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TO: Part D Sponsors and Pharmaceutical Manufacturers

FROM: Cheri Rice, Director, Medicare Plan Payment Group

DATE: December 28, 2016

RE: Annual Benefit Year Closeout for the Coverage Gap Discount Program Invoicing Cycle

This memorandum is a reminder of the upcoming closeout of the benefit year 2013 Coverage Gap Discount Program (CGDP) invoicing cycle. Prescription Drug Event (PDE) records reporting gap discount amounts for benefit year 2013 that require submission, adjustment, or deletion for any reason must be submitted by January 31, 2017 to be included in the 2013 benefit year's final CGDP invoice.

This memorandum is also a general reminder that a benefit year's CGDP invoicing ends 37 months after the end of the benefit year which is January 31 of the Quarter 17 (Q17) invoicing cycle. Manufacturers will no longer be invoiced for benefit year gap discount amounts after Q17. Gap discount PDE records that require submission, adjustment, or deletion for any reason for the benefit year that is closing out must be submitted by January 31 of Quarter 17 to be included in the benefit year's final CGDP invoice. For more information about the invoicing cycles, please see the guidance released through HPMS on December 22, 2010 titled "Coverage Gap Discount Program Payment Process."

After the January 31 Q17 deadline has passed, Part D sponsors should continue to submit any outstanding gap discount PDEs and continue to make corrections to any PDEs that require adjustment or deletion for closed out benefit years for accurate PDE reporting, but these PDEs will not be invoiced for manufacturer payment if the PDEs report a gap discount amount. Please see below for details on the payment process for certain withheld PDEs, disputes, and appeals that may or may not have resolution after the benefit year closeout.

PDEs Withheld from Invoice

When a PDE reporting a gap discount successfully passes CMS' editing process and becomes an accepted record, that PDE is subjected to additional review and analysis prior to being invoiced. CMS may withhold gap discount PDEs from the invoice based on this analysis, and those withheld PDEs are posted to the PDE Analysis website maintained by the PDE Data Analysis Contractor for sponsor review and action. For more information regarding the withheld PDE process, please see the guidance released on July 30, 2012 through HPMS titled, "Prescription Drug Event (PDE) Analysis Website and Data Quality Review Process for the Coverage Gap Discount Program, Manufacturer Disputes, and Part D Payment Reconciliation."

Any gap discount PDEs that are withheld from the invoice for the benefit year that is closing out must be corrected and resubmitted by January 31 to have the opportunity to be included in the final CGDP invoice in Quarter 17. PDEs that remain withheld after the January 31 deadline will not be invoiced.

These withheld PDEs will be posted to the PDE Analysis website and will be on the Q17 Coverage Gap Tracking Report. Because these Q17 withheld PDEs will not be invoiced, sponsors are not required to provide responses to these outliers. Sponsors are still expected to review and correct the PDEs, as appropriate, to ensure accurate PDE reporting.

After the release of the Q17 invoices and the Q17 Coverage Gap Tracking Report, any withheld PDEs that are still outstanding for the benefit year that is closed to CGDP invoicing will no longer be displayed on future Coverage Gap Tracking Reports or posted on the PDE Data Analysis website.

Manufacturer Dispute and Appeals Process

Per Section V(e) of the Medicare Coverage Gap Discount Program Manufacturer Agreement (Agreement), pharmaceutical manufacturers have the right to dispute invoiced gap discount payments within 60 days of receipt of the invoice. If the Third Party Administrator (TPA) confirms the gap discount is correct and denies the dispute, the manufacturer may appeal the unfavorable determination to the Independent Review Entity (IRE) per Section V(g) of the Agreement. The dispute and appeal rights will apply for gap discounts invoiced in Q17, and the process to determine disputes and appeals will proceed as usual. The dispute determinations for Q17 invoices will be reported through the Dispute Resolution Reports released to Part D sponsors and manufacturers.

The Benefit Year Closeout Invoice Reports allows the Part D sponsor to remit payment for any gap discounts invoiced in Q17 that were successfully disputed or appealed and for any successful gap discounts disputed and appealed from previous quarters of the benefit year in which the Part D sponsor has only recently corrected. Manufacturers should note that PDE correction by the sponsor may lead to reimbursement of all, some, or no portion of the gap discount depending on the necessary PDE corrections completed. CMS released guidance on May 2, 2016 on this process in an HPMS memo titled “Coverage Gap Discount Program Benefit Year Closeout Invoice Reports.”

Please direct any questions regarding this guidance to the Third Party Administrator at tpaoperations@tpadministrator.com or 1-877-534-2772, Option 1.