Biotechnology Industry Organization

March 1, 2013

Jonathan Blum
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Director, Center of Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

Paul Spitalnic
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Parts C & D Actuarial Group
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7500 Security Boulevard, Baltimore, MD 21244

Re: Draft 2014 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 2014 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's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

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] We consider it especially important to focus attention on policies that impact access to prescription drugs and vaccines for Medicare beneficiaries in MA and Medicare Part D plans. Therefore, to further improve the ability of these patients to access crucial therapies and immunizations we urge CMS to consider the following comments, discussed in more detail below:

- BIO supports CMS in reiterating its policy that plans cannot require patients to obtain medications, otherwise administered in a physician's office, from a pharmacy and then take them to their physician for administration. Such a scheme inappropriately shifts coverage of these medications from the Part B to the Part D benefit outside of patient preferences.
- CMS should continue to focus on mechanisms to decrease the inappropriate use of prior authorization forms that subvert patient protections in place to allow patients to obtain a prescription from any pharmacy they choose.

[1] CMS (Centers for Medicare & Medicaid Services). 2013 Call Letter. February 17, 2012. 51. Available at: http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2013.pdf.

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- Reward or incentive programs for Part D that focus on encouraging higher rates of utilization of preventive services, such as immunizations, and increased patient adherence to medications have the potential to improve patient health outcomes.
- Due to heightened concerns regarding the quality of compounded products, BIO supports CMS in requiring plans to impose increased safeguards, via prior authorization, to ensure patient safety.
- Because of the nascence of the Part D Policy on Improving Utilization Review Controls and the need for thorough evaluation of their current application to opioids, CMS should not expand this program to other drugs or classes of drugs.
- Updates to the methodology and data for calculating out-of-pocket-costs for CMS' "meaningful difference" standard should be applied to Calendar Year (CY) 2014 to better ensure patients have access to needed prescription medications.
- Cost-sharing in the Part D specialty tier can unduly burden patients with severe and complex diseases. This is exacerbated by the fact that the dollar-per-month threshold to be placed on that tier allows too broad a range of therapies to be included.
- To improve access to vaccines, CMS should require MA plans to deem contracted pharmacy providers as in-network providers for immunizations provided in accordance with state scope-of-practice laws.
- BIO supports the CMS update to the medication adherence measurements for diabetes medications in accordance with the updated Pharmacy Quality Alliance (PQA)-endorsed specifications.

I. <u>BIO supports CMS' reassertion that sponsors cannot require a shift of drug coverage from Medicare Part B to Part D.</u>

BIO appreciates CMS' reiteration of its policy on coverage-shifting in MA plans from Medicare Part B to Part D. Currently, there are some prescription medications that are reimbursed under Part B when administered incident to a physician's services that, alternatively, are covered under Part D if obtained by a patient from a pharmacy and brought to a physician's office for administration. BIO supports the CMS position that such a coverage shift—from Part B to Part D—is at the discretion of the patient, based on his/her preferences, and that MA plans cannot require patients to obtain such medications in a pharmacy to obtain Part D reimbursement. Patient access to Part B-reimbursed drugs is crucial, as many patients needing these therapies are among the most vulnerable and require complex care (e.g., patients with cancer, multiple sclerosis, rare diseases).

II. <u>BIO supports CMS' focus on decreasing the inappropriate use of prior authorization forms.</u>

BIO appreciates CMS' attention to the issue of the inappropriate use of prior authorization forms such that patients are unable to fill a prescription at their pharmacy of choice, but are instead forced to use a sponsor's mail-order pharmacy. BIO agrees that such practices inappropriately bypass important beneficiary protections. The list of non-allowable practices leading to the inappropriate use of prior authorization forms that CMS provides is helpful and improves vigilance on this issue. BIO urges CMS to continue to focus on this matter going forward.

III. BIO supports CMS developing guidance regarding the implementation of reward and/or incentive programs applicable to Part D that are designed to potentially improve utilization of preventive services, including vaccines, and overall medication adherence.

In the Call Letter's "Applicability of Rewards and Incentives in part D" section, CMS states that its current preventive services guidance specifying preventive services with zero-dollar cost share does not apply to Part D, but that the agency is interested in considering applications of its rewards and incentives policy to improve outcomes and create efficiencies in the Medicare program and in Part D specifically.

BIO continues to be concerned that Part D plans are excluded from the immunization coverage standard created by the Patient Protection and Affordable Care Act (PPACA), as this leaves a financial barrier for beneficiaries. PPACA's immunization coverage standard provides improved access to lifesaving vaccines by mandating coverage of all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) without cost-sharing for most individuals if administered by an in-network provider. For patients in Part D, however, cost-sharing for vaccines is not waived by PPACA. BIO appreciates that CMS appears to recognize this disparity in preventive service coverage and access, and potentially views reward or incentive programs applicable to Part D as one approach to improve beneficiary outcomes and to address underutilization of these critical services, particularly immunizations against diseases such as shingles, tetanus, and pertussis.

