BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

By Electronic Delivery

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Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Coverage Gap Discount Program beginning in 2011

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) memorandum entitled the "Medicare Coverage Gap Discount Program Beginning in 2011" issued on April 30, 2010 (the "Guidance"). BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, 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 appreciates CMS's significant efforts to implement this program. We believe 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. BIO supports the coverage gap discount program and believes that it will increase patient access to life-saving and life enhancing therapies. We appreciate CMS's efforts to implement the Part D coverage gap discount program (the "Coverage Gap Program" or the "Program").

I. Manufacturer Discount Payments – Section 40

A. Payments to Part D Sponsors

CMS proposes a process under which a CMS contractor will invoice a manufacturer quarterly on behalf of Part D sponsors, and then the manufacturer "will be required to pay the invoiced amounts to Part D sponsors directly."[1] BIO is concerned that a system under which hundreds of manufacturers are required to pay nearly 300 different Part D sponsors (or nearly 1,000 Part D plans, if paid by plan contract rather than at the sponsor level) each calendar quarter will be administratively burdensome to both Part D sponsors and manufacturers. The statute specifically requires the Secretary to enter into an agreement with a third party administrator for purposes of receiving, distributing, or facilitating "the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements" under the Program.[2] Accordingly, CMS should implement the Coverage Gap Program in a manner that requires manufacturers to pay the CMS contractor on behalf of the Part D sponsors, rather than make payments directly to each Part D sponsor. The CMS contractor would then distribute the payments to Part D sponsors.

An approach that relies on the CMS contractor to facilitate the payments on behalf of Part D sponsors will not only follow the mandate of the statute, it also will ensure that CMS knows whether a manufacturer has paid its invoices in a timely manner, which is information CMS and/or the CMS contractor will need to reconcile CMS's payments with Part D sponsors. Such an approach also will be administratively easier for both Part D sponsors and manufacturers, which in turn will facilitate a more efficient Program. In contrast, establishing a process under which Part D sponsors and manufacturers must process many hundreds of different payments will greatly increase the administrative burden of the Program.

It is particularly critical that smaller manufacturers to be able to make a single payment to the CMS contractor. Many biotechnology companies do not have the resources to process and manage payments to several hundred sponsors each quarter. Some small companies may have only a single employee whose task it is to coordinate rebate payments. BIO asks CMS to require each manufacturer to issue one payment each quarter to CMS's contractor rather than hundreds of separate payments to Part D sponsors.

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[1] Guidance § 40.1.
[2] Social Security Act § 1860D-14A(d)(3)(B).

B. Payments Within 15 Days of Receipt

CMS proposes that manufacturers pay the entire invoiced amount within 15 days of receipt, including any amounts in dispute.[3] BIO is concerned that the 15 day window is not adequate for manufacturers to process these payments, and it is not consistent with payment timeframes under other government discount programs or the industry standard in similar commercial programs. While we believe that 15 days will not be adequate where manufacturers are making a single payment to the CMS contractor, this timeframe is particularly inadequate in the event that a manufacturer is required to make payments to as many as 300 different Part D sponsors. We propose that CMS instead allow at least 60 days from receipt of acceptable data for manufacturers to make payments. While we are aware that the payment period under certain other government discount programs, such as the Medicaid rebate program, currently is 30 days (or rather 38 days to allow for mail delays), the Coverage Gap Program is a new program that will require new systems and processes for all involved parties, and we believe that 60 days would better reflect the realities of getting the Program underway. This will provide all parties with a better ability to review the data prospectively to ensure that invoices and payments are correctly calculated at the outset, to the greatest extent possible.

C. Payments for Amounts in Dispute

CMS proposes that manufacturers pay the "entire invoiced amount within 15 days of receipt *including amounts in dispute.*"[4] BIO proposes that manufacturers instead be required to pay only amounts not in dispute. BIO also recommends that the Guidance make clear that disputes will be subject to the dispute resolution process, to be developed by CMS as required by statute,[5] that provides manufacturers and CMS with a means of determining whether amounts under dispute must be paid. This could work in a manner similar to the Dispute Resolution Program established under the Medicaid drug rebate program,[6] as set forth in Section V of the Medicaid Drug Rebate Agreement, with an added mechanism for final resolution of disputes. Under such a process, the Secretary or the CMS contractor would first attempt to resolve the dispute in conjunction with a manufacturer. Unresolved disputes could be reviewed by an HHS administrative law judge, with a final decision appealable to a court. This process would be separate from and in addition to a manufacturer's audit rights, also established under the statute.[7] It will be important that there be a process for coming to a final resolution, so that manufacturers,

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[3] Guidance § 40.1.
[4] *Id.*
[5] Social Security Act § 1860D-14A(c)(1)(A)(vii).
[6] For a description of the Medicaid Drug Rebate Program Dispute Resolution Program, s*ee, e.g.,* http://www.cms.gov/MedicaidDrugRebateDispR/.
[7] Social Security Act § 1860D-43(c)(1)(A)(vii).

plan sponsors, and CMS all can properly close their books with respect to Coverage Gap discounts for a particular plan year.

