufacturer or pharmacy discounts, charge-backs, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf). Under 42 CFR

§423.886(a)(1), the RDS subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit (i.e., gross eligible costs), and then determining ARC attributable to gross eligible costs. For purposes of providing data for CMS to use to calculate ARC attributable to gross eligible costs for the RDS, a sponsor must take into account manufacturer rebates that are retained by a Pharmacy Benefit Manager (PBM) as discussed below.

RDS sponsors must account for rebates in the same manner as Part D plans (See pages 10-11 of the Instructions for the 2007 Contract Year for Medicare Prescription Drug Plans (2007 PDP Call Letter), which can be found at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2007PDPCallLetter.pdf>).

A sponsor must take into account all manufacturer rebates - whether received directly by such Sponsor or indirectly via reduced PBM administrative fees - in providing data for CMS to use in determining ARC attributable to gross eligible costs. If the PBM passes through to the sponsor all manufacturer rebates, and charges the sponsor directly for the full cost for the PBM's services, the charge would be an administrative cost that cannot be included in gross covered prescription drug costs (and need not be reported as a rebate or similar price concession). If, instead, the PBM retains a portion of the manufacturer rebates, and charges the sponsor less, or even nothing, for the services, the retained rebate is an administrative fee paid by the sponsor that must be excluded from gross costs and reported as a rebate or similar price concession. Consequently, as explained in the 2007 PDP call letter, we assume for purposes of calculating ARC attributable to gross eligible costs, that the entire portion of the retained rebate is an administrative fee indirectly "paid" to the PBM by the sponsor. In other words, the rebates must be taken into account to reduce ARC attributable to gross eligible costs, regardless of whether there is an express administrative fee between the PBM and the sponsor, and regardless of whether the PBM and sponsor negotiate a reduction in any administrative fee in connection with the PBM's retention of the rebates.

Since administrative costs are excluded from gross costs and therefore from ARC attributable to gross eligible costs, a sponsor should have the same amount of ARC attributable to gross eligible costs, regardless of whether the PBM charges an administrative fee, retains manufacturer rebates, or both.

However, to the extent retained rebates are used to increase point-of-sale discounts for sponsors and/or retirees, the retained rebates need not be reported as rebates or similar price concessions to determine ARC attributable to gross eligible costs. This is because the amount of retained rebates will already have been accounted for at the point-of-sale in the form of lower drug prices, which in turn are reflected in lower gross costs as used to calculate ARC attributable to gross eligible costs. See Preamble to MMA Regulations at 70 FR 4404 (January 28, 2005). The following two examples illustrate this point. The examples assume that all drug costs reflect gross eligible costs (i.e., costs are only for Part D drugs between the cost threshold and cost limit):

Example 1: PBM retains a portion of rebate, none of which is used to increase point-of-sale discount

Average Wholesale Price of Part D Drug = \$100

Point-of-Sale Discount = 18%

Dollar Value of Discount = \$18

Manufacturer Rebate = \$10

Amount of Rebate Directly Passed Through to Plan Sponsor (60%) = \$6

Amount of Rebate Retained by PBM (40%) = \$4

Amount of Retained Rebate NOT Used to Increase Point-of-Sale Discount = \$

ARC Attributable to

Gross Eligible Costs = *Gross Eligible Costs* minus *Rebates Directly Passed Through to Plan Sponsor* minus *Retained Rebates Not Used to Increase Point-of-Sale Discount*
= \$82 - \$6 - \$4
= \$72

Example 2: PBM retains a portion of rebate, all of which is used to increase point-of-sale discount

Average Wholesale Price of Part D Drug = \$100

Point-of-Sale Discount = 22%

Dollar Value of Point-of-Sale Discount = \$22

Manufacturer Rebate = \$10

Amount of Rebate Directly Passed Through to Plan Sponsor (60%) = \$6

Amount of Rebate Retained by PBM (40%) = \$4

Amount of Retained Rebate NOT Used to Increase Point-of-Sale Discount = \$0

ARC Attributable to

Gross Eligible Costs = *Gross Eligible Costs* minus *Rebates Directly Passed Through to Plan Sponsor* minus *Retained Rebates Not Used to Increase Point-of-Sale Discount*
= \$78 - \$6 - \$0
= \$72

Example 3: PBM retains a portion of rebate, some of which is used to increase point-of-sale discount

