BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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 Model Manufacturer Agreement – [CMS-4151-NC] RIN 0938-AQ04

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Medicare Coverage Gap Discount Program Model Manufacturer Agreement, published in the Federal Register on May 26, 2010[1] (the "Draft Model Agreement"). 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 1,200 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 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 "Discount Program" or the "Program"), including the issuance of the Draft Model Agreement.

[1] 75 Fed. Reg. 29555 (May 26, 2010).

I. Definition of Manufacturer – Section I(j)

BIO urges CMS to revise the definition of "manufacturer" as set forth in the Draft Model Agreement to make clear that repackagers and relabelers satisfy the definition of "manufacturer" for purposes of signing the agreement and paying discounts on applicable drugs. Repackagers and relabelers reasonably fit within the statutory and Draft Model Agreement definition of "manufacturer", which includes entities that "directly or indirectly"[2] manufacturer prescription drug products. BIO also requests that CMS clarify that the manufacturer does not need to be the entity identified in the labeler segment of the NDC code. In some circumstances, a manufacturer may acquire a single drug or biological from another company without acquiring all drugs and biologicals included within the same labeler code. Allowing the acquiring manufacturer to add the product to its Discount Program agreement even where it is not the entity listed in the labeler code will help to ensure that beneficiary access to therapies under Part D remains robust.

II. Claims Data Provided to Manufacturers – Section I(k)

BIO urges CMS to specify in the final agreement 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 Discount Program, including identification of any duplicate payments or excessive units billed. 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 provision of data also is consistent with the data that manufacturers are able to receive under the Medicaid rebate program.

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); 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. We have provided a chart at the end of this letter that describes the PDE data elements and the reason that

[2] Social Security Act § 1860D-14A, § 1860D-43(d); Draft Model Agreement § I(j).

manufacturers need each element in order to validate claims. Generally, the PDE data elements BIO is requesting allow manufacturers to confirm the validity of a script, the appropriateness of the payment amount, and the potential for duplicate claims. For example, this information will allow a manufacturer to identify situations in which there simply are errors in the data, claims that are being submitted multiple times under the Part D Coverage Gap Discount Program.

This information is needed not only to make accurate payments, but also to help manufacturers comply with their obligations under Generally Accepted Accounting Principles (GAAP) and the Sarbanes-Oxley Act or applicable international accounting principles and laws. For example, GAAP requires manufacturers to recognize customer discounts at the time of recognition of the sale. This recognition often requires complex forecasting of discount amounts, taking into account the various contracts for the manufacturer's products. In addition, Sarbanes-Oxley (SOX) requires certain officers of SEC-reporting companies to certify that the financial statements and other information included in the report fairly present in all material respects the financial condition and results of operations of the company. Detailed data are useful to efforts to certify the payment amounts included in the financial statements.

We note that the provision of this level of data is also consistent with HIPAA. The Department of Health and Human Services expressly allows HIPAA covered entities to disclose information, such as prescription numbers, to a manufacturer for purposes of adjudicating claims submitted under a drug rebate contract. Because the amount of the rebate is based on drug utilization by individual enrollees, such disclosures are permitted as part of a covered entity's payment activities and consistent with restrictions on providing the minimum necessary amount of data, provided that the entity discloses the minimum necessary amount of information to adjudicate claims under the contract.

CMS has included in the Draft Model Agreement a provision obligating manufacturer to use information disclosed under the agreement to be used only for purposes of paying the discount under the Discount Program.[3] BIO supports this provision, which requires that manufacturers not use data received for any purpose other than planning for, making or verifying discount payments. We believe that this requirement should provide CMS with adequate assurances that the data provided under the agreement will be kept confidential, while providing manufacturers with the information they need to verify payments.

III. Timing of Manufacturer Discount Payments – Section II(b)

[3] Draft Model Agreement § VI(b).

