BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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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 2008 Call Letter

Dear Dr. Tudor:

The Biotechnology Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Draft 2008 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 March 22, 2007. 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. BIO strongly supports the Medicare Part D prescription drug benefit, and we appreciate CMS' significant efforts to implement and improve upon this program. Many of the therapies developed by biotechnology companies target conditions that primarily affect seniors. We continue to encourage CMS to focus on patient access in its ongoing implementation and refinement of this important program. This is particularly important as CMS continues to evaluate and update guidance to Part D sponsors.

To ensure that CMS' overall approach to reviewing sponsors' Part D plans continues to provide beneficiaries with access to critical therapies, BIO urges

CMS to revisit and provide additional guidance on certain elements contained in the Draft Call Letter.

I. Drug List Review (pg. 59-60)

BIO appreciates CMS' efforts to ensure beneficiary access to all clinically appropriate therapies. As you know, after extensive input from many key experts and stakeholders, the United States Pharmacopeia (USP) created a separate listing of formulary key drug types (FKDTs) specifically for the purpose of assisting CMS with the Part D formulary review process. The FKDTs were developed by USP to provide additional guidance to CMS regarding drug types to ensure that Part D formularies provide appropriate access and do not substantially discourage enrollment by certain Medicare beneficiaries. BIO believes that CMS' policy of requiring "at least one item in each of the FKDTs" is an important component of CMS' formulary review process that supports the goal of ensuring beneficiary access to needed medicines. In fact, CMS states in previous formulary guidance that including one drug per FKDT is considered a "best practice" by plans. Therefore, BIO is concerned that the proposal to eliminate the FKDT requirement could result in less comprehensive Part D formularies that may not meet the needs of Medicare beneficiaries.

Instead of requiring one drug per FKDT, CMS proposes to use the "presence of the U.S. Pharmacopeia FKDTs as an outlier test to ensure that these drug types are strongly represented on all Part D formularies."[1] BIO believes that this represents a significant policy change. The Draft Call Letter provides no detail or information about how this outlier test will assist CMS in ensuring beneficiary access to needed medications and non-discriminatory formularies. It is unclear whether the outlier test will achieve the same goal as the "one drug per FKDT" policy. BIO asks that CMS provide greater detail as to how the outlier test will equally assist CMS in ensuring appropriate patient access to innovative therapies before finalizing this significant policy change for the 2008 plan year.

The Draft Call Letter seems to imply that CMS is "augmenting" the formulary sub-review process through the following actions: (1) expanding the review of the Medicare/Medicaid commonly used drugs to 200, (2) incorporating the top 100 drugs used the Medicare Drug Discount Card and (3) expanding the number of treatment guidelines used in the review process. BIO appreciates this

[1] 2008 Draft Call Letter, pg. 60.

position, but believes that, by eliminating the one drug per FKDT requirement, the overall impact is a weakening of the formulary review process.

In addition, regardless of the one drug per FKDT requirement, CMS should constantly be updating the quality and number of treatment guidelines used during the formulary review. In previous guidance, CMS provided examples of widely accepted treatment guidelines that are indicative of best practice, but stated that the list was not exhaustive. Therefore, it is already implied that CMS is regularly updating the list of treatment guidelines. This process is a complement to the one drug per FKDT requirement and should not be used in its place, as it is not redundant. Furthermore, we urge CMS to make the current and updated treatment guidelines publicly available such that relevant stakeholders can assess the appropriateness of applying these guidelines to the Medicare population.

Previous Part D formulary guidance has also stated that CMS will analyze the availability and tier position of the most commonly prescribed drugs for the general Medicare and dually eligible population. The data used to derive these drug classes came from 2002 Medicare Current Beneficiary Survey (MCBS) and from an Office of Inspector General (OIG) study on the transition of dual eligibles to Part D. It is unclear how the proposed policy of examining the top 200 drugs and incorporating the top 100 drugs used in the Medicare Drug Discount Card is an "augmentation" of the existing review process. Again, it appears that CMS should have already been utilizing this step in the review process. BIO requests that CMS publish the list of the 200 commonly used drugs relied upon to evaluate Part D formularies, in order to allow stakeholders to assess its clinical appropriateness and whether the drugs reflect the current standard of care for their respective conditions.

As stated previously, the Draft Call Letter proposes a significant policy shift for the formulary review process. The proposal only afforded eight business days for stakeholders to submit comments. BIO is very concerned with the short time frame and urges the agency to issue separate Part D formulary review guidance as it has done previously.

