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



MEDICARE PLAN PAYMENT GROUP

TO: All Part D Plan Sponsors and Drug Manufacturers

FROM: Cheri Rice, Director

Medicare Plan Payment Group

SUBJECT: Updates to the Process for Resolving Coverage Gap Discount Program Negative

Invoiced Amounts

DATE: January 22, 2014

The Third Party Administrator (TPA) for the Coverage Gap Discount Program (CGDP) released Negative Invoice reports to Part D sponsors and drug manufacturers on October 31, 2013. CMS became aware of an error in these reports affecting the summarization of detail records to trailer records that caused incorrect values to be reported as due from Part D sponsors to manufacturers on some of the trailer records. On November 5, 2013, the TPA distributed a message via their listserv notifying all parties that these reports should be disregarded and no payments should be made on account of these reports. An additional reminder to disregard these reports was distributed on November 27, 2013.

This memo defines the revised process by which CMS will reconcile negative invoiced amounts from prior quarters as well as a revised approach to addressing negative invoice amounts going forward.

Invoice Reconciliation:

The Negative Invoice Reconciliation reports for October will not be reissued. Instead, the reports to reconcile negative balances from prior invoices will be issued once on April 17, 2014, and will be for the invoice periods Q1 2011 through Q4 2013. This one-time report will be referred to as the Invoice Reconciliation Report. The file layout for the Manufacturer Invoice Reconciliation Report and the file layout for the Part D Sponsor Invoice Reconciliation Report are posted to the TPA website under the link titled "Invoice Reconciliation Information".

All manufacturers and Part D sponsors will receive an Invoice Reconciliation report even if there have been no negative invoiced amounts on prior invoices. Previously invoiced negative

amounts will be refunded to the manufacturer who owned the labeler at the time that the original invoice was generated. This is consistent with how we will address negative invoiced amounts going forward, i.e. at the time that the negative amount appears on an invoice.

Part D Sponsor Invoice Reconciliation report:

The Part D sponsor Invoice Reconciliation report provides a detail record (DETQT) that reports the total invoiced gap discount amount (whether positive or negative) for each invoice period, for each manufacturer P-number. The "Total Invoiced Gap Discount Amount" on the Invoice Reconciliation Report should match the "Total Gap Discount Amount this Period" field on the trailer of the original quarterly invoice report for the matching reporting period.

Similar to the quarterly invoices, the amount to be paid or received is described in the trailer record (GNSMT) and it is the trailer record that will serve as the basis for payment confirmation. The financial amounts on the trailer record of the Invoice Reconciliation Report are the "Net Total Invoiced Gap Discount Amount" which summarizes for each manufacturer P-number the "Total Invoiced Gap Discount Amount" detail records for all reporting periods. Additionally the "Total Gap Discount Amounts Previously Paid to you by this Manufacturer" field summarizes all positive invoiced amounts for each P-number from invoices from Q1 2011 to Q4 2013. The "Total Overpaid Gap Discount Amounts Owed by you to this Manufacturer" field summarizes all negative invoiced amounts for each P-number from invoices from Q1 2011 to Q4 2013. This field is the amount to be repaid from the Part D sponsor to the specified manufacturer. Part D sponsors should be sure to include the EFT Individual Identification Number, as provided on the trailer record, so that manufacturers can easily identify the source and purpose of the payment.

Finally, the contact trailer record (GNSCT) summarizes all monies that have been paid to you ("Total Gap Discount Amounts Previously Paid to You" field) and are due from you to all manufacturers ("Total Overpaid Gap Discount Amounts Owed by You" field) for the reporting period.

Manufacturer Invoice Reconciliation report:

The manufacturer Invoice Reconciliation report provides a detail record (DETQT) that reports the total invoiced gap discount amount (whether positive or negative) for each invoice period, for each Part D sponsor. The "Total Invoiced Gap Discount Amount" on the Invoice Reconciliation Report should match the "Total Gap Discount Amount this Period" field on the trailer of the original quarterly invoice report for the matching Reporting Period.

Similar to the quarterly invoices, the amount to be paid or received is described in the trailer record (GNSCT) and it is the trailer record that will serve as the basis for payment confirmation.

The financial amounts on the trailer record of the Invoice Reconciliation Report are the "Net Total Invoiced Gap Discount Amount" which summarizes for each Part D sponsor the "Total Invoiced Gap Discount Amount" detail records for all reporting periods. Additionally the "Total Gap Discount Amounts Previously Paid by you to this Contract" field summarizes all positive invoiced amounts for each Part D sponsor from invoices from Q1 2011 to Q4 2013. The "Total Overpaid Gap Discount Amounts Owed to you by this Contract" field summarizes all negative invoiced amounts for Part D sponsor from invoices from Q1 2011 to Q4 2013. This field is the amount to be repaid from the Part D sponsor to the specified manufacturer. Manufacturers should expect that Part D sponsors include the EFT Individual Identification Number, as provided on the trailer record, so that manufacturers can easily identify the source and purpose of the payment.

Finally, the manufacturer trailer record (GNSMT) summarizes all monies that have been paid by you ("Total Gap Discount Amounts Previously Paid by You" field) and are due to you from all sponsors ("Total Overpaid Gap Discount Amounts Owed to You" field) for the reporting period.