CMS proposes that manufacturers pay the entire invoiced amount with 14 days of receipt, including any amounts in dispute.[4] BIO is concerned that 14 days is not adequate for manufacturers to process payments under the Program, especially given the penalty provisions associated with failing to pay plan sponsors on time. This is particularly true if CMS maintains its proposed approach requiring manufacturers make separate 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. A 14 day payment period is not consistent with payment timeframes under other government discount programs nor the industry standard in similar commercial programs. The payment period under the Medicaid rebate program, currently is 30 days (or rather 38 days to allow for mail delays). Tricare allows 70 days for payment by manufacturers. These are appropriate timeframes for long-established programs under which a manufacturer writes a single check to each state each quarter, as for Medicaid, or a single check for the program, as in Tricare. The Discount 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 realties 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.

BIO also does not support the proposal voiced at the June 1, 2010 public meeting that CMS's administrator invoice manufacturers monthly, and instead urges CMS to retain the proposed quarterly invoicing cycle. We are concerned that invoicing manufacturers more frequently than quarterly will be particularly burdensome for our member biotechnology companies. For example, many small biotechnology companies do not have the resources to process and manage payments to hundred of sponsors each month. Some small companies may have only a single employee whose task it is to coordinate rebate and discount payments. Requiring payments more frequently than quarterly will create further challenges for these companies.

IV. Labeler Codes – Section III(h)

CMS proposes to require a manufacturer to specify in the model 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

[4] Draft Model Agreement § II(b).

D sponsors as well as post the list on the CMS website.[5] 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 may not be sufficient and could be confusing to beneficiaries. This is particularly true for biotechnology companies, where the labeler code may include mostly therapies that are not "applicable drugs". Relying on labeler codes alone may lead to beneficiary confusion as well as inaccurate invoicing of manufacturers for therapies that do not meet the definition of "applicable drug". 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 "applicable drugs" as defined by statute and regulations are subject to the discount. By also making this clarification in the list made available on the CMS web site, the opportunity for beneficiary confusion will be minimized.

V. Dispute Resolution – Section V

A. Payments for Amounts in Dispute – Section V(b)

CMS proposes that manufacturers pay the entire invoiced amount within 14 days of receipt and "not withhold any invoiced discount payments pending dispute resolution."[6] BIO proposes that manufacturers instead be required to pay only amounts not in dispute. In particular, we would suggest that manufacturers not be required to pay amounts in dispute where the nature of the dispute is that the drug is not in fact an "applicable drug". As described above, biotechnology companies may have only a few therapies that are "applicable drugs", while other therapies within the labeler code may be eligible only for Part B coverage. Requiring a manufacturer to pay amounts in dispute for a drug that is not an "applicable drug" seems inconsistent with the purpose of the Program, but may occur given the proposed reliance on labeler codes.

We also propose that, in the event that CMS requires advance payment of disputed amounts, CMS establish a mechanism for manufacturers in the event that there are no future invoices. For example, a plan sponsor may not participate in the Part D program the following year, or a manufacturer may no longer have an applicable drug on which it owes future invoiced amounts. At a minimum, all disputed amounts must be reconciled within the time period for reconciling Part D payments generally.

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[5] Draft Model Agreement § III (h).

[6] Model Agreement § V(b).

B. Timeframe for Providing Notice of a Dispute – Section V(a)

CMS proposes that manufacturers pay the entire invoiced amount within 14 days of receipt and "not withhold any invoiced discount payments pending dispute resolution."[7] BIO is concerned that requiring manufacturers to notify CMS of disputes within 60 days of the receipt of information may not provide manufacturers with adequate time to properly identify disputed amounts. This will be particularly true if CMS provides only the proposed "summary-level information" proposed under the Draft Model Agreement.[8] BIO proposes that manufacturers instead be required to pay only amounts not subject to a good faith dispute. This would be consistent with the approach taken by CMS under the Medicaid rebate program.

