BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

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Re: Draft 2013 Call Letter

Dear Mr. Blum and Mr. Spitalnic:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft 2013 Call Letter. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new and innovative vaccines and therapies and ensuring patient access to them. Many of these vaccines and therapies target conditions that affect people age 65 years and older. BIO strongly supports CMS' commitment "to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage (MA) and prescription drug plans (PDP)."[1] In our comments below, BIO provides 3 recommendations to further improve the quality of these plans by: (1) using a pneumonia vaccine quality measure in the star ratings set to increase vaccine uptake and improve beneficiary outcomes; (2) expanding access to recommended vaccines through broader provider networks; and (3) reducing the cost-sharing thresholds for Part D plans in order to advance CMS' goal of improving medication adherence.

I. Pneumonia Vaccine Measure (page 67)

BIO supports the development and use of appropriate, evidence-based quality measures throughout the healthcare system. Quality measures for adult immunizations help ensure that healthcare providers routinely discuss and offer vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) to their

[1] Centers for Medicare & Medicaid Services. "2013 Call Letter." February 17, 2013. Page 51. Available at: http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2013.pdf.

patients, resulting in higher vaccine uptake among adults, better health outcomes, improved population health and cost savings for public and private insurance plans.

In the draft 2013 Call Letter, CMS states, "We are committed to continuing to improve the Part C and Part D quality performance measurement system to increase the focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery."[2] However, in the Call Letter, CMS also states its intent to remove the Pneumonia Vaccine (Part C) measure from the MA Plan Ratings and transition it to the 2013 display page. Following this transition, the Pneumonia Vaccine measure would no longer be part of the star ratings system used to determine Quality Bonus Payments (QBPs) for MA plans. Removing the Pneumonia Vaccine measure from the star ratings system would contradict CMS' aforementioned commitment to improving beneficiary outcomes and population health through the quality measurement system, as MA plans would no longer have the incentive to ensure providers routinely offer pneumococcal vaccination to eligible beneficiaries, thereby undermining both quality of care and the future health of the Medicare population.

CMS has made significant progress toward better patient care and population health by setting standards for improving quality measurement and reporting systems and implementing value-based purchasing programs. The agency is expanding influenza and pneumonia vaccination measures in the hospital setting, and includes both influenza and pneumonia vaccination quality measures in the measure sets for long-term care (LTC) facilities, Electronic Health Records (EHR) Incentive Programs, and the Physician Quality Reporting System (PQRS). Considering current progress, the removal of the pneumonia vaccination measure from the MA Plan Ratings would represent a step backwards for the agency.

As stated in our January 2012 letter [3] to CMS, BIO urges the agency to promptly revise or replace the Pneumonia Vaccine measure with a better measure based on National Quality Forum (NQF) consensus standards for pneumococcal immunization,[4] rather than remove the measure entirely from the star rating system. The exclusion of a pneumococcal vaccination measure in the star rating systems for MA plans could adversely affect uptake of the vaccine, which is recommended for all people age 65 and older and all high risk Medicare patients under 65. This, in turn, would negatively impact the quality of care received by Medicare Advantage beneficiaries and the overall health of the elderly population.

II. In-Network Providers for MA Plans

While the adequacy of MA plans' provider networks is not specifically referenced in the draft 2013 Call Letter, BIO believes that broad immunization provider networks are a critical component in high quality MA plans. Vaccines against influenza and pneumonia are covered benefits under Part B, and there is no cost-sharing for the Medicare beneficiary. However, in Part C, some MA plans limit access to first dollar coverage of these vaccines by requiring the provider who administers the vaccine to be an "in-network provider." Complementary, non-physician office settings that frequently administer vaccines, such as retail and community pharmacies, are typically excluded from these provider networks despite the fact that many states have laws permitting trained pharmacists to administer certain vaccines to adults.

[2] 2013 Call Letter at page 60.
[3] Available at: http://www.bio.org/advocacy/letters/bio-comments-cms-proposed-methodology-2013-star-ratings-medicare-advantage-and-pres.
[4] National Quality Forum. National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Washington, D.C., 2008.