Average Wholesale Price of Part D Drug = \$100

Point-of-Sale Discount = 20%

Dollar Value of Point-of-Sale Discount = \$20

Manufacturer Rebate = \$10

Amount of Rebate Directly Passed Through to Plan Sponsor (60%) = \$6

Amount of Rebate Retained by PBM (40%) = \$4

Amount of Retained Rebate NOT Used to Increase Point-of-Sale Discount = \$2

ARC Attributable to

Gross Eligible Costs = *Gross Eligible Costs* minus *Rebates Directly Passed Through to Plan Sponsor* minus *Retained Rebates Not Used to Increase Point-of-Sale Discount*
= \$80 - \$6 - \$2
= \$72

In Example 1 the PBM has applied none of the retained rebate to increase the point-of-sale discount. In Example 2, the PBM has received, and retained, the same amount of rebate as in Example 1 (\$10 and \$4), but has used all \$4 of that retained rebate to increase the point-of-sale discount from \$18 to \$22. In Example 3, the PBM has received, and retained, the same amount of rebate as in Examples 1 and 2 (\$10 and \$4), but has used only \$2 of the retained rebate to increase the point-of-sale discount from \$18 to \$20. Therefore, the Plan Sponsor in Example 1 must report all \$4 of the retained rebate as a rebate or similar price concession. The Plan Sponsor in Example 2 need not report any of the \$4 retained rebate as a rebate or similar price concession, but must exclude the \$4 from gross eligible costs. The Plan Sponsor in Example 3 must report \$2 of the retained rebate as a rebate or similar price concession and must exclude the other \$2 from gross eligible costs. Thus, in each case, ARC attributable to gross eligible costs equals \$72.

Plan sponsors subject to the requirement to report rebates retained by a PBM, may currently report such rebates that are not used to increase point-of-sale discounts, either by reporting them as rebates or similar price concessions (as in the example above), or by reducing gross costs by that amount. However, for plan years starting on or after January 1, 2009, plan sponsors must account for such retained rebates by reporting them as rebates or similar price concessions.

CMS expects that, for plans with RDS plan years starting January 1, 2007, and beyond, sponsors will take the necessary steps to comply with the requirement to report all rebates, including negotiating contractual provisions in PBM contracts that ensure reporting to the Sponsor of 100% of the manufacturer rebates paid for Part D drugs, including the portion of such rebates retained by the PBM. If a sponsor has a PBM

contract that was executed before that date and that does not include such provisions, the sponsor may make a reasonable good faith estimate of the manufacturer rebates retained by the PBM, using a reasonable accounting or actuarial methodology, with such estimate reflected in the calculation of ARC attributable to gross eligible costs. CMS expects such sponsors to include the appropriate contractual provisions in any new, renegotiated, or renewed PBM contract.

Allocating Manufacturer Rebates and Similar Price Concessions Among Unique Benefit Options, by Month

A sponsor that qualifies for the retiree drug subsidy will receive 28% of allowable retiree costs (ARC) for each qualifying covered retiree. See 42 CFR §423.886(a) and 42 CFR §882 (definitions of “allowable retiree costs” and “qualifying covered retiree”). The computation of ARC requires the subtraction of rebates and similar price concessions (“rebates”). The following discusses how, for purposes of reporting cost data, a sponsor’s actual rebates can be allocated among unique benefit options, by month, as opposed to allocating rebates on a drug-specific basis for each retiree.

Under 42 CFR §423.888(b), a sponsor may elect to receive subsidy payments from CMS on an interim or annual basis. If the sponsor elects an interim basis, it must submit with its interim cost data estimated rebates based on historical data and generally accepted actuarial principles (except as otherwise provided by CMS). The sponsor also must submit actual rebate information within 15 months after the end of the plan year as part of the reconciliation process. See 42 CFR §423.888(b)(2) and §423.888(b)(4). If the sponsor elects payment on an annual basis, it only has to submit cost data and actual rebate information within 15 months after the end of the plan year. Since the ARC must be determined at the individual retiree level, the rebate amounts must be allocated at the individual retiree level. While rebates must be allocated to each individual retiree’s costs, Plan Sponsors are not required to allocate the rebates based on the individual retiree’s actual usage of the specific Part D drugs for which the sponsor received rebates. For purposes of reporting cost data, sponsors may choose instead to allocate rebates using a methodology that determines rebates received under the plan as a percentage of incurred drug costs, and applies that percentage to the gross retiree costs (defined in 42 CFR §423.882) of each qualifying covered retiree between the cost threshold and the cost limit

For example, a sponsor incurred \$1 million in gross costs for Part D drugs in a plan year with respect to all individuals in its qualified retiree prescription drug plan, and received \$30,000 in actual rebates for Part D drugs with regard to that plan for the same plan year. Assume for purposes of this example that the \$30,000 in rebates that the sponsor received represents all actual rebates. Also, assume that all rebates were received by the sponsor after the point of sale.

