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VIA ELECTRONIC DELIVERY

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Re: Revision of USP Medicare Model Guidelines v6.0 for Benefit Years 2015-2017

Dear Members of the Therapeutic Information and Formulary Support Expert Committee:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the U.S. Pharmacopeial Convention (USP) Therapeutic Information and Formulary Support Expert Committee (the "Expert Committee") in response to the Draft Medicare Model Guidelines Version 6.0 (the "Model Guidelines") released October 1, 2013.[1]

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. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have

[1] U.S. Pharmacopeial Convention (USP). 2013. USP Medicare Model Guidelines v6.0 (with Example Draft #3). Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013-09-27_usp_mmg_v6_draft3.pdf.

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reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO appreciates this opportunity to raise several concerns that could limit patient access to vital therapies if left unaddressed in the Version 6.0 Final Model Guidelines. Our comments, described in detail below, are structured in two parts based on the dual responsibilities of the Final Model Guidelines: as a comparator for Medicare Part D prescription drug plans, and as part of the minimum standard for the prescription drug benefit of health insurance plans subject to the Essential Health Benefits (EHB) for 2014 and 2015.[2]

The Medicare Prescription Drug Improvement and Modernization Act of 2003 charged the Centers for Medicare and Medicaid Services (CMS) to cooperate with USP to develop a classification system to be used by Medicare Part D drug plans for formulary development.[3] Updated every three years, the resulting Model Guidelines "utilize pharmacotherapeutic evidence within the context of FDA [Food and Drug Administration] approved indications to create categories and classes…which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class."[4] BIO appreciates the inclusion of several drugs and biologicals approved by the FDA since the last update to the Model Guidelines. However, we are concerned that this Version 6.0 update does not provide the sufficient granularity and comprehensiveness within and across the categories and classes that is necessary to ensure that the Model Guidelines include the spectrum of therapies needed by a Medicare population with diverse health needs. Similarly, BIO is concerned that the three-year update cycle allows a significant gap between when innovative therapies are available on the market and when the Model Guidelines reflect these innovations. To address these issues, BIO recommends that:

- The USP categories and classes be more detailed to adequately represent the drugs needed by enrollees in Medicare Part D prescription drug plans; and,
- The USP Model Guidelines be revised frequently to support timely access to new and innovative medications.

These concerns about the comprehensiveness and the timeliness of updates to the Model Guidelines also apply to the use of the Model Guidelines in the provision of EHB. BIO has significant concerns about the Model Guidelines specific to this EHB role. As established by the Affordable Care Act (ACA), all insurance plans in the individual and small group markets operating both inside and outside of the state health insurance Exchanges must comply with the EHB standard for all ten categories of EHB (of which prescription drugs is one). The EHB standard also applies to all individuals who are newly eligible for Medicaid under the ACA—i.e., childless, non-pregnant adults aged 18 to 64 with incomes at or below

[2] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 Fed. Reg. 12,834 (Feb. 25, 2013).
[3] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2085; Social Security Act § 1860D-4(b)(3)(C)(ii).
[4] USP. 2013. Guiding Principles USP Medicare Model Guidelines v6.0 Therapeutic Information and Formulary Support Expert Committee. Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013_usp_mg_guiding_principle.pdf.

133 percent of the federal poverty level—and enrolled in a Medicaid Alternative Benefit Plan.[5] Though Version 5.0 of the Model Guidelines will be used as part of the EHB minimum drug coverage standard for these insurance plans' in 2014 and 2015, BIO's concerns with the Version 5.0 Model Guidelines persist in the Version 6.0 draft, and this version may be used as the minimum EHB standard in future years. As explained in detail below, BIO urges USP to:

- Address the number, and granularity, of USP categories and classes necessary in order to adequately represent the drugs and biologicals needed by enrollees in plans subject to EHB; and,
- Clarify that the Model Guidelines are intended only to determine the robustness of an insurance plan's coverage of drugs and biologicals within the pharmacy benefit and not for drugs or biologicals covered under a plan's medical benefit.

