How To Extract Certain Medicare Part B Costs From RDS Payment Requests - Updated 7/23/2007 (corrected)

This guidance, issued by the Centers for Medicare & Medicaid Services, applies to Plan Sponsors participating in the Retiree Drug Subsidy program. It interprets Federal regulations at 42 CFR §423.886. This guidance supersedes a document with the same title that was published on February 16, 2007.

Introduction

Plan Sponsors participating in the RDS Program have expressed concerns about their ability to cost-effectively determine whether certain categories of prescription drugs, when dispensed at a pharmacy, have been administered or prescribed in a way that makes them eligible for coverage under Medicare Part D (and thus potentially a qualifying expense under the RDS Program), or whether they instead are eligible for coverage under Medicare Part B (and therefore not a qualifying RDS expense). To provide flexibility, CMS on February 16, 2007, published a document that described four different options for how an RDS Plan Sponsor could extract costs for such drugs in instances when they are not eligible for Part D. Two of those four options consisted of simplified methodologies containing mathematical formulas that would allow a Plan Sponsor to estimate the cost of such drugs in those instances. However, CMS received feedback that some Plan Sponsors' systems were not constructed to make certain data (i.e., Medicare Part B drug cost data) available for RDS purposes. Therefore some Plan Sponsors could not use either of those two simplified methodologies. This new guidance document includes two additional simplified methodologies (Options 5 and 6) consisting of mathematical formulas that don't require Plan Sponsors to maintain that data. In addition to the two new simplified methodologies, this new guidance document also includes the other four options previously available (Options 1 through 4).

Because new Options 5 and 6 consist of a mathematical formula that is focused on a more targeted universe of drug data (i.e., a universe that does not include Part B drug data), they are referred to below as "targeted" methodologies. Existing Options 3 and 4 are referred to below as "global" methodologies.

Regardless of which of the six options a Plan Sponsor chooses, it must maintain documentation of how it excluded costs for Medicare Part B vs. Medicare Part D drugs, in instances where the drug was not eligible for coverage under Medicare Part D. For example, if the Plan Sponsor applied Option 5, it must maintain documentation of how the application of Option 5 specifically impacted the cost data reported by the Plan Sponsor.

To which categories of prescription drugs do the six different options, discussed in this document, apply?

Each of the six options applies to the following three categories of drugs, about which Plan Sponsors have expressed concerns regarding their ability to cost-effectively determine how they were used/administered:

- Drugs that are covered by Medicare Part B when used for immunosuppressive therapy following a Medicare-covered transplant;
- Oral drugs that are covered by Medicare Part B when used for cancer treatment; and
- Oral anti-emetic drugs that are covered by Medicare Part B when administered within 48 hours of chemotherapy.

In general, drugs in these categories could be Medicare Part D-eligible when used/administered other than as described above.

What are the six options from which Plan Sponsors can choose?

Option 1: Do not submit any costs for any drugs within the three categories of drugs.

Under this option, a Plan Sponsor would not submit **any** costs for **any** drugs within these three categories of drugs.

Option 2: Do a claim-by-claim analysis to identify instances where the drug is ineligible for Medicare Part D.

Under this option, a Plan Sponsor would do an analysis of each claim for each drug within these three categories, and submit costs under the RDS Program only for claims that the Plan Sponsor's analysis reveals are eligible for Medicare Part D.

Option 3: Apply CMS' global simplified methodology based on aggregate gross retiree costs ("Global Aggregate Methodology").

CMS originally published this optional simplified methodology on December 13, 2006, and RDS Plan Sponsors may use it for RDS plan years that end in any year (unless and until CMS states otherwise). Under this methodology ("Global Aggregate Methodology"), the Plan Sponsor calculates its costs for **all** pharmacy-dispensed drugs for the relevant period, and then reduces that total by 0.3%. That reduction is intended to be an approximation of the portion of total pharmacy-dispensed drug expense associated with the three categories of drugs that may be eligible for Medicare Part B coverage. From that reduced number, costs for any pharmacy-dispensed drugs that are specifically excluded from Medicare Part D should be subtracted when determining "gross retiree costs." For example, assume a Plan Sponsor determines that costs incurred under the plan for **all** pharmacy-dispensed prescription drugs are $100,000 for a given Benefit Option in a given month. Under this simplified approach, the Plan Sponsor would be allowed to determine "gross retiree costs" by reducing the costs for all pharmacy-dispensed prescription drugs by 0.3%, or $300, and then subtracting any costs incurred under the plan for pharmacy-dispensed drugs that are specifically excluded from Medicare Part D.

