BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Cynthia G. Tudor, Ph.D.,
Director, Medicare Drug Benefit and C & D Data Group
Cheri Rice,
Director, Medicare Plan Payment Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: June 29, 2011 Memorandum on Proposed Changes to the Medicare Coverage Gap Discount Program – Low-Volume Claims and Clarifications

Dr. Tudor and Ms. Rice;

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) memorandum regarding proposed changes to the Medicare Coverage Gap Discount Program Agreement relating to low volume claims (Low-Volume Memorandum). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 biotechnology centers, academic institutions, state biotechnology centers, and related organizations in the United States and in more than 30 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering and ensuring patient access to new and innovative therapies. Many of the therapies developed by biotechnology companies target conditions that primarily affect seniors. BIO has been a strong supporter of the Medicare Part D prescription drug benefit, and believes that the Part D benefit has helped to increase patient access to critical therapies as well as ensure that patients will be able to receive and afford the treatments that best meet their needs. We appreciate CMS's efforts in implementing the Coverage Gap Discount Program.

I. Low-Volume Claims Policy

BIO urges CMS to re-consider whether the low-volume claims policy is necessary in the context of the Coverage Gap Discount Program (CGDP). As CMS recognizes in its Low-Volume Memorandum, the data fields provided to manufacturers as part of the invoices do not include specific beneficiary identifiable information. Nonetheless, CMS has expressed a concern that low-volume claims could be used to identify a beneficiary. While we appreciate this concern, we do not believe that the limited information provided to manufacturers under the nine fields included on an invoice allow identification of a beneficiary as a practical matter. Furthermore, manufacturers are expressly prohibited, under their signed agreements with CMS, from combining the CGDP invoice data with any other data sources. Manufacturers' agreements with CMS also prohibit manufacturers from using this data for any purposes other than carrying out obligations under the agreement, with very limited exceptions. The safeguards in the agreement itself ensure that the information will not be used to identify individual beneficiaries, and we urge CMS not to apply the low-volume policy to the CDGP invoices. In the event that CMS continues to apply its low-volume policy to these invoices, we have provided comments on CMS's proposed options on handling low-volume claims.

II. Low-Volume Claims – Aggregated Information

BIO supports CMS's proposal to provide manufacturers with aggregate information on low-volume claims on a short-term basis. We understand that CMS will provide this information in July 2011, and we appreciate CMS's timely response to manufacturers' concerns that they did not have adequate information to record outstanding liabilities. In its June 29 memorandum, CMS does not address what aggregated information will be available on low-volume claims. We request that CMS provide aggregated information on both a labeler code and an NDC-11 level basis. Companies often allocate reserves at the NDC-11 or drug level. In order to appropriately meet financial obligations related to accruals and recording outstanding liabilities, it will be very helpful to have information broken down by labeler code and NDC-11. The provision of this aggregate information will aid manufacturers in meeting their financial obligations.

II. Proposed Solution for Low-Volume Claims

With respect to the two long-term options CMS has proposed for handling low-volume claims, BIO strongly supports Option 2, under which CMS would: (a) continue to withhold invoices for low-volume claims to minimize the number of claims invoiced without provider information, and (b) continue to provide cumulative pending low-volume discount amounts to manufacturers for the accrual purposes discussed above. Option 2 will ensure that manufacturers will have complete data on as many claims as possible.

We are concerned that Option 1, under which CMS would begin invoicing manufacturers for low-volume claims in the first quarter, but without two data elements, would leave manufacturers without the information they need to verify claims. CMS proposes to withhold the Service Provider Identifier Qualifier and the Service Provider Identifier from all low-volume claims. Under Option 1, CMS proposes to invoice manufacturers for these claims beginning in the first quarter, without these two fields, and also proposes not to provide manufacturers with the additional data fields later in the year should a claim no longer meet the low-volume criteria. The Service Provider Identifier and Service Provider Identifier Qualifier fields contain important information for manufacturers seeking to verify claims. These fields help to properly identify the pharmacy or other provider, which is critical to determining the validity of claims and identifying duplicate claims. In particular, for many BIO members, this information provides a critical indication of whether a claim should have appropriately been covered under Part B, rather than under Part D. Without this data, it will be difficult to determine whether it is appropriate to appeal a claim. We urge CMS not to adopt Option 1.

We believe that Option 2 will greatly reduce the number of claims for which manufacturers have incomplete information. Option 2 would provide manufacturers with the information necessary to meet their financial reporting obligations, while also providing them with the information that often is important in determining whether to appeal a claim. We request that CMS hold low-volume claims as long as possible in the year in order to ensure that all of the data fields can be included, and, if possible, hold claims for longer periods.

To the extent that CMS determines it is necessary to invoice all low-volume claims by the end of a calendar year, we ask that CMS consider a mechanism for invoicing a manufacturer for claims that remain low-volume at the end of the year while allowing for the later provision of the additional data fields by allowing claims to move out of the low-volume category over the course of more than a year. For example, CMS could allow the low-volume claims to be compiled over more than a year. CMS could invoice any remaining low-volume claims in the 4th quarter of a year and provide the remaining data fields during a quarter the following year when the claims moved out of low-volume status. This would necessarily include a revised timeframe for an appeal right with respect to such claims that begins once the manufacturer has received the full data. Such an approach would allow CMS to collect discounts owed while at the same time giving manufacturers the ability to make an appeal determination based on the full 9 data fields. To the extent necessary, CMS could impose a time limit, such as one year after the claim date, at which point it would not provide additional data fields for a claim that remained in the low-volume category.

III. Proposed Technical Correction to Appeals Request Deadline

BIO greatly appreciates CMS's technical clarification regarding the appeals deadlines. We support CMS's proposed change, which would require that a manufacturer's request for review of an independent review entity determination be made by the earlier of (1) 30 days of an unfavorable determination from the TPA, or (2) within 90 calendar days following the TPA's receipt of notice of the dispute, where the manufacturer and the TPA have not resolved the dispute within the initial 60 days of such notice. This is an important technical change that we believe will reduce the likelihood of unnecessary appeals.

Conclusion

BIO appreciates to opportunity to comment on the memorandum regarding low-volume claims and the appeals technical corrections. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Laurel Todd at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy