

CENTER FOR MEDICARE

DATE: July 12, 2013

TO: Drug Manufacturers

FROM: Cheri Rice, Director, Medicare Plan Payment Group

SUBJECT: Instructions for Resolving Coverage Gap Discount Program (CGDP) Negative Invoice Amounts

The Centers for Medicare & Medicaid Services (CMS) is announcing a two-part process to reconcile negative amounts appearing on CGDP invoices. Please direct questions regarding this process to the TPA at tpaoperations@tpadministrator.com, or by telephone at 1-877-534-2772, option 1.

Background:

In certain instances in the CGDP quarterly invoicing process, a drug manufacturer may receive a negative invoice amount on the quarterly Coverage Gap Discount invoice. This can occur when Prescription Drug Events (PDEs), which have been previously invoiced, were either deleted or adjusted by the plan such that the reported gap discount amounts were less than originally invoiced. A negative invoice amount can be thought of as the gap discount amount a manufacturer has overpaid a Part D sponsor in a prior quarter that is now due back to the manufacturer because of a PDE adjustment or deletion. There is presently no mechanism in place for a plan to reimburse a drug manufacturer, nor a process to credit future invoices.

Phase I:

In order to facilitate repayment of negative invoice amounts owed by Part D sponsors to manufacturers, the TPA will distribute the "Manufacturer Negative Balance Report" to manufacturers. The file layout for this report is included as Attachment A of this memo. Similarly, Part D sponsors will also receive a version of the Negative Balance Report. The first set of reports will reflect the negative invoice balances owed by sponsors to manufacturers cumulatively to-date for the period 2011 Quarter 1 through 2013 Quarter 2 (i.e., January 1, 2011 through June 30, 2013). These reports will be released on October 17, 2013. The second distribution of these reports will reflect negative invoice balances owed by sponsors to manufacturers for the period 2013 Quarter 3 through 2013 Quarter 4 (i.e., July 1, 2013 through December 31, 2013). These reports will be released on April 17, 2014. Based on the Contract Negative Balance Report, sponsors shall promptly reimburse manufacturers the cumulative negative Coverage Gap Discount invoice balances owed for the range of Quarters reported; in effect reconciling the outstanding balances between the two parties. This payment shall occur



CENTER FOR MEDICARE

within 38 days of the Negative Balance Report distribution, in accordance with the time allotted for manufacturers to pay sponsors CGDP invoices.

To facilitate this repayment process, the TPA will collect Electronic Funds Transfer (EFT) information from manufacturers and deliver it securely to Part D sponsor’s CGDP mailboxes approximately six weeks prior to report distribution. The table below illustrates the schedule for collection of EFT information from manufacturers, distribution of that information to Part D sponsors, and Negative Balance Report distribution.

EFT Update Timeline-Manufacturers

Schedule	EFT MFR File Update Cutoff	Distribution of EFT MFR file to Part D Sponsors	Manufacturer and Contract Negative Balance Report Distribution
1	8/17/2013	8/25/2013	10/17/2013
2	4/3/2014	4/10/2014	4/17/2014

The EFT form must be completed online. To access the online EFT Information Form, navigate to www.tpadministrator.com and click on the EFT Information link to the left of the home screen and choose the EFT Online form (For Manufacturer Use Only). Complete this form in its entirety. Upon completion, data will be automatically sent to the TPA. A PDF form will be generated that you must print, sign and return by regular or express mail to TPA Operations. The hard copy must be signed by the organization’s Chief Financial Officer (CFO), or an individual designated to act in the CFO’s behalf. Note that your EFT information submission will not be complete if the TPA does not receive your original signed form.

Please direct questions concerning this form to the TPA Operations either by email at tpaoperations@tpadministrator.com, or by telephone at 1-877-534-2772, option 1. Please mail hardcopy documentation to one of the following addresses:

Regular Mail

Palmetto GBA TPA Operations
P.O. Box 100275, AG-507
Columbia, SC 29202-3275

Express Mail

CENTER FOR MEDICARE

Palmetto GBA TPA Operations, AG-507
2300 Springdale Drive, Bldg. One
Camden, SC 29020

The Manufacturers Negative Balance Report is structured in the same way as the CGDP Invoice File. The file consists of one manufacturer header and one trailer record, one to many contract header and trailer records, and one to many detail records. The contract trailer tells manufacturers which contracts owe a refund due to a negative invoiced amount over the reported quarters and how much the refund should be. Also, the contract trailer includes the EFT Individual Identification Number which sponsors will include on their EFT payments so that manufacturers can identify who the EFT payment came from.

The detail records on the Manufacturer Negative Balance Report further delineate the amount owed by a contract to a manufacturer by providing a summary of the negative invoiced amount by quarter and labeler. Since the inception of the CGDP, there have been changes in ownership of a number of labeler codes. As a result, it is possible that a labeler which was owned by one manufacturer at the time of invoice is now owned by a different manufacturer. In this case, any negative invoice amounts attributed to the labeler will appear on the Negative Balance Report of the manufacturer who is the current owner of the labeler.

Phase II:

Beginning in 2014 Quarter 1, a process of maintaining a rolling accounting of negative Coverage Gap Discount balances owed between plans and drug manufacturers each quarter will be implemented as part of the Coverage Gap Discount Manufacturer Quarterly Invoicing process. The negative balances will be carried forward, to be offset by future positive quarterly invoice balances. The net difference between the current quarterly Coverage Gap Discount invoice amount and the prior negative balance owed will be calculated and invoiced each quarter, with the expectation that many negative balances will be reconciled by future quarters' positive invoice amounts. Further information, including revised CGDP invoice file layouts, will be released at a later date.

Recognizing that not all negative balances may be reconciled in all cases, cumulative outstanding negative Coverage Gap Discount invoice balances will be reported annually. This report will be similar to the negative balance reports described in phase I above.