BIO understands that one of the factors driving this policy change is CMS' desire to enhance manufacturer-plan negotiations. BIO appreciates this goal and fully supports negotiations occurring at this level. However, robust and significant negotiations currently exist between plans and manufacturers as a result of current formulary policies. Regardless of the one drug per FKDT requirement, manufacturers must still negotiate with plans for formulary placement.

Additionally, plans possess various utilization management tools like step therapy and prior authorization that also enhance the negotiation process. BIO believes that removing the one drug per FDKT requirement will not achieve CMS's goal of increasing plan leverage, yet will certainly decrease beneficiary access to innovative therapies.

II. Specialty Tiers (pg. 60)

BIO remains concerned about Part D policies with respect to the specialty tier and their impact on beneficiary access to critical therapies. Permitting a plan to place all therapies with negotiated prices 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. Although we question whether it is appropriate to establish a threshold at all for the specialty tier, we support CMS' intention to conduct a statistical analysis of drugs found on 2008 specialty tiers, and recommend that the agency use this information to ensure that Part D plans afford appropriate access and do not discriminate against patients who require these therapies.

We also again ask that CMS more clearly define the way in which plans should calculate the threshold amount. The recently finalized Chapter 6 of the Medicare Prescription Drug Benefit Manual (PDBM) states that "[o]nly Part D drugs with plan negotiated prices that exceed $500 per month may be placed in the specialty tier."[2] This allows plans considerable discretion in setting negotiated prices at a level that qualifies a particular therapy for specialty tier inclusion—an issue not adequately addressed simply by increasing the dollar threshold to $600 for 2008. Instead, BIO reiterates our previous suggestion that if CMS must establish a threshold amount for the specialty tier, CMS permit plans to include a drug on the specialty tier only where the lower of (1) the plan's negotiated price for the drug, or (2) the wholesale acquisition cost for the drug minus any rebates or other price concessions provided to the Part D plan sponsor from the drug's manufacturer is above the threshold amount.

Patients who need therapies that are placed in a specialty tier tend to be particularly medically vulnerable. In addition, because of the distinctive structure of the Part D benefit, these patients are uniquely at financial risk because of the cost-sharing structure of the Part D benefit. Although many Medicare

[2] Medicare Prescription Drug Benefit Manual, Chapter 6, pg. 16, accessed at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf.

beneficiaries are unlikely to hit the "donut hole" or coverage gap at all, or only late in the year, patients needing high cost and unique therapies are likely to enter this gap early in the calendar year and incur substantial out-of-pocket expenses over a very short period of time. It is likely to be extremely difficult for these patients to absorb these significant out-of-pocket expenses all at once. As a result of CMS' proposed threshold for the specialty tier—even with the increase to $600 for 2008—many patients will be subject to the specialty tier and the typically higher cost-sharing associated with such a tier.

Furthermore, the Draft Call Letter does not address the beneficiary coinsurance amount that Part D plans are permitted to assign to drugs placed on the specialty tier. BIO again seeks clarification that the cost-sharing associated with the specialty tier must be limited to 25%. We are concerned that CMS' statement in Chapter 6 of the PDBM that the requirement is 25% "or actuarially equivalent for plans with decreased or no deductible basic alternative benefit designs"[3] would allow plans to increase the cost-sharing percentage for the specialty tier beyond 25%. We also urge CMS to continue to carefully monitor cost-sharing levels for the specialty tier in 2008.

BIO also is concerned about CMS' policy allowing plans to place all therapies within a particular category or class in the specialty tier, as long as all therapies in that category or class meet the criteria for inclusion in the specialty tier. In Chapter 6, CMS states that, in this circumstance, "a plan does not need to identify a preferred drug for that category or class." This directly contradicts CMS' statement later in Chapter 6: "Best practice in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary." CMS goes on to explain that its formulary review will "focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions." BIO strongly supports this approach to formulary review and urges CMS to reconsider this approach to the specialty tier so that a plan's implementation of such a tier does not further result in a plan benefit design structured in a manner that substantially discourages the enrollment of Medicare beneficiaries with certain disorders. BIO urges CMS to establish Part D policies that ensure implementation of the specialty tier is done in a manner that minimizes the inherent discriminatory nature of such a tier. Allowing plans to exclude all

[3] PDBM, Chapter 6, pg. 16.

therapies for treatment of a particular disorder from the preferred formulary tier certainly would seem to discourage the enrollment of certain groups of beneficiaries.