Alternative settings increase access to immunizations, especially for the adult population. For example, more than 150,000 pharmacists are currently trained to administer vaccines in the U.S.,[5] and according to data from the CDC, during the 2010-2011 season, nearly 20% of adult influenza vaccines were administered in retail pharmacies.[6]

BIO recommends that CMS consider requiring MA plans to have an expansive network of locations and providers to ensure sufficient beneficiary access to vaccines recommended for Medicare beneficiaries, especially those 65 and older, by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), such as those against influenza and pneumonia. These networks should include those health care providers and locations allowed by state law to provide immunization services.

III. Integration with ACOs and Other CMS Innovation Models (page 98)

Under this heading, CMS seeks feedback "on innovative payment or service delivery models that promote improved medication adherence."[7] We are pleased to see that the agency is concerned about improving medication adherence. Appropriate medication adherence is known to reduce hospital admissions, help control chronic conditions, improve outcomes with regard to acute illnesses and control overall costs.[8] We strongly support the agency's goal of increasing medication adherence. We also believe CMS can improve medication adherence in the Part D program by modifying certain regulations and guidance that currently create barriers to adherence.

While we believe that CMS' desire to contain overall Medicare costs is sufficient reason for controlling high Part D cost-sharing in order to increase medication adherence, the agency's concern with ensuring that Part D plan designs do not discriminate is another powerful reason for taking such a step. Very high cost-sharing, without an exceptions process, can result in a shift away from a focus on clinical benefits and result in discrimination against certain classes of Part D enrollees, which should be avoided as a matter of fairness. For these reasons, we urge the agency to reduce the very high cost-sharing thresholds for Part D plans proposed in the draft Call Letter and allow the exceptions process to apply across all tiers.

Under the regulation at 42 CFR 423.104(d)(2), during the initial coverage period Part D plans offering standard Part D coverage must have 25 percent coinsurance (or an actuarially equivalent structure with an average expected coinsurance of no more than 25 percent of actual cost). The regulation allows plans to utilize tiered cost-sharing, but requires that such tiered cost-sharing "not exceed levels annually determined by CMS to be discriminatory."[9] Table VI-7 in the draft Call Letter indicates that CMS intends to allow coinsurance up to 50 percent for the non-preferred brand tier and up to 33 percent for the "injectable tier."[10]

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[5] Rothholz M. Role of Pharmacists in Adult Vaccination: Overview from the American Pharmacists Association. Presentation to the National Vaccine Advisory Committee. September 14, 2011.

[6] Centers for Disease Control and Prevention. Place of influenza vaccination among adults – United States, 2010-11 influenza season. *MMWR Morb Mortal Wkly Rep*. 2011;60(23):781-785.

[7] 2013 Call Letter at page 98.

[8] There is an extensive literature to support this concept. See, for example, Sokol, Michael C. MD, MS, et. al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," Medical Care: June 2005 - Volume 43 - Issue 6 - pp 521-530, Mojtabai, Ramin, and Mark Olfson, "Medication Costs, Adherence, And Health Outcomes Among Medicare Beneficiaries," Health Affairs, vol. 22, no. 4, pp. 220-29, and Osterberg, Lars ,M.D., and Terrence Blaschke, M.D., "Adherence to Medication," in the New England Journal of Medicine, vol. 353, pp. 487-497, 2005.

[9] 42 CFR 423.104(d)(2)(iii).

[10] The Call Letter did not specify whether the "injectable tier" is the same as the "specialty tier" and (if not) what drugs would be contained in the injectable tier. If the specialty and injectable tiers are the same, then CMS should clarify that the maximum permitted coinsurance for this tier is not 33 percent but 25-33 percent, depending on the plan's deductible; for specialty tier

While we recognize that Part D plans are permitted to vary their cost-sharing by tier (subject to actuarial equivalence requirements), we are very concerned that such high co-insurance will result in medication abandonment by Part D enrollees – especially for specialty tier drugs, where no tiering exceptions are available.[11] We believe that medication abandonment in the Part D program is a significant problem for patients taking many of the drugs in the high cost tiers.

