BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Cynthia Tudor, Ph.D.
Director, Medicare Drug Benefit and C & D Data Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-26-16
Baltimore, MD 21244

Re: Medicare Coverage Gap Discount Program Draft Third Party Administrator and Data Use Agreements

Dear Dr. Tudor:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Medicare Coverage Gap Discount Program Draft Third Party Administrator Agreement ("TPA Agreement" and the Draft Data Use Agreement ("DUA") released by CMS on July 9, 2010. 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 TPA Agreement and DUA.

I. DUA and TPA Agreement – Applicability of Federal Privacy Laws

BIO appreciates CMS's willingness to work with manufacturers to provide the data necessary for manufacturers to carry out their responsibilities under the Discount Program. We

also understand the importance of carefully maintaining the security of data transmitted for purposes of Discount Program administration, including data transmitted to manufacturers. We note, however, that manufacturers generally are not considered covered entities under the HIPAA Privacy and Security Rules, nor are they subject to the federal Privacy Act. We are concerned that CMS, both in Section I of the DUA and in Section IV(c) of the TPA Agreement, may be suggesting that manufacturers would comply directly with the requirements of the HIPAA Privacy and Security Rules, as well as with the Privacy Act. We urge CMS to make clear in both the DUA and the TPA Agreement that a manufacturer's obligation with respect to specific security requirements references only the portions of those security requirements necessary to protect the transmission and retention of data pursuant to the Discount Program.

For example, we would expect that a manufacturer entering into the TPA Agreement is agreeing, under Section IV(c), to establish security measures with respect to data transmissions covered by that Agreement that parallel the HIPAA Security Rule standards specific to the transmission of data. We would not expect, however, that this contractual language would obligate a manufacturer to comply with other components of the Security Rule, such as the administrative requirements related to the identification of a Security Officer or the establishment of Security Rule policies and procedures. Similarly, under the DUA, a manufacturer would be agreeing to security measures consistent with those listed in Section II.G., but would not be agreeing to comply with HIPAA more broadly.

II. Use of Data for Payment Purposes – DUA Section II.B

CMS proposes to limit the use of data provided under the DUA to those uses necessary to conduct the accurate calculation of and to resolve disputes concerning the manufacturer's payment obligations under the Discount Program. We urge CMS to make clear that these purposes include activities that enable verification of the accuracy of the payments made under the Discount Program, including identification of any duplicate payments or excessive units billed. Conducting accurate calculations of payment amounts would include confirming the validity of a script, the appropriateness of the payment amount, and the potential for duplicate claims and similar activities that will allow a manufacturer to identify situations in which there simply are errors in the data or claims that are being submitted multiple times under the Part D Coverage Gap Discount Program.

As a technical matter, BIO urges CMS to make clear that this information can be used not only for accurate calculation of discount payment amounts and for dispute resolution, but also for purposes of actually making the discount payments. We believe this is consistent with CMS's purpose in drafting this Section II.B., but we urge CMS to explicitly make use for payment purposes permitted under the agreement. This would allow manufacturers to use the information not only to calculate the accuracy of the amounts owed, but also to carry out the payments to the Part D plan sponsors. This also would make the DUA more consistent with the

Draft Model Agreement between the Secretary and the Manufacturer. 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.[1]

III. Use, Disclosure, and Reuse of the Data – DUA Sections II.B, II.D.

CMS proposes to require a manufacturer to agree "not to disclose, use or reuse the data, including data derived from the data, except as set forth in the DUA or as authorized by CMS guidance, or as otherwise required by law." BIO proposes that CMS enumerate in the DUA or in accompanying guidance specific purposes for which manufacturers could use aggregate data for certain internal business purposes. For example, BIO believes that it would be appropriate for manufacturers to use aggregate data – e.g., total amounts paid by quarter, total number of scripts by NDC-11 on which discounts were paid by quarter – for internal business purposes, such as calculating the annual amounts paid by a manufacturer under the Discount Program for purposes of business forecasting.

Manufacturers need to be able to aggregate data for purposes of establishing reserve rates and net sales estimates. Specifically, manufacturers typically hold back "reserves" as a percentage of sales to cover operating expense related to commercial functions, as part of Generally Accepted Accounting Practice standards. Based on a strict reading of the DUA, CMS may be prohibiting manufacturers from using the data to forecast future reserves that need to be withheld. Because patients experience the donut hole at varying times throughout the calendar, to most accurately reserve funds for these payments, manufacturers need to be able to use the summary level data from prior years and quarters.