Under this simplified methodology, a Plan Sponsor applies the formula described in the previous paragraph, only to calculate **aggregate** gross retiree costs. (Gross retiree costs are defined in

RDS regulations at 42 CFR §423.882). The Plan Sponsor would **not** apply the formula to calculate **each retiree's** gross retiree costs for purposes of determining the threshold reduction and cost limit reduction. Rather, the Plan Sponsor would report, for the period, the same threshold reduction and cost limit reduction amounts as it would if it were **not** using the simplified methodology (and as if it were requesting the RDS for all claims for all drugs within the three categories of Medicare Part B vs. Medicare Part D drugs in question).

In applying this formula, it is possible (but very unlikely) that the calculation of aggregate gross retiree costs might yield a negative number (i.e., a number less than $0). In such cases, a Plan Sponsor should enter $0 in the applicable data field when reporting cost data.

Option 4: Apply CMS' global simplified methodology based on each retiree's gross retiree costs ("Global Retiree-Specific Methodology").

CMS published this simplified methodology on February 16, 2007, and RDS Plan Sponsors may use it for RDS plan years that end in any year (unless and until CMS states otherwise). Under this Global Retiree-Specific Methodology, a Plan Sponsor would determine aggregate gross retiree costs by summing each retiree's gross retiree costs. However, **each retiree's** gross retiree costs would be calculated by using the formula described above (i.e., for each retiree, reduce the cost of **all** pharmacy-dispensed drugs by 0.3%, and subtract, from that figure, the costs for any pharmacy-dispensed drugs that are specifically excluded from Medicare Part D).

To calculate the total threshold reduction and cost limit reduction for the period, the Plan Sponsor would total each retiree's threshold reduction and cost limit reduction based on each retiree's gross retiree costs, as calculated by using the formula described above (i.e., for each retiree, reduce the cost of **all** pharmacy-dispensed drugs by 0.3%, and subtract, from that figure, the costs for any pharmacy-dispensed drugs that are specifically excluded from Medicare Part D).

The following example demonstrates how a Plan Sponsor would apply the Global Retiree-Specific Methodology, with regard to one specific retiree:

Retiree "A" has $7,000 in total pharmacy-dispensed drug costs, of which $6,400 are for Medicare Part D drugs, $200 are for drugs in the three categories of Medicare Part B vs. Medicare Part D drugs described above, and $400 are for pharmacy-dispensed drugs that are specifically excluded from Medicare Part D. The Plan Sponsor would reduce $7,000 by 0.3%, yielding a result of $6,979. It would then subtract $400 (costs for pharmacy-dispended drugs that are specifically excluded from Medicare Part D) from $6,979, resulting in gross retiree costs of $6,579. When reporting cost data, the Plan Sponsor would enter $250 in the threshold reduction field, and $1,579 in the limit reduction field (calculated by subtracting $5,000 from $6,579). (This assumes the Plan Sponsor is subject to the 2006 cost threshold and cost limit amounts for the RDS application in question). This results in gross eligible costs (the amount of costs between the cost threshold and cost limit) of $4,750. (Any rebates, discounts, chargebacks or similar price concessions would be subtracted from $4,750 to arrive at allowable retiree costs).

Thus, the Global Retiree-Specific Methodology differs from the Global Aggregate Methodology in that a Plan Sponsor using the Global Aggregate Methodology would use the formula described above to calculate aggregate gross retiree costs, but would **not** apply the formula to calculate each retiree's gross retiree costs. Rather, each retiree's gross retiree costs would be calculated as if the

Plan Sponsor were not using any simplified methodology, and as if it were requesting the RDS for all claims for all drugs within the three categories of Medicare Part B vs. Medicare Part D drugs in question. In contrast, a Plan Sponsor using the Global Retiree-Specific Methodology **would** use the formula described above to calculate **each retiree's** gross retiree costs.

In applying this formula, it is possible (but very unlikely) that the calculation of aggregate gross retiree costs and/or an individual retiree's gross retiree costs might yield a negative number (i.e., a number less than $0). In such cases, a Plan Sponsor should enter $0 in the applicable data field.

