DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

TO: Pharmaceutical Manufacturers

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group
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SUBJECT: Medicare Coverage Gap Discount Program

DATE: June 29, 2011

This memorandum provides manufacturers with Medicare Coverage Gap Discount Program updates and proposed changes on the following:

- Upcoming provision of aggregate pending "low-volume" discount dollar amounts;
- Comment Period for Proposed Changes to the Medicare Coverage Gap Discount Program Agreement
    - Proposed solution for "low-volume" issue;
    - Proposed technical correction to appeals deadline in the Medicare Coverage Gap Discount Program Agreement; and
- Future Codification of Discount Program Requirements through notice and comment rulemaking.

Discounts on "Low-Volume" Claims

Through communications with manufacturers, CMS has identified an issue associated with the provision of "Medicare Part D Discount Information" to manufacturers and with CMS' obligation to protect the identities of Medicare beneficiaries. Under the current Medicare Coverage Gap Discount Program (Discount Program) Agreement with manufacturers, "Medicare Part D Discount Information" refers to the information derived from applicable data elements available on prescription drug event (PDEs) and set forth in Exhibit A of the Agreement that will be sent from the third party administrator (TPA) to the manufacturer along with each quarterly invoice. However, section III (f) of the Agreement generally prohibits CMS from disclosing any identifying beneficiary

information under the Discount Program. Although the "Medicare Part D Discount Information" does not include specific beneficiary identifiers, an issue arises when the volume of claims for an applicable drug is so low that the data provided as "Medicare Part D Discount Information" could be used to identify a Medicare beneficiary.

In order to protect the identity of Medicare beneficiaries, CMS has a cell-size suppression policy that prohibits disclosure of data if the data cell contains 10 or fewer individuals. In applying this policy to the Discount Program, CMS is unable to disclose all the data elements specified as "Medicare Part D Discount Information" when 10 or fewer beneficiaries with the same 9-digit national drug code (NDC) have claims at the same pharmacy. This threshold is based on all Part D claims for an applicable drug (9-digit NDC) at the same pharmacy, not 10 or fewer applicable beneficiaries with coverage gap claims. We refer to these claims as "low-volume" and, as a result of the conflict between level of information provided as Medicare Part D Discount Information and CMS' data policy for protecting beneficiary identities, CMS decided not to invoice manufacturers for any "low-volume" claims on the 2011 first quarter invoice.

Manufacturers have raised concerns about potential outstanding discount payment liabilities that may have been withheld from their first quarter invoice and questioned when they will eventually get invoiced. The first quarter likely has the most low-volume claims and as pharmacies continue to process more prescriptions for more Medicare beneficiaries, many of these original low-volume claims likely will be removed from low-volume status and appear on the next scheduled invoice. Nevertheless, we understand the manufacturers' need to record outstanding liabilities and, obviously, we eventually will need to invoice manufacturers for all discount payments. To address this issue, we will begin providing additional information with the invoices immediately, and we propose a longer-term solution.

Provision of Cumulative Pending Low-Volume Discount Dollar Amounts

CMS will begin providing manufacturers with the cumulative pending dollar amounts for those discounts reported on PDEs by the end of a quarter but not invoiced to the manufacturers. Manufacturers will only receive an aggregate dollar amount without any claims-level detail. We expect to provide this information on pending 2011 first quarter discount payments to each affected manufacturer by the end of July 2011 and will continue to provide updated information each quarter on the cumulative pending discount amounts incurred by manufacturers but not yet invoiced.

Proposed Solution for Low-Volume Issue

CMS cannot adequately protect beneficiary identities and also provide manufacturers with all of the data elements specified in Exhibit A for low-volume claims. While we initially thought our only option was to invoice manufacturers for these discounts without any claims-level detail, we now believe we may be able to provide most of the information specified in Exhibit A for the low-volume claims. Specifically, we believe that we must provide fewer data elements to manufacturers when 10 or fewer beneficiaries have received the same applicable drug (9-digit NDC) at the same

pharmacy by withholding the Service Provider Identifier Qualifier and Servicer Provider Identifier. We propose to amend the definition of "Medicare Part D Discount Information" in the Discount Program Agreement by specifying in Exhibit A that the Service Provider Identifier Qualifier and Service Provider Identifier will be withheld for low volume claims (only). While we understand that manufacturers would prefer to receive the service provider information, we believe this is the best solution that still allows us to provide most of the claims-level detail originally specified as Medicare Part D Discount Information without jeopardizing the privacy of Medicare beneficiaries. We do not expect to be able to implement this approach until the first or second quarter of 2012. We seek comments on this proposal and any alternative recommendations that would ensure the protection of beneficiary identities.

If we implement this change to "Medicare Part D Discount Information", CMS would publish only the allowable claims-level detail when the manufacturer is invoiced the applicable discount, and we would not provide additional data elements (i.e. would not provide the service provider identifier information) in the future if or when a previously invoiced low-volume claim no longer qualified as low-volume. In other words, manufacturers will only get data without the service provider identifier information once they get invoiced for these claims. Consequently, CMS needs to determine whether it should 1) begin invoicing manufacturers for these low-volume claims with the first quarter invoice each year or 2) continue to withhold invoicing these low-volume claims until the third or fourth quarter each year in order to minimize the number of discounts that will be invoiced without service provider information. If we do not begin invoicing with the first quarter, we would continue to provide the cumulative pending low-volume discount amounts to manufacturers until these discounts are invoiced. We invite manufacturers to comment on their preferred billing approach for these low-volume claims.

Proposed Technical Correction to Appeals Request Deadline

Section V(g) of the Medicare Coverage Gap Discount Program Agreement states, in part, that "A request for review must be made within 30 calendar days of the Manufacturer's receipt of an unfavorable determination from the TPA, or 60 calendar days after CMS' receipt of notice of the dispute if the Manufacturer and TPA cannot resolve the dispute within 60 calendar days, whichever is earlier." However, the TPA has 60 calendar days to make a determination, thus requiring a Manufacturer to wait until the very last day of the dispute timeframe before requesting an appeal if it did not receive a determination from the TPA prior to 60 days as well as limiting the Manufacturer to making this request on the very last day of the dispute timeframe. We propose changing the sentence at issue to read "A request for review must be made within 30 calendar days of the Manufacturer's receipt of an unfavorable determination from the TPA or **90** calendar days after the **TPA's** receipt of notice of the dispute if the Manufacturer and TPA cannot resolve the dispute within 60 calendar days, whichever is earlier". [Emphasis added] This would provide the Manufacturer with the a 30 day timeframe to consider making a request for an appeal from either receipt of an unfavorable TPA determination or expiration of the dispute resolution timeframe if the TPA does

not make a determination within 60 days of receipt of notice of the dispute. We seek comments on this proposal.

Future Rulemaking

CMS is preparing to undertake formal notice and comment rulemaking to codify aspects of the Discount Program. We intend to include the new definition of "Medicare Part D Discount information" discussed above in the notice of proposed rule-making, which we expect would be published this fall. We expect to publish the final rule in the spring of 2012.

Please submit any comments on the provision of the cumulative pending low-volume discount dollar amounts, the preferred billing methodology for low-volume claims, and the extension of the appeals deadline to CGDPandmanufacturers@cms.hhs.gov by August1, 2011. Please also direct any questions to the same mailbox.