VI. Timeframe for Entering Into the Agreement

In response to comments raised at CMS's June 1, 2010 meeting regarding the Draft Model Agreement, BIO also recommends that CMS establish a process for new companies or companies who have not previously had a Part D drug to enter into an Discount Program agreement with CMS mid-year. BIO is concerned that prohibiting emerging companies from entering into agreements off-cycle may delay beneficiary access to new therapies. This delay would be inconsistent with CMS's longstanding practice of ensuring beneficiary access to new therapies. For example, CMS requires that a Part D plan sponsor's P&T committee make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days and make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or provide a clinical justification if this timeframe is not met.[9] Drugs within the six classes of clinical concern must be reviewed and added to formularies within 90 days.[10] New drugs are available through the exceptions process during these review periods.

While manufacturers with existing therapies may have the opportunity to enter into an agreement with CMS in advance of having any applicable drugs as part of their product portfolio, this may not be the case with a new company with its first marketed product or for

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[7] Draft Model Agreement § V(b).

[8] Draft Model Agreement § I(k).

[9] Prescription Drug Benefit Manual § 30.1.5.

[10] Id. § 30.2.5.

companies who have not previously had a Part D drug. Without a process for permitting new companies the opportunity to enter into an agreement with CMS when a new therapy first comes to market, beneficiaries may not have access to that new therapy for an extended period of time.

BIO represents an industry that is devoted to discovering new and innovative therapies and ensuring patient access to them. Our members continually are developing promising new medicines. It is imperative that these new therapies be available to Medicare beneficiaries in a timely manner so that they may have the advantage of life-saving and life prolonging innovations. Providing an opportunity for new companies or companies not previously in the Part D market to enter into an agreement under the Discount Program that is effective as soon as their therapy comes to market is consistent with CMS's approach to the consideration of new therapies under the Part D program. This approach will help to ensure that the timeframe for the consideration of new therapies is meaningful and that Part D benefits are comprehensive and appropriately reflect evolving standards of care, including new and innovative therapies.

Conclusion

BIO appreciates the opportunity to comment on the Draft Model Agreement. We look forward to continuing to work with CMS on the administration of the Discount 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,

/s/

Laurel Todd, Director, Reimbursement
and Health Policy

Necessary Medicare Part D Prescription Drug Event (PDE) Data Elements

Verification of from whom the request coming and to whom the manufacturer has a commitment to pay:

PDE #	Data Element	Field Description	Rationale	Fields Included in Commercial Rebate Utilization	Fields Included in Medicaid Rebate Program Data
1	Contract Number	This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS.	To confirm validity; script came from Part D plan; Because there can be duplication in plan names, Plan ID code; Need to be able to cross-reference to plan name	Equivalent to Plan ID	Equivalent to State
2	Plan Benefit Package (PBP) Identifier	This field contains the unique number CMS assigns to identify a specific PBP within a contract.	To confirm validity; Need for payment purposes.	N/A	N/A

How to verify this is a valid transaction and confirm an obligation to pay:

PDE #	Data Element	Field Description	Rationale	Fields Included in Commercial Rebate Utilization	Fields Included in Medicaid Rebate Program Data
3	Claim Control Number	This field is an optional field, free-form field. It is intended for use by plans to identify unique events or for other plan purposes.	Can uniquely identify claims. Used in duplicate claims checking and will assist in dispute resolution.	N/A	N/A
8	Date of Service	This field contains the date on which the prescription was filled.	To ensure eligibility (e.g. utilization occurred in the correct time frame); used in duplicated claims checking.	Yes	Yes

