BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Charlene Frizzera, 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: Draft 2011 Part D Call Letter

Dear Acting Administrator Frizzera:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Draft 2011 Call Letter. 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. We continue to encourage CMS to focus on patient access in its ongoing implementation and refinement of this important program. As such, we provide below some comments regarding the 2011 Part D Call Letter.

<u>Clinical Trial Policy</u>

BIO strongly supports CMS's proposal that Medicare Advantage (MA) plans reimburse enrollees for cost sharing for clinical trial services that exceed the plan's in-network cost sharing, as well as CMS's proposal that clinical trial cost sharing be included in out-of-pocket maximum calculations. We believe that this policy will foster the goal of increasing the participation of such patients in clinical

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trials, rather than limiting the number of trials available to the Medicare population. This proposal represents a positive step in CMS's efforts to ensure that Medicare beneficiaries are not denied access to medically necessary care simply because that care is provided in the context of a clinical trial. Assuring MA enrollees of typical cost-sharing for the routine costs of clinical trials will help facilitate their participation in clinical trials, while also helping to ensure that innovative therapies are developed in a manner that takes into account this critical patient population.

Specialty Tier

BIO remains concerned about the discriminatory effect of the specialty tier in Part D. Because of the distinctive cost-sharing structure of the Part D benefit, patients prescribed drugs or biologicals on a plan's specialty tier are uniquely at risk for large out-of-pocket costs. Although only a small percentage of Medicare beneficiaries reach the coverage gap or "donut hole" during a plan year, patients needing therapies on a plan's specialty tier are more likely to encounter the donut hole earlier in the calendar year and to incur the donut hole's substantial out-of-pocket expenses all at once.[1] In 2011, patients not eligible for the Part D low income subsidy must incur true out-of-pocket expenses (TrOOP) of $4,550 before catastrophic coverage begins – an amount not practical or feasible for many beneficiaries. If this amount were spread throughout the calendar year, it might be more financially feasible for Medicare beneficiaries. However, many patients will reach these out-of-pocket amounts within a few months if their prescribed drugs or biologicals are placed on the specialty tier. Moreover, since assistance provided by other insurance or sources is not counted for purposes of TrOOP, there is little opportunity for a beneficiary to obtain other insurance to assist with the Part D cost-sharing obligations. These cost-sharing challenges have been exacerbated as the cost thresholds for the standard Part D benefit design have increased each year.

Under CMS's proposed threshold for 2011, a drug or biological can be placed on the specialty tier of a Part D plan's formulary, and thus be subject to a higher coinsurance, if it has a negotiated price of $600 per month or more.[2] BIO is concerned that permitting a plan to place any therapy with a negotiated price greater than $600 per month on the specialty tier grants plans too much discretion in setting

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[1] See, e.g., National Opinion Research Center et al, "Drugs on the Specialty Tier", a study conducted for the Medicare Payment Advisory Commission, February 2009, available at http://www.medpac.gov/documents/Feb09_DrugsonSpecialtyTiers_CONTRACTOR_RS.pdf.
[2] Draft 2011 Call Letter at 96.

negotiated prices and allows the inclusion of far too wide a range of therapies on the specialty tier.

As BIO understands CMS's rationale for creating the specialty tier, the intent was at least in part to protect plans from the cost of having to place all high-cost therapies on the preferred formulary tier, either directly or through the exceptions process, and it was originally intended to include only very high cost therapies. Establishing a threshold amount of $600 goes far beyond this apparent intent by allowing plans to include a wide range of drugs and biologicals on the specialty tier. This is exacerbated by the fact that 2011 would be the fourth plan year in which a $600 threshold would be in place. While all other components of the Part D benefit design have increased each year, CMS has maintained the specialty tier threshold at the same level, ensuring that more beneficiaries will be subject to the specialty tier and the typically higher cost-sharing associated with such a tier. Although we question whether it is appropriate to establish a threshold at all for the specialty tier, where CMS does establish such a threshold, BIO requests that CMS substantially increase the threshold amount for the specialty tier in order to more appropriately limit the significant impact this tier has on patient access to critical therapies. In addition, to the extent CMS does allow specialty tiers, BIO supports CMS's proposed efforts to review claims data as a means of ensuring that drugs and biologicals are placed on the specialty tier only where the claims data reflects that the majority of claims for the drug are consistent with CMS's established threshold for the specialty tier.