Option 5: Apply CMS' targeted simplified methodology based on aggregate gross retiree costs ("Targeted Aggregate Methodology")

This methodology can be used for RDS plan years that end in any year (unless and until CMS states otherwise). Under this methodology ("Targeted Aggregate Methodology"), a Plan Sponsor totals its costs for all Medicare Part D drugs, plus its costs for all Medicare Part B vs. Medicare Part D drugs in the three categories of drugs specified above (i.e., drugs that are covered by Medicare Part B when used for immunosuppressive therapy following a Medicare-covered transplant; oral drugs that are covered by Medicare Part B when used for cancer treatment; and oral anti-emetic drugs that are covered by Medicare Part B when administered within 48 hours of chemotherapy). The Plan Sponsor then reduces that total by 0.3%. For example, assume a Plan Sponsor determines that costs incurred under the plan for Medicare Part D drugs, plus the three categories of Medicare Part B vs. Medicare Part D drugs specified above, is $10,000 for a given benefit option in a given month. Under this simplified approach, the Plan Sponsor would be allowed to determine "gross retiree costs" by reducing $10,000 by 0.3%, or $30. (Note: A Plan Sponsor would exclude costs for all other noneligible drugs, e.g., Medicare Part B drugs, and Medicare Part B vs. Medicare Part D drugs in categories other than those mentioned above in instances where such drugs are not eligible for Medicare Part D, before this simplified approach is applied). Under this simplified methodology, a Plan Sponsor applies the formula described in the previous paragraph, only to calculate **aggregate** gross retiree costs. The Plan Sponsor would **not** apply the formula to calculate each retiree's gross retiree costs for purposes of determining the threshold reduction and cost limit reduction. Rather, the Plan Sponsor would report, for the period, the same threshold reduction and cost limit reduction amounts as it would if it were **not** using the simplified methodology (and as if it were requesting the RDS for all claims for all drugs within the three categories of Medicare Part B vs. Medicare Part D drugs in question).

Option 6: Apply CMS' targeted simplified methodology based on each retiree's gross costs ("Targeted Retiree-Specific Methodology")

This methodology can be used for RDS plan years that end in any year (unless and until CMS states otherwise). Under this "Targeted Retiree-Specific Methodology," a Plan Sponsor would determine aggregate gross retiree costs by summing each retiree's gross retiree costs. However, **each retiree's** gross retiree costs would be calculated using the formula described in Option 5 (i.e., for each retiree, total their costs for Part D drugs, plus their costs for drugs that are covered by Medicare Part B when used for immunosuppressive therapy following a Medicare-covered transplant; oral drugs that are covered by Medicare Part B when used for cancer treatment; and

oral anti-emetic drugs that are covered by Medicare Part B when administered within 48 hours of chemotherapy), and reduce that total by 0.3%.

To calculate the total threshold reduction and cost limit reduction for the period, the Plan Sponsor would total each retiree's threshold reduction and cost limit reduction based on each retiree's gross costs, as calculated by using the formula in the previous paragraph (i.e., for each retiree, total their costs for Part D drugs, plus their costs for the three categories of Medicare Part B vs. Medicare Part D drugs specified above, and reduce that total by 0.3%).

The following example demonstrates how a Plan Sponsor would apply the "Targeted Retiree-Specific Methodology" with regard to one specific retiree. The example illustrates a given retiree's drug costs for one specific month, and assumes this retiree had no drug costs during any previous months in the RDS plan year.

Retiree "A" has $7,000 in Medicare Part D drug costs and $500 in costs for the three categories of Medicare B vs. Medicare Part D drugs described above. The Plan Sponsor would add these numbers, which totals $7,500. The Plan Sponsor would then reduce $7,500 by 0.3%, resulting in gross retiree costs of $7,477.50.[1] When reporting cost data, the Plan Sponsor would enter $250 in the cost threshold field, and $2,477.50 in the cost limit field (calculated by subtracting $5,000 from $7,477.50). (This assumes the Plan Sponsor is subject to the 2006 cost threshold and cost limit amounts for the RDS application in question). This results in gross eligible costs of $4,750. (Any rebates, discounts, chargebacks or similar price concessions would be subtracted from $4,750 to arrive at allowable retiree costs).

Thus, the Targeted Retiree-Specific Methodology differs from the Targeted Aggregate Methodology in that a Plan Sponsor using the Targeted Aggregate Methodology would use the formula described in the previous paragraph to calculate aggregate gross retiree costs, but would **not** apply the formula to calculate each retiree's gross retiree costs. Rather, each retiree's gross retiree costs would be calculated as if the Plan Sponsor were not using any simplified methodology, and as if it were requesting the RDS for all claims for all drugs within the three categories of Medicare Part B vs. Medicare Part D drugs in question. In contrast, a Plan Sponsor using the Targeted Retiree-Specific Methodology **would** use the formula described above to calculate **each retiree's** gross retiree costs.

Might Options 3, 4, 5, or 6 described above for extracting certain Medicare Part B costs from RDS payment requests change over time?

CMS may refine the options in the future. For example, the percentage reduction may be adjusted at some point for future periods, based on data that CMS may obtain.