While the Part D program does not cover preventive services with zero-dollar cost share, Part D does cover preventive services that could and should be incentivized to encourage uptake. BIO supports making reward or incentive programs available to Part D patients to increase vaccination rates for ACIP-recommended vaccines among Part D patients, and looks forward to reviewing Part D sponsor ideas and input on currently available reward and incentive programs used in commercially insured populations. BIO and its members are eager to work with CMS and other stakeholders to implement approaches to vaccination among the Medicare population that improve patient health outcomes and the efficiency of the program.

Finally, BIO appreciates CMS' focus on incentives or rewards as a potential mechanism to improve medication adherence "by motivating enrollees to comply with their medication regimens".[2] We encourage CMS is its effort to design and utilize effective programs to improve medication adherence and agree that the success of such an effort can improve the overall quality of MA and Part D plans.

IV. CMS should finalize its proposal to utilize prior authorization to impose additional safeguards for compounded products.

BIO appreciates CMS' attention to the very important issue of the safety and quality of sterile compounded products covered under Part D. Concerns around compounding are pervasive: in a current survey of pharmacists and pharmacy technicians conducted by the Institute for Safe Medication Practices, 13 percent of respondents reported that contamination of high-risk compounded sterile products had happened in their facility during

[2] CMS. 2014 Call Letter. February 15, 2013. At 136. Available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2014.pdf.

the past year, and only half (50 percent) of all staff pharmacists and 38 percent of pharmacy technicians were confident that contamination had not occurred.[3] Also, despite increased public scrutiny, Massachusetts recently conducted surprise inspections of 40 compounding pharmacies, and only 8 passed those inspections.[4] While CMS notes that states regulate compounding pharmacies, the adequacy of such state regulation has been questioned. For example, although CMS points to the U. S. Pharmacopeia (USP) 797 guidelines as an example of quality and safety standards that could be used by states, fewer than half of states incorporate the USP 797 guidelines into their laws and regulations, and some state have no law or regulation referencing sterile compounding.[5] Therefore, based on these realities, BIO supports implementing additional safeguards via prior authorization that require providers to justify the use of a compounded drug by demonstrating why "no FDA approved product is clinically suitable for the patient."[6] This will ensure that there is a demonstrated medical need for the use of a compounded product (e.g., patient cannot take oral medications and needs a suspended drug).

V. CMS should not expand the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs.

BIO believes in the public health imperative to identify the overuse, underuse, and misuse of medications, and recognizes the need to educate and inform prescribers about the appropriate use of medicines. However, proposed expansion of the Part D Policy on Improving Utilization Review Controls beyond opioids to include antipsychotics, amphetamine derivatives, benzodiazepines, and non-benzodiazepine sleep aids is inappropriate at this time. The existing effort on opioids only begins in CY 2013 and requires thoughtful and systematic evaluation to ensure it is achieving stated goals before CMS considers expanding the scope of the program to other drug classes. Specifically, careful assessment of the use of certain drug utilization management (DUM) strategies is needed, since current evidence suggests that those such as prior authorization, for example, may not be the most effective mechanism to decrease unnecessary utilization by patients.[7] The ability to translate the results from the opioids program is also in question because of the significant differences between opioids and these other drug classes. Additionally, the Call Letter does not provide any guidance on developing the targeted methodologies and utilization protocols for other drug classes that may require a different focus than the current opioids protocols. While BIO reiterates our support for efforts to reduce inappropriate use of medications, CMS should ensure that any such efforts are not overly burdensome to prescribers. Instead, the current requirement that prescribers justify the use of medications within certain drug classes based on sound clinical judgment is sufficient. Therefore, BIO urges CMS not to expand the Part D Policy on Improving Utilization Review

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[3] ISMP survey results are available at: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?id=40. Last accessed February 22, 2013.
[4] See Massachusetts Department of Public Health press release, available at: http://www.mass.gov/eohhs/gov/newsroom/press-releases/dph/update-on-unannounced-pharmacy-inspections-announced.html. Last accessed on February 22, 2013.
[5] A map, based on research by CriticalPoint LLC and the National Association of Boards of Pharmacy, showing whether and how states' laws and regulations address sterile compounding, is available at: http://www.clinicalig.com/797-state-survey. Last accessed February 22, 2013.
[6] CMS. 2014 Call Letter. At 137.
[7] Commonwealth Fund. April 2009. Health Care Opinion Leaders' Views on Slowing the Growth of Health Care Costs. Figure 6, p. 5. Available at: http://www.commonwealthfund.org/~/media/Files/Publications/Data%20Brief/2009/Apr/Slowing%20the%20Growth%20of%20Health%20Care%20Costs/1263_Stremekis_HCOL_Slow_Data_Brief_FINAL.pdf.