Finally, we reiterate our concern about the specialty tier more generally. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifically grants Part D enrollees the right to request an exception to a plan's tiered cost-sharing structure. CMS' continued implementation of the specialty tier, eliminating the ability of an enrollee to seek a tiering exception for high-cost drugs and biologicals, is inconsistent with the statute.

III. Six Classes of Clinical Concern (pg. 60)

BIO appreciates and strongly supports CMS' decision to extend the "all or substantially all" guidance into the 2008 plan year and again encourages CMS to make it permanent. It is critical that beneficiaries with chronic diseases such as HIV and cancer have access to a wide range of drugs and biologicals in certain therapeutic categories and classes. BIO greatly appreciates CMS' continued implementation of this "all or substantially all" requirement. We believe that this approach plays a critical role in assuring that many of the most vulnerable Medicare beneficiaries have access to the therapies they need.

The therapies used to treat these diseases typically are not interchangeable. A plan that includes a limited number of therapies from the antineoplastics category, for example, will necessarily be discriminating against individuals with certain types of cancer. Cancer treatment is complex, and the types of agents used 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. Thus, it is critical that CMS continue its policy of requiring all of these therapies to be on a plan's formulary. This will ensure that the full range of these therapies is available to Medicare beneficiaries.

BIO remains concerned that establishing the April 16, 2007 deadline for determining which products are eligible for the "all or substantially all" requirement unfairly discriminates against beneficiaries who need access to innovative treatments and therapies. A key requirement of the MMA is to assure that plans provide beneficiaries access to all medically necessary treatments. Yet the April 16 cut-off date may unfairly deny patient access to medically necessary

new drugs. Part D plans must include all or substantially all therapies in the six protected categories. Thus, Medicare beneficiaries reasonably expect, and are entitled to, a benefit structure that aligns with currently available therapies, or at the very least, with the beginning of their benefit period. BIO is concerned that the April 16, 2007 date could leave patients without access to critical, life-saving therapies that come onto market more than eight months prior to the beginning of the 2008 benefit period.

In 2006, the first year of the Part D benefit, CMS established a cut-off date of January 1, 2006, so that the "all or substantially all" policy applied to all drugs and biologicals on the market as of that date. BIO urges CMS to change the proposed April 16, 2007 cut-off date so that all or substantially all products within the six protected categories must be included in the plans' formularies, no matter when they come to market. At the very least, CMS should establish January 1, 2008 as the cut-off date, similar to its policy for 2006. Medicare patients deserve to have a drug benefit that keeps pace with the latest developments in the standard of care.

BIO supports CMS' continued prohibition on the implementation of prior authorization or step therapy requirements for patients already stabilized on drugs or biologicals within one of the six categories, as well as the extension of this policy in circumstances where a plan cannot determine at the point-of-sale whether the enrollee currently is taking the drug or biological. We also urge CMS to prohibit prior authorization and step therapy for those beneficiaries who have previously tried but failed to respond to one or more drugs in a class of clinical concern.

BIO also supports CMS' continued policy that prohibits plans from subjecting HIV/AIDS drugs to utilization management tools at all, with a very limited exception. However, we urge the agency to extend this approach to the drugs and biologicals in the other protected classes as well. We strongly urge CMS not to permit plans to impose utilization management tools on these six drug classes in a manner that will impede patient access in any way.

BIO also requests that CMS modify its statement in Chapter 6 of the PDBM that "Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug."[4]

[4] PDBM, Chapter 6, pg. 16.

We are concerned that plans may interpret this phrase as permitting prior authorization or step therapy requirements for an enrollee currently taking a drug or biological as long as the plan couches those requirements in a manner that is not, on its face, intended to steer the enrollee to preferred alternatives in the class. In its 2006 guidance on the "all or substantially all" classes, CMS stated its expectation that, for patients already stabilized on a drug, "plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances." We encourage CMS to take this approach in updating Chapter 6 of the PDBM for 2008 and subsequent years to ensure that patients have full access to therapies in these six classes.

We also encourage CMS to include coverage of extended release therapies where (1) an immediate-release therapy is on formulary and (2) a unique dosage form of an existing chemical entity is already on formulary. Sometimes, it is incremental innovation that makes a significant difference in patients' lives, such as the development of extended release formulations or ready-to-use presentations of existing therapies or the development of a unique combination or method of administration. These advances benefit Medicare patients by reducing the burden of disease and improving health outcomes through enhanced safety, reduced risk of medication errors, and ease of self-administration, where appropriate. We encourage CMS to recognize the important difference that these types of therapies may offer patients when the agency updates Chapter 6 with respect to the "Six Classes of Clinical Concern."