Can Plan Sponsors using Option 3, 4, 5, or 6 also arrange to have the drugs in these three categories submitted under Medicare Part B?

[1] Gross retiree costs might exceed $7,477.50 if, for example, the retiree had costs for Medicare Part B vs. Medicare Part D drugs in a category other than one of the three that is the focus of this paper, in instances where the drug is eligible for Part D.

No. Consistent with the goal of these being simplified methodologies, any Plan Sponsor electing to use Option 3, 4, 5 or 6 would not be permitted to also arrange to have these same drugs submitted under Medicare Part B.

If a Plan Sponsor had applied Option 2 (i.e., did a claim-by-claim analysis for the three categories of Medicare B vs. Medicare D drugs) for every claim throughout the plan year, may the Plan Sponsor switch to Option 3, 4, 5, or 6 for purposes of reporting costs during reconciliation?

If a Plan Sponsor has done a claim-by-claim analysis for the three categories of drugs for every claim throughout the plan year, and knows that the claim-by-claim analysis is accurate, the Plan Sponsor cannot switch to Option 3, 4, 5, or 6 for purposes of reconciliation, This is because CMS' intent in offering the simplified methodologies described in Options 3, 4, 5, and 6 is to relieve Plan Sponsors of the burden of doing a claim-by-claim analysis. If a Plan Sponsor had already done such an analysis, and it knows what its actual Part-D eligible costs for these three categories of drugs are, then providing any other figure, for purposes of reconciliation, that the Plan Sponsor knows is not accurate (i.e., an estimate), is prohibited. However, if, at reconciliation, the Plan Sponsor has reason to believe that its claim-by-claim analysis was inaccurate, it is acceptable for the Plan Sponsor to switch to Option 3, 4, 5, or 6 for purposes of reconciliation.

If a Plan Sponsor had applied Option 1 or Option 2 for part of the plan year (e.g., January through March), may the Plan Sponsor switch to Option 3, 4, 5, or 6 for purposes of reporting cost data for the remainder of the plan year? Conversely, if a Plan Sponsor had applied Option 3, 4, 5, or 6 for part of the plan year, may the Plan Sponsor switch to Option 1 or Option 2 for purposes of reporting cost data for the remainder of the plan year?

Yes. Be aware that a Plan Sponsor must calculate each retiree's cumulative gross retiree costs from the first day of the plan year through the month for which costs are being reported (in order to calculate each retiree's threshold reduction and cost limit reduction). A Plan Sponsor switching options as described in this question would not need to change any accurate data already reported before it switched options. For example, a Plan Sponsor switches from Option 2 to Option 6. For months in which the Plan Sponsor is no longer applying Option 2, but is instead applying Option 6, the Plan Sponsor should add the cumulative gross retiree costs total that had already been calculated for that retiree, for the months in which the Plan Sponsor was applying Option 2, to the cumulative gross retiree costs total for that retiree for each month that the Plan Sponsor is using Option 6. For each month that the Plan Sponsor is using Option 6, the plan would calculate each retiree's gross retiree costs as described in the section of this paper that discusses Option 6. If a Plan Sponsor has reason to believe that its claim-by-claim analysis undertaken under Option 2 for those initial months is incorrect, it may switch to Option 6 for those months, by rereporting cost data for those months accordingly. (Be aware that if a second cost reporting source is rereporting cost data for any given month, the first cost reporting source must zero out the costs for that month, to avoid duplicate cost reporting for the same retirees).

Like drugs within these three categories, there are other drugs that are not always Medicare Part B drugs or Medicare Part D drugs, but might be one or the other, based on circumstances. How should Plan Sponsors account for these other drugs?

Plan Sponsors may not submit costs for RDS for such drugs in instances when they are eligible for Medicare Part B and not Medicare Part D. Plan Sponsors may use any reasonable methodology to ensure that they are extracting costs for such drugs in such instances. A Plan Sponsor must maintain documentation of how it excluded costs for Medicare Part B vs. Medicare Part D drugs, in instances where the drug was not eligible for coverage under Medicare Part D

Can Plan Sponsors use Option 3, 4, 5, or 6 for purposes other than the RDS Program?

No.

How can I find more details about drugs that do not qualify for RDS because they are specifically excluded from Medicare Part D coverage?

There are certain categories of drugs that are specifically excluded from Medicare Part D coverage and thus they are not qualifying RDS expenses. They include drugs eligible for coverage under Medicare Part B such as influenza vaccines and injectable/intravenous drugs administered predominantly by physicians, and a list of drugs identified by statute such as non-prescription drugs and barbiturates. For details about these ineligible drugs, see the applicable portions of the Medicare Part D Manual, which can be found at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts.pdf