D. Claims Data Provided to Manufacturers

BIO urges CMS to specify in final guidance the claims information that will be provided to manufacturers to enable them to verify the accuracy of payments made under the program. It is critical that manufacturers have access to data that is sufficiently detailed to enable verification of the accuracy of the payments made under the Coverage Gap Program, including identification of any duplicate payments or excessive units billed. We suggest that the CMS contractor, on behalf of the Part D sponsors, provide manufacturers with detailed claims data. Detailed claims data routinely is provided by health plans and PBMs under commercial and Part D rebate agreements and under other discount arrangements between manufacturers and purchasers. This also is consistent with the data that manufacturers are provided under the Medicaid rebate program.

BIO proposes that the CMS contractor provide both aggregate summary information and claim-level data fields in order to allow companies to verify the accuracy of the payments and to ensure that companies do not pay duplicate discounts. Consistent with industry standards for utilization reports, the claim-level fields will need to include at least the following: plan information (e.g., name, contract number, Plan ID); service provider ID (e.g., pharmacy number and address); product ID; quantity dispensed; days supply; NDC-11; prescription number; date of service; patient pay amount; fill number; dispensing status; patient liability due to other payer amount; and dispensing fee. Manufacturers also will need detailed data on all elements of the negotiated price for the claim, and information detailing the initial coverage limits, out-of-pocket thresholds and supplemental coverage information associated with each prescription number to verify that discounts are appropriately applied.

BIO also urges CMS to specify a period of time in which Part D sponsors may provide claims information for the collection of these discounts consistent with the CMS reporting requirement for Part D sponsors. For example, under the "Medicare Part D Reporting Requirements" effective January 1, 2010, Part D sponsors are required to provide data on numerous components of the Part D program on a quarterly basis, with data due to CMS no later than 180 days following the end of a quarter. We believe this approach is appropriate for the Coverage Gap Program. Part D sponsors tend to invoice manufacturers for these rebates, provided for under rebate agreements, on a quarterly or monthly basis. With respect to the Coverage Gap Program discounts, we suggest that CMS establish quarterly reporting deadlines for Part D sponsors, requiring data submission within 180 days of the end of a quarter. CMS could permit Part D sponsors to "true-up" any errors in these reports until the final report to CMS by June 30 of the year following the plan year, consistent with CMS's other reporting

requirements. This would ensure that coverage gap discounts are reported and invoiced on a timely basis and are taken into account for purposes of CMS's annual reconciliation process with Part D sponsors. This also helps to ensure that manufacturers will not be invoiced for excessively old claims.

II. Conditions for Coverage Under Part D – Section 50

CMS proposes to implement the requirement that all covered Part D drugs must be covered under a manufacturer discount agreement with CMS for coverage to be available under Part D by having the manufacturer specify in the discount agreement the labeler code(s) covered under the agreement. CMS also proposes to maintain an updated list of the labeler codes that are covered by manufacturer discount agreements and distribute this list to Part D sponsors as well as post the list on the CMS website. Because some labeler codes include both covered Part D drugs and drugs not eligible for coverage under Part D, we are concerned that reliance on labeler codes could be confusing. BIO urges CMS to make clear in the agreement between a manufacturer and the Secretary that not all drugs included under a particular labeler code are subject to the Coverage Gap discount. Instead, only those drugs within a labeler code that are otherwise "covered Part D drugs" as defined by statute and regulations are subject to the discount.

We note that, as part of this process, it will be critical that CMS establish a mechanism for manufacturers to contact CMS with potential errors or other issues in the Coverage Gap Program. BIO urges CMS to establish an e-mail address, staff member, and/or other mechanism(s) by which manufacturers can directly contact CMS to address errors in this list of labeler codes or other issues that arise in administration of the Coverage Gap Program. Historically, CMS has preferred that Part D sponsors serve as the primary point of contact for program issues. Given the nature of the discount program, however, it will be critical for manufacturers to be able to address any administrative issues with CMS directly. This is consistent with CMS's approach under the Medicaid drug rebate program.