Necessary Medicare Part D Prescription Drug Event (PDE) Data Elements

10	Service Provider Identifier Qualifier	This field indicates the type of provider identifier used in field 11 (Service Provider Identifier).	To properly identify the pharmacy, either NABP or NPI #. Need for IT processing purposes.	Yes	No
11	Service Provider Identifier	This field identifies the pharmacy where the prescription was filled. CMS will transition to the use of the National Provider Identifier (NPI) when it is implemented. In the interim, this field typically contains the NCPDP number which all NCPDP billers are assigned. Some Part D service providers who submit in Non-Standard Format (e.g., home infusion, physicians when providing vaccines, etc.) will not have NCPDP numbers. For these providers, the Unique Provider Identification Number (UPIN), State License Number, Federal Tax Identification Number, Employer Identification Number, or the default value of 'PAPERCLAIM' will be the identifier.	Determine validity and duplicate claims; Determine which pharmacy dispensed drug and that pharmacy is valid.	Yes	Yes
14	Prescription/Service Reference Number	This field contains the prescription reference number assigned by the pharmacy at the time the prescription is filled.	To identify the Rx # assigned at the pharmacy; Duplicate claims checking.	Yes	Yes
15	Product/Service Identifier	This field identifies the dispensed drug using a National Drug Code (NDC). The NDC is reported in NDC11 format. In instances where a pharmacy formulates a compound containing multiple NDC drugs, the NDC of the most expensive drug is used.	Industry standard and necessary for validation purposes; Aberrant quantity; Duplicate claims checking. It will critical to use the NDC-11 rather than the NDC-9, as NDC-9 data does not include package size and would not provide the information necessary to validate claims.	Yes	Yes

Necessary Medicare Part D Prescription Drug Event (PDE) Data Elements

20	Fill Number	This field indicates the number fill of the current dispensed supply.	To validate data and check for duplicates.	Yes	Yes
23	Adjustment/Deletion Code	This field distinguishes original from adjusted or deleted PDE records so CMS can adjust claims and make accurate payment for revised PDE records.	To explain changes in claims duplicate claims checking.	N/A	N/A

Verification of accuracy of discount amount:

PDE #	Data Element	Field Description	Rationale	Fields Included in Commercial Rebate Utilization	Fields Included in Medicaid Rebate Program Data
18	Quantity Dispensed	This field indicates how many dosage units of the medication were dispensed in the current drug event.	To validate quantity of drug dispensed; Check for aberrant quantity; assists to determine if amount of discount requested is reasonable.	Yes	Yes
19	Days Supply	This field indicates the number of days' supply of medication dispensed by the pharmacy and will consist of the amount the pharmacy enters for the prescription.	Aberrant quantity; assists in reconciling the total quantity of pills dispensed to determine if amount is reasonable.	Yes	Yes
30	Gross Drug Cost Below Out of-Pocket Threshold (GDCB)	This field represents the gross drug cost paid to the pharmacy below the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a positive dollar amount. For claims above the attachment point, this field will contain a zero dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 31 (GDCA).	To test for reasonableness of the requested gap discount amount.	N/A	N/A

Necessary Medicare Part D Prescription Drug Event (PDE) Data Elements

New	Reported Gap Discount Amount (new)	Reported Gap Discount is the reported amount that the sponsor advanced at point-of-sale for the Gap Discount. Part D sponsors advance the Gap Discount at point-of-sale to applicable beneficiaries who purchase an applicable drug that falls, in part or in full, in the Coverage Gap. The Gap Discount is based on the plan-defined benefit phase. The Gap Discount applies to the negotiated price as defined in §1860D-14A(g)(6) (excludes dispensing fee). For purposes of the Gap Discount, the negotiated price is the sum of the Ingredient Cost Paid, Total Amount Attributed to Sales Tax, and Vaccine Administration Fee.	To reconcile the requested discount amount.	N/A	N/A
New	CMS Calculated Gap Discount Amount (new)	CMS Calculated Gap Discount is the Gap Discount amount calculated by CMS during on-line PDE editing, based on the facts reported in the PDE. CMS will populate the CMS Calculated Gap Discount in the return file sent back to submitters after PDE records are edited. CMS will evaluate differences between the Reported Gap Discount submitted by the sponsor and the CMS Calculated Gap Discount and base the decision to accept or reject the PDE on discrepancies between these two amounts.	To reconcile the requested discount amount.	N/A	N/A