A recent study of oral oncolytic drug abandonment that had the Medicare program as one focus found that:

- Ten percent of patients in the general population abandoned newly initiated oral oncolytic therapy.
- Patients over the age of 65 were more likely than the general population to abandon such therapy. For example, 13 percent of patients over age 80 abandoned their first oral oncolytic.
- Sixteen percent of Medicare beneficiaries abandoned their oral oncolytics, versus 9 percent of the general population.
- Claims with cost-sharing above $500 had an abandonment rate of 25 percent, more than four times the rate for those with cost-sharing of $100 or less.
- Eighty percent of commercially insured patients paid $100 or less out of pocket, compared to 35 percent of Medicare beneficiaries.
- Only 11 percent of commercially insured patients paid more than $500, versus 46 percent of Medicare patients.[12]

CMS allows plans to place drugs on a specialty tier if the 1-month, in-network cost of the drug exceeds $600.[13] Assuming that plans set their cost sharing for such drugs between 25 and 33 percent in the initial coverage period, patient costs under these plans would, at a minimum, range between $150 and $200 in the initial coverage period. Such high cost-sharing inappropriately shifts the focus away from the total cost of care and likely clinical benefit to one aspect of care and, importantly, may result in a very large percentage of Part D cancer patients simply abandoning their medication – a very serious outcome that would impact appropriate clinical care.

We understand that decreases in cost-sharing are tied to increased premiums. However, while Part D plans have kept their premiums relatively flat, cost-sharing in higher tiers have increased by nearly 19 percent in 2012. A recent analysis of the 2012 Part D formularies found that the enrollment-weighted average cost-sharing among five-tier PDPs using one coinsurance tier grew from 27.1 percent in 2011 to 32.2 percent in 2012. The authors concluded, "The 2012 Medicare drug program will result in higher cost-sharing for many patients with serious illnesses like cancer, multiple sclerosis, and rheumatoid arthritis."[14] CMS should carefully examine this trend and take steps to ensure that premium stability is not being maintained by increasing cost-sharing for a sub-set of beneficiaries with serious health conditions. As CMS is aware, several widely used brand drugs have either recently lost their exclusivity,

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drugs, plans with a standard Part D deductible must charge coinsurance less than or equal to 25 percent and only a plan with a zero deductible may charge 33 percent. Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.4.

[11] See 42 CFR § 423.578(a)(7), permitting Part D plans to design their exceptions processes "so that very high cost or unique drugs are not eligible for a tiering exception."

[12] Streeter, Sonya Blesser, MPP, MPH, et. al., "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions," Journal of Oncology Practice, vol. 7, issue 3S, pp. 46s-51s, 2011.

[13] 2013 Call Letter at page 100.

[14] See the Avalere study available at: http://www.avalerehealth.net/wm/show.php?c=&id=893 Last accessed on February 27, 2012.

or are on the verge of doing so. The transition to generic utilization for these drugs should offer Part D plans the opportunity to moderate cost-sharing in their higher tiers.

In addition to the concerns raised above, CMS should think carefully about the divergence between Part B and Part D cost-sharing levels and the potential incentive created for sub-optimal therapeutic substitution based purely on costs rather than clinical benefit or even considering the total cost of care (versus a single component of care). For example, a Part B drug with 20 percent coinsurance would look more costly to an MA-PD plan than a Part D competitor with 33-50 percent coinsurance, even if the total costs of the two drugs were the same.

We again encourage the agency to reduce the very high cost-sharing thresholds for Part D plans proposed in the draft Call Letter and allow the exceptions process to apply across all tiers.

IV. Conclusion

BIO appreciates the opportunity to comment on the draft 2013 Call Letter. We look forward to continuing to work with CMS to address these critical issues in the future. Please contact me if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

With Sincerest Regards,

/s/

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