Controls (i.e., compiling with DUM requirements) to other drugs or classes of drugs outside of the current application to opioids.

VI. BIO supports the CMS proposals to update the methodology for the Out-of-Pocket-Cost (OOPC) calculation, but urges CMS to do so for CY 2014.

CMS uses plan-specific per member per month (PMPM) OOPC estimates to determine whether a sponsor is in compliance with the requirement that there is a "meaningful difference" between plans offered in the same geographical area.[8] BIO is concerned that the methodology and data used to calculate OOPC through CY 2013 can incentivize sponsors to undermine the inclusiveness of their formulary—and thus risk sufficient patient access to vital prescription medications—in order to meet the meaningful difference standard. Therefore, BIO supports CMS' proposal to update the methodology for calculating OOPC so that Medicare Current Beneficiary Survey (MCBS) cohort drugs not on plan formularies are priced at the cost-sharing of the Part D sponsor's exception tier.[9] BIO also supports the use of the latest available MCBS data in the OOPC calculation (CY 2013 calculations are based on the outdated CY 2008/2009 data set).[10] BIO urges CMS to implement these two proposals for CY 2014, instead of waiting until CY 2015, to more immediately ensure that the OOPC calculation is an accurate reflection of current patterns of spending and utilization.

VII. BIO remains concerned about the discriminatory effect of the specialty tier in Medicare Part D plans.

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. While beneficiary costs are mitigated by the Coverage Gap Discount Program, BIO continues to be concerned about high out-of-pocket costs.

Under CMS's proposed threshold for 2014, 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. 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' 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 2014 would be the seventh plan year in which a $600 threshold would be in place. That CMS has maintained the specialty tier threshold at the same level ensures that more beneficiaries will

[8] CMS. 2014 Call Letter. At 115.
[9] Id. at 144.
[10] Id. at 115.

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 continues to have concerns with CMS' review of PDP and MA-prescription drug benefit package data for 2014 to determine "whether the coinsurance values are discriminatory."[11] CMS evaluates only non-specialty tiers for purposes of determining whether the cost-sharing for a particular tier is discriminatory. The Part D statute specifically states the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals. 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.

VIII. BIO recommends that CMS require MA plans to deem contracted pharmacy providers as in-network providers for immunizations provided in accordance with state scope-of-practice laws.

While the adequacy of MA plans' provider networks for immunization is not specifically referenced in the draft 2014 Call Letter, the discussion of preferred/non-preferred pharmacies offers the opportunity to raise an important immunization access issue that reduces the likelihood of reaching important public health goals.

Pharmacists may not be considered members of an MA plan's provider network for the purpose of administering immunizations, even though they are typically authorized to administer vaccines under state law, and are contracted as part of an MA plan's pharmacy network to dispense prescription drugs. This can increase out-of-pocket costs and reduce access to vaccines for MA beneficiaries, since pharmacy immunization administration has become prevailing community practice in recent years. Vaccines against influenza, pneumonia and hepatitis B (for high/medium risk populations) are covered under Part B without cost-sharing for the Medicare patient, including when administered by pharmacists. However, some MA plans limit access to coverage without cost-sharing for these vaccines by not recognizing pharmacists as in-network providers for vaccine administration. In order to broaden the number and variety of sites that administer immunizations, CMS should require MA plans to deem contracted pharmacy providers as in-network providers for immunizations provided in accordance with state scope-of-practice laws.

In fact, several vaccines are administered efficiently and conveniently in community settings by pharmacists and other authorized vaccinators. Such settings increase access to immunizations, especially for adults. HHS has several active programs that encourage pharmacists, public health departments, and other community providers to become access sites for vaccine administration. As an example of the additional immunization capacity available through pharmacies, more than 185,000 pharmacists are currently trained to administer vaccines in the U.S.,[12] and according to data from the CDC, during the 2010-

[11] Id. at 141.
[12] Rothholz M. Opportunities for Collaboration to Advance Progress towards 'the Immunization Neighborhood': Recognition and Compensation of Pharmacists. Presentation. American Pharmacists Association. August 30, 2012.

2011 season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[13]

IX. CMS should finalize its proposal to adopt Pharmacy Quality Alliance (PQA)-endorsed updates to the medication adherence measurements for diabetes medications.

BIO urges CMS to finalize its proposal to adopt the PQA-updated specifications to add two new drug classes, meglitinides and incretin mimetic agents, to the measurement for adherence to diabetes medications of Part D patients for the 2015 Star Rating. As stated previously, medication adherence is crucial to improving patient care in the Part D program, and BIO appreciates CMS' attention to timely updates to the measurements that reflect the dynamic and evolving practice of medicine.

X. Conclusion

BIO appreciates the opportunity to comment on the draft 2014 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) 962-9220 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/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy

[13] 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.