Manufacturers use data from government programs for these same purposes in other instances. For example, manufacturers may use data submitted by states for purposes of establishing reserves for the Medicaid rebate program, data submitted by wholesalers for sales to 340b-eligible entities for purposes of DSH chargeback reserves, and data submitted by wholesalers for sales under these programs for VA/DoD chargebacks. These are routine business uses of aggregate sales data.

Manufacturers, like many businesses, also typically go through an annual cycle of estimating upcoming gross and net sales for each product and each product's indication. This is part of normal operating procedures, so that commercial teams can plan their sales forecasts, operating expenses, and otherwise budget accordingly. Since some of a given manufacturer's products will be affected by the Discount Program more than others (even among those therapies covered under Part D), the business needs to have accurate information about the dollars paid in the past under the Discount Program in order to be able to project future payments.

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[1] Draft Model Agreement § VI(b).

In addition to the general restrictions on disclosure and use contain in the Data Use Agreement, Section II.G. of the Data Use Agreement would require Manufacturers to establish "administrative, technical and physical safeguards" which "provide a level and scope of security that is not less than the level and scope of security requirements" set forth in three Federal documents. The standards set forth in these documents are onerous and inappropriate in light of the script-level data that Manufacturers might receive, and consequently these requirements should be removed.

IV. Use of Third Party Vendors – DUA Section II.G

In its cover memorandum to the TPA Agreement and DUA, CMS specifically seeks comments explaining business models by which a manufacturer would delegate functions such as file transmission, invoice review, or invoice payments to third party vendors. In Section II.G of the DUA, CMS proposes to require a manufacturer to agree that the data may not be physically moved, transmitted or disclosed in any way. This restriction would appear to prohibit manufacturers from using a third party to process Discount Program payments.

Some manufacturers routinely use third party vendors to carry out administrative responsibilities related to rebate payments. Specifically, a manufacturer may use a third party vendor to receive data, perform analyses on the data to ensure that payments are accurately calculated, and distribute payments owed. BIO urges CMS to provide a mechanism within the DUA (and, as appropriate, the TPA Agreement) for a manufacturer to disclose the data to third party vendors for purposes of carrying out the manufacturer's responsibilities under the program. One option for CMS to consider in permitting manufacturers to use third party vendors to carry out certain administrative responsibilities under the Discount Program would be to permit disclosure of data to such vendors only where the vendor has agreed to substantially the same security requirements as the manufacturer agrees to under the DUA and the TPA Agreement. This would help to ensure that the data is fully protected without limiting the ability of manufacturers to utilize third parties to carry out their responsibilities under the Discount Program.

Additionally, BIO urges that CMS clarify in the data use agreement that manufacturers may disclose data and analysis derived from data to corporate legal affiliates for permitted uses. This clarification would facilitate efficient implementation and processing of manufacturer obligations under the program within conglomerate or merged corporations. For example, in some cases, the price reporting component of a manufacturer may reside in a corporate affiliate, and manufacturers would need the ability to share the information required for price reporting purposes with a corporate affiliate where this type of corporate structure exists.

V. Data Breaches – DUA Section II.K.

CMS proposes that a manufacturer report to CMS any security breaches within one hour. BIO would urge CMS to impose a somewhat longer reporting requirement, such as requiring a report to CMS as soon as is reasonably practicable, but not later than a certain number of days following the breach. This would be consistent with breach notification provisions more generally established by the Department of Health and Human Services in other circumstances, such as those required of HIPAA covered entities. In addition to this more reasonable time frame for reporting breaches, BIO also urges CMS to clarify that as a matter of practicality, the time frame for reporting a breach begins when the manufacturer becomes aware of the breach and not from when the breach occurred.

