BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

January 30, 2008

BY ELECTRONIC DELIVERY

Cynthia Tudor, Ph.D.
Director, Medicare Drug Benefit Group
Centers for Medicare & Medicaid Services
Mail Stop C4-13-01
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on Draft CY 2009 Call Letter

Dear Dr. Tudor:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Draft 2009 Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Cost-Based Plan, and Stand Alone Prescription Drug Plan (PDP) Call Letter released on the CMS web site on January 16, 2008.[1] 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 companies, academic institutions, state biotechnology centers, and related organizations in the United States. 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. As such, BIO strongly supports the Medicare Part D benefit, and we greatly appreciate CMS' continued efforts to implement and improve upon this successful program, which has delivered increased prescription drug access and savings to millions of our nation's seniors. It is in this spirit that we offer the following comments on the CY 2009 Draft Part D Call Letter:

[1] Draft CY 2009 Call Letter, January 16, 2008, available at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf.

III. FORMULARY, A. *Six Classes of Clinical Concern* (pg. 54-55)

BIO appreciates and strongly supports CMS' decision to extend the "all or substantially all" formulary guidance into the 2009 plan year, and urges the agency to make it permanent. We believe that this policy has played an important role in assuring that many of the most vulnerable Medicare beneficiaries have access to the therapies they need under Part D. BIO requests that CMS continue to monitor beneficiary access to all drugs and biologicals within the six protected classes. Specifically, we urge CMS to ensure that enrollees have access to the latest therapies approved after the April 21, 2008 plan formulary submission deadline. We also urge CMS to include combination therapies, as well as all package sizes, product strengths, and formulations of drugs and biologicals that fall under the classes.

In addition, BIO agrees with CMS' determination, based on experience with Part D to date, that physicians should be provided "wide discretion"[2] in initiating antiretroviral therapy, and supports the agency's policy of prohibiting plans from subjecting HIV/AIDS drugs to utilization management tools in 2009 without exception. However, BIO notes that such discretion is important to prescribers of drugs and biological therapies in the other protected classes as well. Two examples illustrate the point that for high-risk populations, access to appropriate medications can significantly improve patient care. Cancer treatment is highly complex, and the types of therapies used in oncology continue to evolve rapidly. Antineoplastics may be used for more than one organ system, for more than one type of cancer, for different stages of diseases, and often in combination with other agents, and thus, affording access to the range of therapies available is critical to medical decision-making. In the neurosciences, a wide array of effective treatments should be available because of the treatments that are equally effective in general for the entire population, many of them are not equally effective for significant subgroups. As such, BIO strongly urges CMS not to permit plans to impose utilization management tools on any therapies in the six protected classes in a manner that will impede patient access to needed medications in any way.

[2] Draft CY 2009 Call Letter, pg. 55

III. FORMULARY, B. *Prior Authorization* (pg. 55)

BIO applauds CMS for establishing a new requirement that Part D plans post their approved prior authorization (PA) criteria on their web sites by the start of the 2009 enrollment period. The success of the Part D program depends in large measure on the ability of beneficiaries to select a plan that best matches their individual prescription needs. Requiring Part D plans to post PA criteria for drugs and biologicals in a uniform manner would augment the existing measures that CMS has undertaken to increase transparency in the Part D marketplace, and enhance the ability of beneficiaries to compare the various plan options available to them. The posting of PA criteria on plan web sites will also allow physicians and patients to more readily determine the specific requirements for drug and biologicals covered under different plans, making the process easier to navigate for both plans and enrollees.

In addition to PA criteria, BIO also urges CMS to require Part D plans to post the other utilization management tools they use for drugs and biologicals on their plan web sites, such as step therapy requirements and quantity limits. Posting this information would also improve the transparency of the Part D benefit, and assist beneficiaries in making appropriate plan choices.

III. FORMULARY, D. *Specialty Tiers* (pg. 56-57)

BIO remains concerned about CMS' policies regarding the specialty tier and their impact on beneficiary access to critical therapies under Part D. As detailed in previous comments submitted to the agency, BIO believes that CMS' continuation of the specialty tier places a significant out-of-pocket burden on medically vulnerable patient populations who often require unique therapies. We also continue to believe that the specialty tier is inconsistent with the statute in not affording enrollees the ability to request an exception to a plan's tiered cost-sharing structure.[3]

Nevertheless, should CMS continue the specialty tier in 2009, BIO urges the agency to do so in a way that minimizes the inherent discriminatory nature of such a tier and to closely monitor its effects on patient access. BIO is

[3] BIO Letter to Dr. Cynthia Tudor, Comments to Draft 2008 Call Letter, April 3, 2007, available at: http://bio.org/healthcare/medicare/20070403.pdf.

particularly concerned that CMS has elected to maintain the specialty tier cost threshold at $600 in 2009, and we request that CMS substantially increase the threshold amount in order to more appropriately limit the significant effect this tier has on patient access to critical therapies.

BIO appreciates CMS' clarification that plans are required to evaluate the negotiated prices of drugs and biologicals at the individual "product strength, package size, and formulation level" in order to determine their appropriate inclusion on the specialty tier.[4] However, BIO is concerned that CMS has not gone far enough in establishing a transparent and consistent methodology for plans to use to address potential methodological issues in calculating the threshold. Because the specialty tier can have a profound impact on beneficiary access to critical therapies, we urge CMS to provide greater clarity on the threshold calculation. We will continue to work with the agency to ensure the threshold calculation employs a sound, accurate methodology that is transparent to all stakeholders, including beneficiaries, CMS, and manufacturers.

Conclusion

BIO appreciates CMS' consideration of these comments and would welcome the opportunity to discuss them with you in depth. Please contact me at (202) 312-9281 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

John Siracusa
Manager, Medicare Reimbursement
& Economic Policy

[4] Draft CY 2009 Call Letter, pg. 55