

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR BENEFICIARY CHOICES

Date: May 08, 2008

To: All Part D Plan Sponsors

From: Tom Hutchinson,
Director, Medicare Plan Payment Group

Subject: The Part D Reopenings Process and the Part D Appeals Process

In the attached guidance, “Explanation of the Reopenings Process and the Appeals Process for 2006 Part D Payment Reconciliation”, CMS provides operational guidance on the reopenings and appeals processes, which are mutually exclusive processes. Generally, a request for reopening is filed when a plan sponsor believes there is a data submission issue. Appeals are filed when a plan sponsor does not believe that CMS applied its stated payment methodology correctly.

Specific deadlines for filing appeals will be provided when CMS announces the availability of the results of the 2006 Part D Payment Reconciliation Reopenings. Any questions regarding the reopenings process or the appeals process should be directed to StrategicHealthSolutions, LLC at PartDPaymentReview@strategichs.com

Explanation of the Reopenings Process and the Appeals Process for 2006 Part D Payment Reconciliation

Each year, CMS will perform a Final Part D Payment Reconciliation in accordance with §1860D-14 and §1860D-15 of the Social Security Act and associated regulations and guidance. Sections 423.346 and 423.350 of Title 42 of the Code of Federal Regulations (C.F.R.) set forth the regulatory requirements for reopenings and payment appeals. The following guidance will further explain both processes.

Reopening(s) Process- 42 C.F.R. §423.346

CMS has the authority to reopen and revise initial or reconsidered final payment determinations. The final payment determination must be reopened and revised within the time periods specified below. Therefore it is crucial that the plan sponsor submit its request for reopening in time for CMS to evaluate the request and if granted, proceed with reopening and revising the final payment determination within the time periods specified below. Final payment determinations include determinations of the final amounts of direct subsidy, reinsurance, low income subsidy, or risk corridor payments.

CMS may reopen a final payment determination within 12 months from the date of the notice of final determination to the Part D sponsor for any reason. After 12 months but within 4 years, CMS may reopen upon establishment of good cause. “Good cause” is defined in the regulation as:

- New and material evidence that was not readily available at the time the final determination was made;
- A clerical error in the computation of payments; or
- When evidence that was considered in making the determination clearly shows on its face that an error was made.

CMS may reopen final payment determinations at any time in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D Sponsor. Except in instances of fraud or similar fault, the regulation does not allow for reopenings beyond the four-year period.

Subject to 42 C.F.R. §423.346 and applicable guidance, CMS may reopen on its own volition or a plan sponsor may request that CMS, at its discretion, reopen and revise a final payment determination.

- To request a reopening, send requests and all applicable documentation to StrategicHealthSolutions, LLC (Strategic) at:

StrategicHealthSolutions, LLC
10040 Regency Circle, Suite 150
Omaha, NE 68114

Or submit an electronic copy of your request and all applicable documentation to Strategic at:

PartDPaymentReview@strategichs.com

- Submit sufficient documentation of your reason(s) for your reopening request and include a thorough analysis of the estimated financial impact for each reason stated within the request, including the specific amount of money you believe is at issue. If a reason is specific to one contract or a subset of contracts, please note this in your request. The attached spreadsheet must be completed and submitted with your request for reopening, unless directed otherwise by CMS.
- If you submit your request via email, **your request is not considered received until you receive a confirmation email from Strategic.** You should receive a confirmation within one business day of filing your request. If not, please contact Strategic. Your request is considered received on the actual date the email is received by Strategic, which may differ from the date Strategic sends the confirmation. If you submit your request via mail, you must have proof of delivery.
- Strategic will send your request and accompanying information to CMS. Upon receipt of your request, CMS will analyze your submission and make a decision whether or not to reopen the final payment determination. The regulation does not establish a time period for this review; however, CMS will attempt to make a timely decision on the reopening request.

If a sponsor anticipates requesting a reopening of a Part D Payment Reconciliation for a benefit year because of additional Prescription Drug Event (PDE) data, CMS expects that the sponsor will continue to submit PDE data beyond the established PDE data submission deadline for the Part D Payment Reconciliation for that benefit year, and otherwise continue communicating with CMS (via Strategic) in order to resolve the issue.

If a sponsor anticipates requesting a reopening for other reasons, such as an error in the annual Direct and Indirect Remuneration (DIR) Report, it is expected that the sponsor will perform its due diligence, including working with CMS to resolve the issue, prior to requesting a reopening. CMS will not grant a reopening to a sponsor that has not attempted to provide CMS (through Strategic) with the additional data the sponsor is requesting to be considered in the reopening process.

- Once a decision is made on whether to reopen or not, Strategic will email the sponsor the CMS decision. The email will be sent to the sponsor contact

person(s) designated to communicate with Strategic on Part D Payment Reconciliation issues.

- If a decision to reopen is made, a sponsor can expect to receive further guidance from CMS. The reopening and revision process requires substantial CMS preparation and resources and cannot be expected to be performed immediately after the sponsor receives the decision to reopen. A decision not to reopen is final and is not subject to review.