Finally, we request that CMS clarify the exception to the substantially all requirement regarding the "same active ingredient or moiety" outlined in Chapter 6. We are concerned that plans may interpret moiety to mean something other than the FDA definition of this term. Therefore, we suggest that in the final Chapter 6 CMS make clear that moiety has the same meaning as used by FDA in its definition of "new molecular entity." We also suggest that this exception only apply where there exists an AB-rated generic for the specific product(s) in question, consistent with the intent of addressing products that have the "same active ingredient or moiety."

IV. Vaccine Formulary Coverage (pg. 61)

In the Draft Call Letter, CMS states that it will add a new section to Chapter 6 of the PDBM that will require Part D plan sponsors' formularies to include all commercially available vaccines that are not covered under Part B.

BIO supports this change, and views it as a positive step toward making sponsors more aware of the role of vaccines in the Part D benefit.

V. Vaccine Administration (pg. 61-63)

The Draft Call Letter states that CMS does not believe it is appropriate for a vaccine and its administration to be billed by separate providers. However, in implementing this policy, CMS should recognize that, as of June 2006, there are six states in which pharmacists are not permitted to administer vaccines and another six states in which pharmacists are generally limited to administration of influenza and pneumococcal vaccines. CMS should clarify how it intends to ensure access to Part D vaccines in these situations.

CMS should also clarify that a Part D sponsor cannot restrict the method by which patients access Part D-covered vaccines. The Draft Call Letter focuses heavily on the pharmacy intermediary role in dispensing and billing for vaccines. CMS should clarify that physicians continue to have the option to bill for the Part D vaccine and its administration. It is important to ensure that physician billing option remains available since most vaccination will occur in physician offices for Part D eligible vaccines and the pharmacist intermediary role may not develop immediately. CMS should clarify that Part D sponsors must have both a pharmacy approach and an out-of-network approach that allows physician billing and beneficiary reimbursement.

The Draft Call Letter does not indicate any intention of assisting in informing Medicare providers about how vaccine coverage and billing will operate in 2008. Providers need information about their billing and payment options and information about how to locate information about their specific patient's coverage. It would seem that since most of the Part D-eligible inoculation will occur in the physician office setting, CMS should do more to make physician administration and billing feasible for Part D sponsors and physicians.

The Draft Call Letter states that "Part D sponsors must require that their network pharmacies establish relationships with immunizers when requested to do so, whereby the pharmacy performs vaccine dispensing to immunizer offices, accommodates in-network billing, and reimburses the immunizer for the administration fee." BIO encourages CMS to provide further guidance on issues such as whether pharmacists will be compensated for this administrative duty and how these costs and payments will be included in the system. BIO also urges CMS to address whether the agency anticipates that there will be a higher dispensing fee

for the pharmacist effort (i.e., delivery costs, accounting costs, payment costs) in addition to an administration fee to the immunizer. Finally, BIO requests that CMS provide further clarification regarding who the agency views as the party responsible for verification that vaccine administration has occurred.

CMS states that it envisions Part D sponsors and pharmacists will determine vaccine administration fees through negotiations. However, there are a range of issues associated with the determination of these fees that are not addressed in the Draft Call Letter and require further guidance. For example, does CMS anticipate that these same fee levels will apply to physicians billing the Part D plan directly for product and administration? Will CMS provide guidance on whether the negotiated administration fee will be passed through in full to an administering physician? Does CMS anticipate that there will be different levels of compensation to administering physicians and administering pharmacists given that even when a pharmacist administers, some level of effort was already expended by the physician in order to screen the patient, gain agreement to accept inoculation, and write the prescription that may be taken to the pharmacy for fulfillment in certain states? BIO encourages CMS to issue further guidance clarifying all of these issues.

Finally, the Draft Call Letter states that CMS will be reviewing vaccine administration fees to look for outlier payment levels that might be discriminatory. BIO recommends that CMS review vaccine administration fees at both the pharmacy level and the physician level to ensure beneficiaries retain access. CMS should consider reviewing the level at which the fee is passed through in full or in part to non-pharmacist immunizers in the situation where the pharmacist is the intermediary. CMS may also want to review the compensation provided to the pharmacist for the effort and cost of being the fiscal intermediary between the physician and the Part D plan. It seems that there are several levels at which the system could be inadequately compensated such that beneficiary access will suffer because physicians and pharmacists are not willing to become involved with Part D vaccines.