CMS also proposes that, where CMS determines that a data breach by a manufacturer requires notification to individuals of the security breach or determines that other remedies are appropriate, the manufacturer would agree to carry out these remedies without cost to CMS. BIO has provided detailed information to CMS regarding the data that it believes is necessary for a manufacturer to receive from CMS in order to enable verification of the accuracy of the payments made under the Discount Program, including identification of any duplicate payments or excessive units billed. None of the fields we have proposed would provide information necessary to send breach notifications to individuals. Indeed, we do not expect that CMS will provide manufacturers with data that directly identifies individuals, nor do we do expect that it would be appropriate for a manufacturer to receive information from CMS sufficient to send notification to affected individuals. BIO instead urges CMS to provide general parameters for the types of remedies that CMS may contemplate under this section. We are concerned that requiring manufacturers to pay the unspecified costs of any remedies that CMS determines to be appropriate is overly broad and does not give manufacturers adequate notice of the range of costs that CMS may deem appropriate here, particularly in the context of data that does not contain information that is identifiable on its own.

VI. Definition of Medicare Part D Discount Information – DUA Section II and TPA Agreement Section I

The DUA and the TPA Agreement both incorporate the definition of Medicare Part D Discount Information from the Draft Model Agreement between the Secretary and a Manufacturer. We note that the definition provided for in the Draft Model Agreement means information "consisting of summary-level information showing the total units dispensed and total applicable discounts paid by Part D sponsors for each Manufacturer's NDC number during the applicable quarter."[2] We have commented extensively to CMS on that Draft Model

[2] Draft Model Agreement § I(k).

Agreement; in particular, we have commented on the need for manufacturers to receive robust data under the Discount Program. We assume that the development of the DUA and the security provisions in the TPA Agreement suggest that CMS will be revising that definition to allow for the provision of more robust PDE data to manufacturers. Our comments on the DUA and the TPA Agreement are based on that assumption. Should CMS intend to retain the definition of Discount Information set forth in the Draft Model Agreement – which contemplates only summary level information – we would instead suggest that CMS eliminate the DUA as well as the security provisions of the TPA Agreement, as we do not believe these security measures are necessary for summary level data and would impose an undue burden on manufacturers.

VII. Data Transmission Security – TPA Agreement Section IV(c)

CMS proposes to require that the manufacturer and the TPA employ security measures necessary to protect Data Transmissions between them, including authentication, encryption, password use, or other security measures in compliance with Social Security Act §1173(d) and any HHS implementing regulations or guidelines and as set forth in the Program Agreement, the Data Use Agreement, and in the contract between CMS and the TPA. BIO urges CMS to make clear that this provision applies to the Data Transmissions and only to those Security Rule requirements related to the transmission of data and is not intended to obligate manufacturers to the Security Rule more generally.

BIO also requests that CMS not make the Data Transmissions subject to provisions in the contract between CMS and the TPA. Manufacturers are not a party to the contract between CMS and the TPA, nor have manufacturers had the benefit of reviewing or commenting on that contract. All requirements to which the Data Transmissions are subject that relate to manufacturers should be stated in the agreement between a manufacturer and the TPA or in the Data Use Agreement. This will fairly put manufacturers on notice of the obligations to which they are agreeing to comply and allow manufacturers to develop appropriate plans for that compliance.

VIII. Aggregate Data for Manufacturers Not Able to Meet the Security Requirements

BIO greatly appreciates CMS's willingness to consider the importance of providing manufacturers with adequate data under the Discount Program. As BIO has commented in the past, we believe it is critical to provide manufacturers with data sufficient to enable them to verify the accuracy of payments made under the Program. Some manufacturers, however, may not have security systems that meet the requirements of these agreements and may need time to build the systems necessary to secure the data in compliance with CMS requirements. In order for these manufacturers to fully participate in the Discount Program, BIO urges CMS to allow a manufacturer, upon request, to receive aggregate data from CMS necessary to pay invoices

without entering into the DUA or making the security requirements of the TPA Agreement effective. This would provide manufacturers with adequate time to adapt any computer systems in a manner that would enable the manufacturer to meet the security requirements of these agreements.

IX. Timeframe for Entering Into the 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 the TPA Agreement and the DUA, as well as the underlying 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.[3] Drugs within the six classes of clinical concern must be reviewed and added to formularies within 90 days.[4] 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 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

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[3] Prescription Drug Benefit Manual § 30.1.5.

[4] Id. § 30.2.5.

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 TPA Agreement and the DUA. 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 L. Todd
Director, Reimbursement and Health Policy