Finally, we reiterate our concern about the specialty tier more generally. The Part D statute specifically grants Part D enrollees the right to request an exception to a plan's tiered cost-sharing structure, stating that a "PDP sponsor *shall have an exceptions process*"[3] pursuant to which a beneficiary may request a non-preferred drug. The statute grants CMS the authority to establish guidelines that Part D sponsors must follow when making a determination with respect to an exceptions request, but it does not permit CMS to eliminate the exceptions process altogether with respect to a subset of covered Part D drugs. CMS's continued implementation of the specialty tier eliminates the ability of an enrollee to seek a tiering exception for high-cost biologicals, and therefore is inconsistent with the statute.

[3] SSA § 1860D-4(g)(2) (emphasis added).

Curbing Waste of Unused Drugs Dispensed in the Retail Setting

BIO supports CMS's goal of containing Part D costs and reducing waste, and supports the voluntary nature of the proposed program for beneficiaries. However, BIO suggests that CMS further explore the potential implications of such a policy prior to implementation. A partial fill program for Medicare Part D beneficiaries raises new questions on a range of issues, including medical appropriateness, drug efficacy, product integrity, and patient comprehension and compliance. Accordingly, BIO believes it would be advisable for CMS to thoroughly assess the potential benefits and risks of such a program, perhaps through a pilot program, prior to adoption.

If CMS does adopt the proposed policy, it is paramount that CMS ensures that a beneficiary's physician deems any partial fills to be medically appropriate. Some drugs and biologicals, for example, antidepressants, may require a longer period of time in order to gauge tolerance or efficacy, and in those circumstances a partial fill may not be medically appropriate. In other situations, a shorter course of a medication may simply not be effective. For example, if a patient does not refill a partial fill of an antibiotic, his or her infection could resurface, with much greater clinical and cost consequences. It is also crucial that patients understand the partial fill concept. A partial fill option could unintentionally convey to a patient that a course of therapy should be concluded in the course of a week, and the patient may thus fail to fill the remaining prescription, resulting in a less than effective course of therapy. Such situations would not only compromise patient care, they may ultimately cost the patient, the plan and the Medicare program more money.

CMS must also keep in mind that partial fill may not be possible for some biopharmaceuticals. Given that many therapies currently are dispensed in larger quantities, there may be circumstances in which the integrity of the packaging or the labeling may not accommodate partial fills. In particular, in many cases it may not be feasible to divide biologicals into smaller quantities. Moreover, pharmacies may not stock all Part D products, and could be unwilling to order a product for a particular patient if they know only a partial fill will be dispensed and the remainder will be left in inventory. In order to ensure that this type of program proceeds in a manner that reflects the current realities of prescribing, dispensing and packaging practices, BIO urges CMS to consider piloting this program on a limited demonstration basis to evaluate the effect of the program on beneficiary treatment and compliance, pharmacy dispensing fees, and to identify any unintended consequences of the policy.

Release of Part C and Part D Payment Data

In the Draft 2011 Call Letter, CMS proposes to routinely release Part C and Part D payment data on an annual basis. While BIO supports CMS's efforts to provide greater transparency, we urge CMS to ensure that any release of Part C and Part D payment data does not result in the release of commercially sensitive data such as data on rebates and other price concessions, or that data that is released does not allow for "reverse g engineering" or analysis of the data such that the rebate information may be determined. As CMS has acknowledged in the past, the statute contains express disclosure limitations; specifically, § 1927(b)(3)(D) of the Social Security Act expressly protects rebate information that Part D plans are required to disclose to the Secretary pursuant to § 1860D-2(d)(2) as well as information that Part D plans are required to disclose to the Secretary regarding the amount of fees paid to providers of a plan's medication therapy management programs. These provisions protect competitively sensitive financial data regarding rebates, discounts, and other negotiated price concessions. We urge CMS to clarify that any disclosure of Part C and Part D payment data will not undermine the § 1927(b)(3)(D) protections of this confidential financial information.

Conclusion

BIO appreciates the opportunity to comment on the 2011 Draft Call Letter. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-470-5207 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Lauren P. Neff
Manager, Medicare Reimbursement
& Health Policy