BIO acknowledges that the Model Guidelines are one piece of a multifaceted system of setting standards for and regulating the health insurance plans that are required to provide EHB to a broad population. As such, we have included both CMS and the CMS Center for Consumer Information and Insurance Oversight (CCIIO), specifically, as recipients of this letter to foster and promote coordination between the groups that can directly affect whether this EHB population is able to access medically appropriate innovative therapies. BIO applauds CCIIO's efforts to include stakeholders in this collaboration through the formation of a Pharmacy Stakeholder Outreach group. While the following discussion addresses issues specific to the draft Version 6.0 Model Guidelines Version 6.0 draft, BIO urges CMS and CCIIO, specifically, to review the concerns and recommendations herein—and expressed in previous communications[6]—as they are relevant and applicable to the broader implementation of EHB. BIO encourages CMS and CCIIO also to consider these issues in the development of internal, agency assessment metrics to measure the implementation of EHB generally, and the use of the Model Guidelines specifically, to analyze the potential for policy changes to improve EHB compliance in future plan years.

[5] Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 Fed. Reg. 42,160 (July 5, 2013).

[6] *See:* Biotechnology Industry Organization (BIO). 2012. *BIO's Comments on the Essential Health Benefits Proposed Rule*. Washington, DC: BIO, http://www.bio.org/advocacy/letters/ehb-bio%E2%80%99s-comments-essential-health-benefits-proposed-rule. *See Also:* BIO. 2013. *Medicaid, Children's Health Insurance Programs, and Exchanges*. Washington, DC: BIO, http://www.bio.org/advocacy/letters/medicaid-childrens-health-insurance-programs-and-exchanges. *See Also:* BIO. 2013. *BIO Comments on Affordable Exchanges Guidance: Letter to Issuers on Federally-facilitated and State Partnership Exchanges*. Washington, DC: BIO, http://www.bio.org/advocacy/letters/bio-comments-affordable-exchanges-guidance-letter-issuers-federally-facilitated-and.

I. The Role of the Model Guidelines in Medicare Part D Prescription Drug Plans

A. The USP categories and classes should be more detailed to adequately represent the drugs needed by enrollees in Medicare Part D prescription drug plans.

As an organization dedicated to biomedical innovation, BIO strongly supports the Expert Committee's efforts to conduct a systematic review of all FDA actions related to drugs and biologicals between December 31, 2010 and November 30, 2013 and to update the USP categories and classes for drugs and biologicals to reflect new therapeutic and pharmacologic innovations. In finalizing the Model Guidelines, BIO urges USP to consider that 16 percent of beneficiaries are eligible for Medicare based on disability status not age.[7] Thus, more than 7 million Medicare beneficiaries[8] are younger than 65 years-old and have healthcare needs that may differ significantly from those of the traditional, 65 years-old and older, Medicare population. To ensure that this younger population has access to the therapies most appropriate for them, the categories and classes in the Final Model Guidelines must be sufficiently broad in scope. In addition, BIO urges the Expert Committee to increase the granularity within the categories and classes to ensure that the healthcare needs of the entire Medicare population are met. Increased granularity will help to identify therapies used for distinct purposes or conditions and distinguish among therapies with clinically relevant differences. While BIO has always had concerns about the granularity of categories and classes in the Model Guidelines for the entire Medicare Part D population, these concerns have become more acute since the elimination of the formulary key drug designation, which had provided another level of granularity that helped to ensure robust formularies.

BIO urges the Expert Committee to provide granularity both within categories and among classes. For example, the Immunosuppressant category, as currently designed, does not distinguish between the disparate pharmacological, physiological, and clinical effects of the therapies it includes. To be consistent with the approach the Expert Committee has taken in the past in the Antiretroviral category, BIO recommends USP revise the Immunosuppressant category to create four distinct classes: post-transplant, biological disease modifying antiheumatic drugs (DMARDs), non-biological DMARDs, and other therapies. Similarly, an example of the need for more granular classes is in the use of abuse-deterrent formulations of opioid analgesics. Prescription drug abuse impacts tens of thousands of Americans each year, and that number is only growing. In fact, the Centers for Disease Control and Prevention (CDC) has described prescription drug abuse in the United States as a "deadly epidemic."[9] Fortunately, scientific advances in drug formulations have

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[7] Medicare Payment Advisory Commission (MedPAC). 2013. *A Data Book: Health Care Spending and the Medicare Program*. Chart 2-2, p.34. Washington, DC: MedPAC, Available at: http://www.medpac.gov/documents/Jun13DataBookEntireReport.pdf.

[8] CMS. 2011. *Data Compendium: 2011 Edition*. Populations: Table IV.1: Medicare Enrollees Selected Years: 2009. Available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/2011_Data_Compendium.html.