To determine the amount of rebates that must be reported for RDS purposes for a given month, the sponsor could apply the following procedure:

Step 1 – Determine the amount of costs for Part D drugs that are attributable to qualifying covered retirees in the qualified prescription drug plan between the cost threshold and the cost limit (gross eligible costs), as a percentage of all costs for Part D drugs for all individuals in the qualified retiree prescription drug plan.

In this example, assume the sponsor has determined, based on regulations at 42 CFR §§ 423.880 – 423.888 and other CMS documents, that it incurred \$800,000 in gross eligible costs for qualifying covered retirees for the plan year. This means that 80% of total Part D drug costs (\$800,000 divided by \$1 million) are attributable to eligible gross costs for qualifying covered retirees.

Step 2 – Determine the amount of rebates for Part D drugs that are attributable to costs for Part D drugs between the cost threshold and cost limit (gross eligible costs) for qualifying covered retirees.

In Step 1, it was determined that 80% of total Part D drug costs for the qualified retiree prescription drug plan were attributable to gross eligible costs for qualifying covered retirees. Therefore, the sponsor, for purposes of RDS, can assume that 80% of total rebates for Part D drugs, or \$24,000 ($\$30,000 \times 0.8$), are attributable to gross eligible costs for qualifying covered retirees.

Step 3 - Determine the amount of total rebates for Part D drugs for qualifying covered retirees for costs between the cost threshold and cost limit (gross eligible costs) as a percentage of gross eligible costs for Part D drugs for qualifying covered retirees.

In this example, total rebates for Part D drugs for qualifying covered retirees for gross eligible costs, as a percentage of total gross eligible costs for Part D drugs for qualifying covered retirees, is calculated by dividing \$24,000 by \$800,000, yielding a percentage of 3%.

Step 4 - For the month in question, determine the amount of rebates for Part D drugs that are attributable to Part D drug costs for qualifying covered retirees that fall between the cost threshold and cost limit (gross eligible costs), for the entire qualified prescription drug plan.

In this example, assume the sponsor had \$4,000 in gross eligible costs for qualifying covered retirees for the month, across its entire qualified retiree prescription drug plan. Based on the fact that total rebates for Part D drugs for qualifying covered retirees for gross eligible costs as a percentage of total gross eligible costs for Part D drugs is 3% for the entire plan year (see step 3), the sponsor can assume that, for any given month, the rebates for Part D drugs as a percentage of gross eligible costs is also 3%. For this particular month, this would mean that the amount of rebates for Part D drugs attributable to gross eligible costs for qualifying covered retirees for the entire plan, is \$120 ($\$4,000 \times .03$). If

the plan has only one unique benefit option, the sponsor would report \$120 in actual cost adjustments for the month.

Step 5 (if applicable) - For the month in question, determine the amount of rebates for Part D drugs that are attributable to Part D drug costs for qualifying covered retirees that fall between the cost threshold and cost limit (gross eligible costs), for each benefit option within the plan.

In this example, assume the plan had three different benefit options. Also assume that of the \$4,000 in gross eligible costs the plan had for its qualifying covered retirees for the entire RDS plan for the month, \$3,000 of those costs were attributable to Unique Benefit Option Identifier (UBOI) A, \$1,000 were attributable to UBOI B, and \$0 were attributable to UBOI C. Because 75% of those monthly costs (\$3,000/\$4,000) were attributable to UBOI A, the sponsor can assume that 75% of the \$120 monthly rebate amount for the entire plan for all qualifying covered retirees, as calculated in Step 4, or \$90, is attributable to UBOI A for the month. Therefore, the sponsor would enter \$90 as the actual cost adjustment for UBOI A for the month. Similarly, the sponsor would enter \$30 (25% of the monthly \$120 rebate amount) as the actual cost adjustment for UBOI B for the month, and would enter \$0 (0% of the monthly \$120 rebate amount) as the actual cost adjustment for UBOI C for the month.

