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TO: Pharmaceutical Manufacturers and all Part D Sponsors

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SUBJECT: Medicare Coverage Gap Discount Program—Updated Guidance

DATE: October 28, 2011

This memorandum provides manufacturers and Part D sponsors with new and revised Coverage Gap Discount Program (Discount Program) guidance specific to:

- Invoicing and Payment of Discounts on “Low-Volume” Claims
- Low Dollar Invoice Amounts
- Technical Correction to Appeals Request Deadline

Consistent with our requirement to consult with manufacturers on the model Coverage Gap Discount Program Agreement, CMS issued draft guidance on June 29, 2011 and September 9, 2011, for public comment. We would like to thank the more than thirty manufacturers and Part D sponsors that submitted comments in response to the draft guidance. We thoroughly considered their comments in finalizing this guidance.

Invoicing and Payment of Discounts on “Low-Volume” Claims

On June 29, 2011, CMS issued the draft guidance for public comment to manufacturers concerning the issue associated with the provision of “Medicare Part D Discount Information” to manufacturers and CMS’ obligation to protect the identities of Medicare beneficiaries. We subsequently proposed this policy in our proposed rule for contract year 2013 and requested comment.

Under the current 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 Discount Program 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 Discount Program 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 the policy to the Discount Program, CMS will not 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 the levels of information provided as Medicare Part D Discount Information and CMS’ data policy for protecting beneficiary identities, CMS has not invoiced manufacturers for any “low-volume” claims.

Pending the outcome of the rulemaking process, we are now finalizing a change –for 2011 and 2012 only – to Exhibit A of the Discount Program Agreement to amend the definition of “Medicare Part D Discount Information” by specifying in Exhibit A that the Service Provider Identifier Qualifier and Service Provider Identifier will be withheld for low-volume claims. We believe this is the best solution for 2011 and 2012 because it 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 while we consider the comments on the 2013 proposed rule. We expect to implement this approach and begin invoicing manufacturers for 2011 low-volume claims no later than second quarter of 2012.

While some manufacturers proposed that because the data in Exhibit A is being used to fulfill functions associated with the Discount Program, it should be considered “routine use” and therefore exempted from cell-size limitation policies, we disagree. The Department of Health and Human Services (HHS) established a framework for routine use of data in the Privacy Act Regulation (45 CFR Subtitle A § 5b). The regulation also discusses disclosure of information to non-Federal entities and contractors. Non-Federal entities are defined as those that operate as agents of the Department for purposes of carrying out Federal functions (45 CFR Subtitle A § 5b.2 (2)(b)(1)) and contractors are described as maintaining a system of records to accomplish a Department function (45 CFR Subtitle A § 5b.12 (a)). In other words, the definition of a non-Federal entity/contractor entitled to receive data under the “routine use” provision is limited to those contractors that perform a CMS function on our behalf, not just an entity with a CMS contract. We do not believe that manufacturers participating in the Discount Program meet this definition.

It was also suggested that a low-volume policy is not warranted since manufacturers receive these data elements from Medicaid and commercial programs. We have found that the policies governing the release of beneficiary data vary among State Medicaid programs, with some programs releasing more data sets and others fewer. It is also difficult to compare a commercial health plan’s standards with those of Medicare given the disparity in size, mission and applicable laws. Thus, for 2011 and 2012 we will apply the cell size suppression policy, and we will further consider comments on this issue in connection with our 2013 proposed rule.

CMS will provide only the allowable claims-level detail when the manufacturer is invoiced the applicable discount, and we will not provide additional data elements (i.e. will 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. CMS plans to withhold invoicing low-volume claims until at least the third quarter of the 2012 contract year in order to minimize the number of discounts that will be invoiced without service provider information. However, as we gain experience with the Discount Program, if CMS determines that low-volume claims did not appreciably diminish after the first quarter of 2011, we may revisit this policy and begin invoicing for low-volume claims earlier in the year. We will continue to provide the cumulative pending low-volume discount amounts to manufacturers until these discounts are invoiced.

Low Dollar Invoice Amounts

On September 9, 2011, CMS issued draft guidance for public comment concerning a potential issue associated with the requirement to pay Part D sponsors through Electronic Fund Transfer (EFT). Under the current Discount Program Agreement, section II (m) requires manufacturers to pay quarterly invoices directly to accounts established by Part D sponsors via EFT. Some manufacturers have raised logistical concerns associated with EFT payments when the invoice amount is very low. For example, some manufacturers claim that banks establish minimum dollar thresholds for making EFT payments that may be more than invoiced amounts to Part D sponsors, or have fees associated with the EFT transactions that exceed the invoiced amounts to Part D sponsors. In our May 2010 Discount Program guidance, we responded to a comment about establishing thresholds for payment to Part D sponsors. At that time, CMS did not believe making small payments to Part D sponsors would impose significant burden on manufacturers.

After considering all of the comments, CMS will not be changing the requirement that all discount payments be made via EFT regardless of invoice amount. We received nearly the same number of comments in favor of and opposed to making an exception to this requirement. The comments in favor of making an exception to the EFT requirements basically reiterated that some (but not all) banks have minimum EFT requirements and that some EFT transfer methods can be prohibitively more expensive than the amounts being transacted. However, other commenters opposed making an exception because they said that it would introduce significant administrative burden and complexity associated with the manual processing and tracking of paper checks, that most manufacturers successfully used Automated Clearing House (ACH) even for low dollar invoice payments, and that ACH is less expensive than paying by check. Given that most manufacturers were able to successfully use EFT for all of their payments, that there are inexpensive EFT processes available, and that not all banks establish minimum EFT requirements, we do not believe that an exception to the EFT requirement is justified and further believe that such an exception would negatively impact the overall accuracy and efficiency of the payment process.

Technical Correction to Appeals Request Deadline

Section V(g) of the 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 proposed to change this sentence so as to extend the timeframe a manufacturer has to request review from the independent review entity when the manufacturer does not receive a determination from the TPA within 60 calendar days. Specifically, the section would be changed to read: “If the Manufacturer receives an unfavorable determination from the TPA, the Manufacturer must request review within 30 calendar days of the Manufacturer’s receipt of the unfavorable determination from the TPA. If the Manufacturer does not receive a determination from the TPA within 60 calendar days, the Manufacturer must request review within 90 calendar days from the TPA’s receipt of notice of the dispute.” We subsequently proposed to codify this timeframe in the 2013 proposed rule.

CMS did not receive any comments in opposition to the proposed change and will implement the modified appeals time frame for 2011 and 2012 beginning the 2nd quarter of the 2011 invoicing cycle. Therefore, manufacturers will be afforded 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 will consider the comments on the 2013 proposed rule and determine a final policy for 2013 in the rulemaking process.

In summary, CMS will:

- Begin invoicing manufacturers for “low-volume” claims without providing the service provider data elements no later than the second quarter for 2012 for 2011 low-volume claims and no earlier than the third quarter of 2012 for 2012 low-volume claims;
- Maintain EFT requirement for all discount payments regardless of dollar threshold; and
- Implement the change to the appeals timeline beginning with the 2nd quarter 2011 invoices.

Questions about this document may be submitted to CGDPandmanufacturers@cms.hhs.gov.