[9] CDC. 2013. *Policy Impact: Prescription Painkiller Overdoses*. Atlanta, GA: CDC, Available at: http://www.cdc.gov/homeandrecreationalsafety/rxbrief/.

the potential to significantly decrease abuse and accidental exposures while preserving the quality of life for patients who are prescribed these therapies.[10,11] Both the FDA and the Department of Health and Human Services (HHS) have recognized the need to distinguish the positive clinical and therapeutic impact that these abuse-deterrent formulations make.[12,13] Yet currently the Draft Model Guidelines retain only two classes of opioid analgesics, "long-acting" and "short-acting". BIO believes these classes are too broad to reflect the current advances in therapy and insufficient to ensure patient access to needed medications. We urge USP to increase the granularity of the opioid analgesics category by creating a new class for abuse-deterrent formulations that will afford patients, in conjunction with their providers, the flexibility they need to make the best treatment decision for them.

Increased granularity of the Model Guidelines' categories and classes also can improve access to medically appropriate therapies for patients with rare diseases. For the approximately six thousand patients suffering from hereditary angioedema (HAE), FDA-approved therapies are available to help them avoid often unpredictable, debilitating attacks of swelling of the face, extremities, abdomen, and airway, which can be fatal. Unlike thousands of rare diseases for which there are no treatments, the FDA has approved therapies for both acute and prophylactic use. However, the Draft Model Guidelines do not reflect this clinical distinction; instead, all HAE agents are grouped into a single drug class. By doing so, access to all available FDA-approved HAE agents may be limited and patients and providers may not retain the flexibility they need to choose the most medically appropriate HAE therapy for the variability—in location of incident, intensity, frequency, and duration—of an individual's specific symptoms. The Expert Committee should follow its own lead in distinguishing two classes of HAE agents, acute and prophylactic, a distinction it has made previously in the opioid analgesics and antimigraine agents categories.

Additionally, the Draft Model Guidelines should adequately recognize the importance of combination drugs and therapies. For example, Chronic Obstructive Pulmonary Disease (COPD) affects tens of millions of people in the U.S. and is a major leading cause of death.[14] Combination drugs—distinct chemical entities that are combined into a single vehicle for administration—are an important part of COPD treatment regimens, yet they are not included in the Draft Model Guidelines. Combination drugs, like Atripla, used to treat Human Immunodeficiency Virus (HIV), also are excluded. Atripla has garnered HHS' HIV Guidelines'

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[10] FDA. 2013. *Guidance for Industry: Abuse-Deterrent Opioids: Evaluation and Labeling*. White Oak, Maryland: FDA, Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.
[11] Office of Inspector General. 2013. *Prescribers With Questionable Patterns in Medicare Part D*. Washington, DC: HHS, Available at: http://oig.hhs.gov/oei/reports/oei-02-09-00603.asp.
[12] Coplan, P. M., H. Kale, L. Sandstrom, C. Landau, and H. D. Chilcoat. 2013. Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics. *Pharmacoepidemiology and Drug Safety* [epub ahead print].
[13] Severtson, S. G., B. B. Bartelson, J. M. Davis, A. Muñoz, M. F. Schneider, H. Chilcoat, P. M. Coplan, H. Surratt, and R. C. Dart.. 2013. Reduced abuse, therapeutic errors, and diversion following reformulation of extended-released oxycodone in 2010. *Journal of Pain* 14(10):1122-1130.
[14] CDC. 2012. *6.3% of U.S. Adults Report Having COPD*. Atlanta, GA: CDC, http://www.cdc.gov/Features/copdadults/index.html.

highest evidence rating level[15] and robust evidence suggests that a single tablet regimen, such as Atripla, can improve patients' medication adherence and reduce the need for hospitalization.[16] However, despite this evidence, Atripla still is not included as an example drug in the Model Guidelines, which may limit Medicare patients' access to this important therapy. The case is similar for most combination therapies—multiple drugs prescribed for the same condition that are distinct entities and delivered separately. In its Guiding Principles for developing the Draft Model Guidelines, the Expert Committee states that "combination drugs are generally not listed but may be included in the associated list if there is a scientifically valid and clinically meaningful patient care issue."[17] Because of the importance of combination products to patient treatment, BIO urges USP to be transparent about the process for determining the inclusion of combination drugs and therapies in the Model Guidelines. USP also should engage stakeholders through a public comment process to discuss how the determination of scientific validity and clinical meaningfulness is made and whether and how the decision criteria can be improved to best reflect patients' needs.