Invoice Reconciliation Report Payment Confirmation:

In response to the Invoice Reconciliation Report, Part D sponsors and drug manufacturers must provide payment confirmation to the TPA by May 30, 2014. The formats for both the sponsor and manufacturer version of payment confirmation are available on the TPA Website under the "Invoice Reconciliation Information" section. Similar to payment confirmation for quarterly invoicing, the basis for the Invoice Reconciliation Report Payment Confirmation is the trailer record (GNSMT on the sponsor report and GNSCT of the manufacturer report). Payment confirmation must be submitted even if the Invoice Reconciliation Report indicates that no money is to be repaid or received.

Addressing Negative Amounts on Future invoices:

We are also modifying our previously announced approach to ongoing resolution of negative balances, which was previously called Phase 2 of Negative Invoice processing. On July 12, 2013, the Centers for Medicare & Medicaid Services (CMS) released two HPMS memorandums, one to Part D sponsors and another to drug manufacturers, both entitled, "Instructions for Resolving Coverage Gap Discount Program (CGDP) Negative Invoiced Amounts." These memorandums discussed a second phase that included modifications to the current CGDP Quarterly Invoices to add a rolling balance to carry forward any negative amounts due from Part D sponsors back to drug manufacturers to be offset by future positive invoice amounts. We are redesigning this process to more closely align with the Plan-to-Plan (P2P) process familiar to Part D sponsors, which allows for a reconciliation of payables and receivables between parties

on a flow basis. Negative amounts will be paid by Part D sponsors to drug manufacturers at the time the invoice is received as opposed to carrying the negative balance forward. This approach will eliminate the need for an annual reconciliation of CGDP invoices as originally envisioned.

The CGDP Quarterly Invoice file layouts and associated payment confirmations will remain unchanged, however, manufacturers and sponsors are now directed to confirm negative amounts as those amounts are paid by Part D sponsors and received by manufacturers. This means that a manufacturer shall confirm a negative invoiced amount if that amount was received from the Part D sponsor. Manufacturers shall confirm a positive amount to indicate that the manufacturer has issued payment to a Part D sponsor. Manufacturers may confirm \$0 if no payment was received when the invoiced amount was negative or if no payment was sent if an invoiced amount was positive. Manufacturers may also confirm an alternate amount if a partial payment was received when the invoiced amount was negative or partial payment was sent if an invoiced amount was positive.

EFT information:

In order to be reimbursed the negative amounts found on previous invoices and to address negative amounts beginning in Q1 2014 (discussed above), drug manufacturers must supply valid EFT information to the TPA for secure distribution to Part D sponsors. If manufacturers who have previously supplied EFT information to the TPA have changes, the changes may be reported to the TPA on an ongoing basis. Valid EFT information must be received by March 3, 2014 to be included for distribution to Part D sponsors on March 18, 2014, in advance of the Invoice Reconciliation Report distribution. Manufacturers who have not supplied this information should expect outreach from the TPA to collect this information. Failure to provide this information will result in non-payment from Part D sponsors.

In advance of the invoice that will be issued for Q1 2014 and in advance of every quarterly invoice going forward, the TPA will distribute Manufacturer EFT information securely to Part D sponsors to facilitate the repayment of negative invoice amounts as they are reflected on the invoice each quarter. The schedule provided in Attachment A specifies the date that any additions or changes to Manufacturer EFT information must be received by the TPA and the date on which the TPA will deliver the EFT information to Part D sponsors. This calendar is consistent with the EFT update schedule that is currently used for the TPA to communicate Part D sponsor EFT information to manufacturers on a quarterly basis. This schedule is posted on the TPA website under the "CGDP Calendar" link. As a reminder, both manufacturers and Part D sponsors must use the EFT update forms available on the TPA website at http://tpadministrator.com to notify the TPA of any changes. After choosing "EFT Information"

on the left side menu, manufacturers should use the EFT Online Form (For Manufacturer Use Only) and sponsors should use the EFT Online Form (For Sponsor Use Only).

If you have any questions or concerns, please contact TPA Support Center either by Email at tpaoperations@tpadministrator.com, or by telephone at 1-877-534-2772, Option 1.

Attachment A: EFT Quarterly Update Timeline

Benefit Year and Quarter	PDE Invoice Reporting Period End	EFT File update cutoff	Updated EFT file distributed	Quarterly Invoice Distribution
2014 Q1	3/31/2014	04/10/2014	04/25/2014	4/30/2014
2014 Q2	6/30/2014	08/10/2014	08/25/2014	8/31/2014
2014 Q3	9/30/2014	10/10/2014	10/25/2014	10/31/2014
2014 Q4	12/31/2014	01/10/2015	01/25/2015	1/31/2015
2015 Q1	3/31/2015	04/10/2015	04/25/2015	4/30/2015
2015 Q2	6/30/2015	08/10/2015	08/25/2015	8/31/2015
2015 Q3	9/30/2015	10/10/2015	10/25/2015	10/31/2015
2015 Q4	12/31/2015	01/10/2016	01/25/2016	1/31/2016