VI. Home Infusion Drugs (pg. 63)

BIO appreciates CMS' efforts to improve beneficiary access to home infusion drugs under Part D, and we applaud CMS for planning to require a specific reasonable time period for the delivery of home infusion drugs for 2009. Timely access to home infusion drugs under Part D, particularly upon discharge from an acute hospital stay, is vital to ensuring that patients receive care in the

most convenient and clinically appropriate setting without disruption to therapy that could adversely affect patient health. Currently, Medicare fails to cover the home infusion services considered necessary for effective medication usage, forcing many patients to forgo medically necessary therapy because the associated supplies, equipment, or professional services needed to use the therapy are not covered. Part D provides critical coverage, filling one part of this gap in Medicare coverage by providing payment for many drugs and biologicals administered in the home setting. Yet Part D plans are precluded from paying for the special costs associated with the administration of these drugs under the Part D benefit. Chapter 5 of the PDBM expressly states that Part D plans are not permitted to provide coverage of the supplies, equipment, and services associated with the administration of home infusion therapies. In Chapter 5 of the PDBM, CMS also states that "Part D sponsors must require that contracted network pharmacies that deliver home infusion drugs ensure that the professional services and ancillary supplies necessary for the provision of home infusion therapy are in place before dispensing home infusion drugs."[5] This requires a home infusion pharmacy to provide the Part D plan with assurances that the professional services and supplies necessary to provide the home infusion therapy are provided through Medicare Parts A, B, or C, or through a third party insurance plan or some other arrangement, including self-pay, prior to dispensing the drugs.

In many cases there is no other Medicare coverage available for these supplies and services. Currently, home infusion is covered under Part B infrequently, typically under the durable medical equipment (DME) benefit when an external infusion pump is used and strictly controlled infusion of the medication is medically necessary. Certain homebound beneficiaries eligible for home health services under Part A may receive assistance with nursing services, as well as with infusion equipment and supplies. Yet for many Medicare beneficiaries, payment for these supplies and services is not available, and the beneficiary must pay for these supplies and services out-of-pocket; many will instead chose to forgo therapy for lack of funding.

As BIO has stated previously, the lack of coverage is not a result of the Medicare statute but of CMS-created regulations and policies. We refer the agency to BIO's previous comments on draft Chapter 5 of the PDBM submitted on September 18, 2006, and urge the agency to reconsider the approach that precludes

[5] PDBM, Chapter 5, pg. 27.

payment under Part D for the supplies, equipment, and services necessary to make home infusion a reality for many patients.[6]

VII. Part D Benefits (pgs. 64-65)

Although CMS has indicated that it intends to encourage the coverage of brand-name drugs through the coverage gap, the agency may have, in fact, proposed policies to further eliminate access to brands. In the Draft Call Letter, CMS states that it will consider four bids from an organization if at least one plan offers coverage of all generics and all preferred brands through the entire coverage gap. In addition, CMS states that Part D sponsors may include, as part of an enhanced alternative benefit design, coverage of a subset of drugs—including either an entire tier or particular covered Part D drugs—throughout the entire coverage gap. The Draft Call Letter defines this as "coverage gap coverage." Coverage of less than an entire tier throughout the entire coverage gap, or coverage of a specific monetary amount will be considered "limited gap coverage." Although CMS notes that sponsors should be mindful of discrimination implications, CMS should recognize that this may encourage sponsors to offer highly restrictive formularies with few preferred brands so that they can market their product as having complete coverage of preferred brands throughout the coverage gap. For instance, CMS touted the fact that several sponsors were offering brand coverage in the coverage gap when in reality only one plan offered substantial brand coverage. CMS should further clarify that if a plan covers "all preferred brands" through the entire gap, those preferred brands should represent a substantial number of drug classes.

VIII. 2008 Reporting Requirements (pgs. 78-79)

BIO applauds CMS' proposal to update Part D sponsor data reporting requirements to include new sections on vaccine administration and home infusion. Given the unique delivery issues associated with these two important services, it is critical that CMS continually monitor plans to ensure that Medicare beneficiaries are afforded appropriate access under Part D. Requiring Part D sponsors to submit additional data on home infusion and vaccine administration will assist CMS in identifying patient access issues and making further improvements to the program.

[6] BIO Comment Letter Regarding the Medicare Prescription Drug Benefit Manual – Draft Chapter 5, September 18, 2006, available at: http://www.bio.org/healthcare/medicare/20060918.pdf.

IX. 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) 312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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