March 4, 2011

By Electronic Delivery

Donald M. Berwick, M.D., MPP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Draft 2012 Part D Call Letter

Dear Administrator Berwick:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Draft 2012 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 1,100 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 continue to encourage CMS to focus on patient access in its ongoing refinement of this important program. As such, we provide below some comments regarding the 2012 Draft Part D Call Letter.

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

1201 Maryland Avenue, SW • Suite 900 • Washington, DC 20024-2149 • 202.962.9200 • Fax 202.488.6301 • www.bio.org

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. While beneficiary costs are mitigated by the Coverage Gap Discount Program, BIO continues to be concerned about high out-of-pocket costs until the donut hole is completely closed in 2020.

Under CMS's proposed threshold for 2012, 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.[1] 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 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 2012 would be the fifth 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. 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, BIO has concerns with CMS's proposed review of PDP and MA-PD benefit package data for 2012 to determine "acceptable cost sharing thresholds." CMS proposes to evaluate only non-specialty tiers for purposes of determining whether the cost-sharing for a particular tier is discriminatory.[2] The Part D statute specifically states the Secretary can only approve a plan if the design

[1] Draft 2012 Call Letter at 119.
[2] Draft 2012 Call Letter at 115.

of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals.[3] BIO believes that the specialty tier is inherently discriminatory due to the high cost-sharing imposed on Medicare's most vulnerable beneficiaries. It is critical that CMS carefully review the specialty tier, which has the greatest potential to be discriminatory, in examining acceptable cost sharing thresholds.

Medication Adherence

BIO supports CMS's proposal to improve quality and performance measurement of Part C and D plans as it relates to medication adherence. BIO believes that incorporating a Part D medication adherence measure set into the Plan Ratings may improve beneficiary health outcomes and reduce inefficiencies in health care delivery. BIO strongly supports policies that increase patient adherence to therapies, and believes that improved adherence can have a significant positive impact on patient care and reduce costs over the long term. BIO urges CMS to move forward with its proposal to add the Part D medication adherence measure for the 2012 Plan Ratings.

Conclusion

BIO appreciates the opportunity to comment on the 2012 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 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 Todd
Managing Director
Reimbursement and Health Policy

[3] SSA §1860D-11(e).