A key point to keep in mind, as illustrated through the example above, is that a plan sponsor is required to report aggregate rebate amounts only for Part D drug costs between the cost threshold and cost limit, for qualifying covered retirees. Also, the aggregate rebate amount must be reported separately, as an actual cost adjustment during reconciliation (and as an estimated cost adjustment when reported as part of interim cost data), as opposed to merely reducing the amount of gross costs reported.

Sponsors that wish to report rebates and other price concessions in a more precise way, such as by determining aggregate rebate data by totaling each qualifying covered retiree's rebates based on the retiree's utilization of drugs for which rebates are given, may do so. The methodology used for allocating rebates in such a way must be documented and made available if audited.

Reporting and Retaining Rebate Data in Cases Where a Sponsor Does Not or Cannot Disclose Drug-Specific Rebate Data

In accordance with 42 CFR §423.888(a) (incorporating §423.322(a) and §423.888(b)), payment of the RDS is conditioned on the sponsor providing to CMS the information necessary to ensure accurate subsidy payments, including rebate data for Part D drugs provided to the sponsor's qualifying covered retirees between the cost threshold and cost limit. Such information must be provided in the manner specified by CMS. Although we believe we have the authority to require RDS sponsors to report drug-specific rebate data, we directed RDS sponsors to submit aggregate rebate data on a monthly basis (i.e.,

monthly rebate data for all included drugs in the aggregate, without reporting the specific rebate allocated to each drug). (See How to Prepare RDS Cost Data for Submission to the RDS Center, originally published on June 8, 2006 (http://www.rds.cms.hhs.gov/how_to/prepare_cost_data.htm#supposed)). However, in accordance with 42 CFR §423.888(d), an RDS sponsor must maintain and furnish to CMS or the U.S. Department of Health & Human Services Office of Inspector General (OIG), upon request, records documenting its costs and other relevant information utilized for calculating its RDS amount, including drug-specific rebate data.

CMS is aware that some RDS sponsors contracting with PBMs might not have received from the PBMs drug-specific rebate data, as PBMs maintain that their confidentiality agreements with pharmaceutical manufacturers prevent them from disclosing this data to an RDS sponsor. We therefore provide under 42 CFR §423.888(d) that the relevant records utilized for calculating a sponsor's RDS amount may be maintained and furnished to CMS or the OIG by the sponsor's "designee," which we interpret as including those entities with which the RDS sponsor (or its subcontractors) contract to administer its plan or perform other plan functions, including any PBM. In addition, 42 CFR §423.884(b) requires that a RDS sponsor have a written agreement with its health insurance issuer or group health plan regarding disclosure to CMS, on behalf of the sponsor, of the information necessary for the sponsor to comply with its requirements under 42 CFR §423, subpart R, including the requirement that the sponsor or its designee maintain and permit CMS or the OIG to access the aforementioned records for auditing purposes. The sponsor also certifies, in the Plan Sponsor Agreement it executes with CMS, to maintain such a written agreement. Accordingly, payment of the RDS is conditioned upon a PBM providing to a RDS sponsor, or directly to CMS, the required aggregate rebate data. In addition, if CMS or the OIG requests drug-specific data pursuant to an audit or as otherwise necessary to ensure the accurate calculation of a RDS sponsor's subsidy, the RDS sponsor will not be required to provide such data directly to CMS or the OIG if the following conditions are satisfied:

- The PBM retains records sufficient to document drug-specific rebate data;
- The agreement between the sponsor (or its contractor) and the PBM includes a provision obligating the PBM to provide drug-specific rebate data to CMS auditors and the OIG in accordance with 42 CFR §423.888(d); and
- The aggregate rebate data is reported as a separate data element as required by the RDS cost submission and reconciliation process. (See How to Prepare RDS Cost Data for Submission to the RDS Center, originally published on June 8, 2006 (http://www.rds.cms.hhs.gov/how_to/prepare_cost_data.htm#supposed)).

In the event the PBM refuses to provide CMS auditors or the OIG access to drug-specific aggregate rebate data as required under its agreement with the RDS sponsor, CMS reserves the right to impose sanctions against the RDS sponsor as appropriate.