Appeals Process- 42 C.F.R. §423.350

Appeals can be filed upon receipt of an initial determination or a determination based upon a reopening. As stated in §423.350, an appeal can be filed if a plan sponsor believes that CMS did not apply its stated payment methodology correctly. Payment information submitted to CMS under §423.322 and reconciled under §423.343 is among items not subject to appeal. (See the Reopenings Process section above).

In submitting an initial reconsideration, be sure to include all information and data necessary to evaluate your request. All levels of the appeals process are based upon the information and data submitted in the initial reconsideration request.

The appeals process should occur in the order outlined below.

Request for Reconsideration

- Send requests for reconsideration to Strategic at:

StrategicHealthSolutions, LLC
10040 Regency Circle, Suite 150
Omaha, NE 68114

Or submit an electronic copy of your request and all applicable documentation to Strategic at:

PartDPaymentReview@strategichs.com

- Your request must be filed (sent) with Strategic within 15 days of the date on which CMS releases an adverse determination, which includes the Reconciliation Reports. If you submit your request via email, your request is not considered filed until you receive a confirmation email from Strategic. You should receive a confirmation within one business day of filing your request. If not, please contact Strategic. Your request is considered filed on the actual date the email is received by Strategic, which may differ from the date Strategic sends the confirmation. If you submit your request via mail, you must have proof of mailing/receipt.

Your request for reconsideration must specify the findings or issues with which you disagree and the reason(s) for the disagreement(s). The request for reconsideration may include additional documentary evidence you wish CMS to consider but may not include new payment information.

- Indicate all contract numbers for which you are requesting a reconsideration when sending in your request. If a disagreement relates to one of many contracts or a subset of contracts, please indicate which disagreements relate to which contracts.
- Strategic will forward your information to CMS for review. The regulation does not establish a time period for this review; however, CMS will attempt to make a timely decision in response to a request.
- Once the reconsideration decision is made, Strategic will email the sponsor with the CMS decision. The email will be sent to the sponsor contact person(s) designated to communicate with Strategic on Part D Payment Reconciliation issues. CMS, via Strategic, will notify a plan sponsor of its decision by letter, instead of email, only if the sponsor requested a response by letter within the request for reconsideration. The letter will be sent to the sponsor contact person(s) designated to communicate with Strategic on Part D reconciliation issues. The reconsideration decision is final and binding unless a request for an informal hearing with a CMS Hearing Officer is filed.
- If CMS reconsiders in the plan sponsor's favor, the plan sponsor can expect to receive further guidance from CMS on the next steps.

Informal Hearing Process

If CMS denies a reconsideration request, the sponsor can request an informal hearing with the CMS Hearing Officer. A Part D sponsor should not submit a request to the CMS Hearing Officer prior to receiving the reconsideration decision from CMS. The reconsideration decision will give the specific address where the request for an informal hearing and a copy of the reconsideration decision should be filed. The sponsor should also send a copy of the request to Strategic so that CMS knows to forward the appropriate information to the CMS Hearing Officer, as discussed below. The process and requirements for a hearing are outlined below.

- If a sponsor requests an informal hearing, the request must be made in writing and must be filed (sent) within 15 days of the date that the Part D sponsor receives the CMS reconsideration decision. You must have proof of mailing/receipt.
- The request for a hearing must include the copy of the CMS reconsideration decision. The sponsor must attach a written statement specifying the findings or issues in the decision with which the Part D sponsor disagrees and the basis for the disagreements. No additional evidence should be attached to the submission. Once CMS receives a copy of the request for informal hearing from Strategic,

CMS will promptly forward to the CMS Hearing Officer, a copy of all the materials which were in the record before CMS when it made its initial and reconsidered determinations. CMS will also send a copy of such documents to the sponsor to ensure that the sponsor has a copy of the record before the Hearing Officer.

- The CMS Hearing Officer will provide the time and place of the informal hearing at least 10 days before the scheduled date. The CMS Hearing Officer will consider requests to hold the hearing in person, by telephone, by video conference, or on the record.
- The CMS hearing officer will not consider new evidence or accept witness testimony. However, the representative (s) will be expected (in written briefs and, if held, at oral hearing arguments), to provide a complete explanation of the evidence in the record to support their position.
- The CMS Hearing Officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision. The decision is final and binding, unless the sponsor requests a review by the CMS Administrator.
- If the CMS Hearing Officer finds in the plan sponsor's favor, the plan sponsor can expect to receive further guidance from CMS on the next steps.

Review by the CMS Administrator

If the CMS Hearing Officer upholds a CMS reconsideration determination, the sponsor can request a review by the CMS Administrator. A Part D sponsor should not submit a request for Administrator review prior to receiving the decision from the Office of Hearings. Do not send in your request directly to the Administrator. The CMS Hearing Officer's decision will provide the details on how and where to file a request for Administrator review. The process and requirements for an Administrator review are outlined below.

- The regulation requires the request for Administrator review to be filed within 15 days of the date on which the sponsor receives the hearing officer's decision.
- The request should not contain additional information. The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision.
- If the Administrator finds in the plan sponsor's favor, the plan sponsor can expect to receive further guidance from CMS on the next steps.
- The decision of the Administrator is final and binding.