III. Date of Dispensing/No Retroactivity – Section 70.4

CMS has proposed that the discount will be owed based on the information available to the pharmacy at the point-of-sale and that discounts will not be adjusted later if that information is found to be in error. CMS should retroactively correct erroneous discount amounts. Retroactive corrections are the industry standard, and are required in both Medicaid and the Part D program. In the Medicaid drug rebate program, for example, manufacturers are permitted to submit recalculations of pricing data that may ultimately result in retroactive adjustments to rebate amounts owed to States and/or owed to the manufacturer. In Part D, both CMS and Part D sponsors have in place processes to facilitate retroactive adjustments; nothing about the Coverage Gap Discount Program would prevent similar adjustments. For example, CMS has

detailed requirements under which Part D sponsors must work with other payers – including other Part D sponsors, state pharmaceutical assistance programs (SPAPs), and others – to retroactively adjust claims.[8] CMS also requires retroactive adjustment of eligibility determinations for low income subsidy individuals.[9] CMS also reconciles its payments to Part D sponsors on an annual basis;[10] indeed, in the Guidance CMS notes that it will reconcile its payments to sponsors under the Coverage Gap Program.[11] Clearly, it is possible – and even routine – for CMS and Part D sponsors to retroactively correct payments in the Part D program. In order to ensure that coverage gap discounts are provided in the manner set forth in the statute, it is critical that CMS implement basic retroactive corrections to discount amounts improperly invoiced.

IV. Negotiated Price – Section 100.13

The Guidance defines "negotiated price" in reference to the Part D regulations, at 42 C.F.R. § 423.100. While the Guidance does not indicate that sales tax or vaccine administration fees will be included in the negotiated price, CMS's accompanying memorandum entitled "Prescription Drug Elements (PDE) Record Changed Required to Close the Coverage Gap" suggests that both sales tax and vaccine administration fees will be included in the negotiated price for purposes of the Coverage Gap Discount Program. BIO is concerned that this approach to negotiated price is more expansive than is contemplated by the statute and is not consistent with CMS's approach to the definition of negotiated price.

In revising the definition of negotiated price in 2009, CMS explained at length its rationale for clarifying this definition.[12] Specifically, CMS proposed changes to the definition to make clear that it intended for the negotiated price to reflect the "pass-through price", which CMS describes as the price paid by the Part D plan sponsor or its PBM to the pharmacy.[13] CMS specifically explains that it has revised the first part of the definition of negotiated price to "state that negotiated prices are prices that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy, or other network dispensing provider, have negotiated as the amount the network dispensing pharmacy or other network dispensing provider will receive, in total, for a particular drug."[14] Because sales tax is not an amount negotiated between the Part D sponsor and the pharmacy as the amount the pharmacy will receive, it is not

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[8] Prescription Drug Benefit Manual, Ch. 14 § 15.5.
[9] *Id. See also,* 42 C.F.R. § 423.800.
[10] *See, e.g.,* 42 C.F.R. § 423.343.
[11] Guidance § 30.3.
[12] 74 Fed.Reg. 1494 (Jan. 12, 2009).
[13] 74 Fed. Reg. at 1505.
[14] *Id.*

appropriately part of the drug's negotiated price. Rather, as generally is the case with sales tax on any item purchased, the sales tax of a drug dispensed in the coverage gap will be calculated after the application of the 50% discount. We urge CMS to clarify that sales tax will not be considered part of the negotiated price for purposes of the Coverage Gap Program.

BIO also urges CMS to clarify that the vaccine administration fee is not part of the negotiated price for purposes of the Coverage Gap Program. A vaccine administration fee functions like a dispensing fee – it is the payment to the provider for the provider's service. It is not a component of the drug or the drug's price. The statute expressly excludes dispensing fees from the Coverage Gap Program,[15] and we believe this logically extends to vaccine administration fees.

V. Point-of-Sale Exceptions – Section 70.5

In the Guidance, CMS states that "Part D sponsors shall provide the applicable discount for out-of-network paper claims submitted by Part D enrollees."[16] BIO suggests that CMS define the amount on which the Coverage Gap discount will be based for out-of-network claims (paper or otherwise) as the plan allowance minus any dispensing fees, vaccine administration fees, and sales tax. The Part D regulations define "plan allowance" as the amount that Part D plans (other than those offering the standard benefit design) use to determine plan payment and enrollee cost-sharing for Part D drugs purchased at out-of-network pharmacies.[17] For plans offering defined standard benefits, the Coverage Gap discount would be based on the price charged to the beneficiary, typically the pharmacy's usual and customary price, minus dispensing fee, vaccine administration fee, and sales tax.

Conclusion

BIO appreciates the opportunity to comment on the Guidance. We look forward to continuing to work with CMS on the administration of the Coverage Gap Program. Please feel free to contact Laurel Todd at 202-962-9220 if you have any questions or if we can be of further assistance.

Sincerely,

Laurel Todd
Director, Reimbursement and Health Policy

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[15] Social Security Act § 1860D-14A(g)(6).
[16] Guidance at 10.
[17] 42 C.F.R. § 100.