Increased granularity, leading to increased comprehensiveness, is especially important for categories and classes of therapies outside of the six protected Medicare Part D classes. The Draft Model Guidelines, for example, lists 23 drugs—representing different mechanisms of action—within the Antidiabetic class of the Blood Glucose Regulator category. Since this is not a protected class, Medicare Part D plans only must cover at least two drugs per class, which can limit patient access to many of these therapies. Moreover, this classification structure ignores recent advances in the clinical and therapeutic management of diabetes, and thus decreases the flexibility of patients and their providers to make individualized treatment decisions to mitigate the impact of this highly prevalent, resource- and cost-intensive disease. Therefore, ensuring that the Model Guidelines accurately reflect the treatments needed by the Medicare Part D population is all the more important to guard against discrimination. Even with the protected classes, patient access can be threatened by the imposition of stringent utilization management (UM) techniques, such as specialty tier cost-sharing, prior authorization, and step therapy/fail-first protocols. The potential for UM techniques to delay or prevent patient access to the most appropriate and effective treatments for them exists even when those therapies are covered. We urge CMS to limit the potential for UM techniques, particularly on therapies within the protected classes.

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[15] Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. p.71. Washington, DC: HHS, Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.

[16] Highleymen, L. 2013 (September 23). ICAAC 2013: *Single-tablet Regimen Improves ART Adherence and Reduces Hospitalization*. HIVandHepatits.com. Available at: http://www.hivandhepatitis.com/hiv-aids/hiv-aids-topics/hiv-treatment/611-treatment-adherence-treatment-adherence/4305-icaac-2013-single-tablet-regimen-improves-art-adherence-and-reduces-hospitalization.

[17] USP. 2013. *Guiding Principles USP Medicare Model Guidelines v6.0 Therapeutic Information and Formulary Support Expert Committee*. Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013_usp_mg_guiding_principle.pdf.

B. The USP Model Guidelines must be revised frequently to support timely access to new and innovative medications.

Frequent updates to the Model Guidelines are crucial to both its role in the Medicare Part D program and the EHB standards. Every American covered by these two programs should be guaranteed timely access to new and innovative medications. Although the USP is meant to be revised "from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs,"[18] the infrequency with which the USP updates its categories and classes in practice presents a significant barrier to accessing these medications.

BIO appreciates that USP itself has urged CMS to adopt an annual revision process for the Model Guidelines.[19] BIO wholeheartedly shares USP's concerns that the three-year revision cycle is not consistent with the intentions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and believes that, similarly, the intention of the ACA's EHB provisions was to ensure that the American public has timely access to new therapies. BIO is concerned that, in the absence of timely updates to the USP, patients will lack access to innovative healthcare, such as first-in-class drugs, that are not represented in existing categories or classes. Therefore, we urge USP to update the Model Guidelines at least annually. Similarly, we ask that greater detail be provided around the process for updating and the methodology around the use of the CMS Formulary Reference File Alignment File as a crosswalk tool for the Model Guidelines. Increased transparency into the crosswalk methodology is especially important so that stakeholders can better understand and alert USP and CMS to any inconsistencies.

II. The Role of the Model Guidelines in the Coverage of Prescription Drugs Under EHB

Because the USP Model Guidelines were originally created for use by Medicare Part D prescription drug plans, BIO has serious concerns that the categories and classes in Version 5.0—to be used in 2014 and 2015—may not adequately represent the range of drugs needed by the populations seeking coverage under the EHB. This is because the age, socioeconomic status, medical conditions, and health care needs of individuals in the EHB population are dramatically different than those of the Medicare Part D population. If the Model Guidelines remain part of the EHB minimum coverage standard after 2015, and the Expert Committee simply follows the same Part-D-focused approach to its updates, we are concerned that Version 6.0 also will not take into account the diverse health care needs of the broader population. Therefore, USP should consider undertaking a transparent public comment process to modify the Model Guidelines to ensure that individuals enrolled in health plans subject to EHB have access to the medications that they need.

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[18] Social Security Act § 1860D-4(b)(3)(C)(ii).
[19] USP. 2011. *Final Report, Summary of Methodology and Approach: USP Model Guidelines v5.0*. Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2011-03-11methodologyandapproach.pdf.

A. The USP categories and classes are not sufficiently detailed to adequately represent the drugs needed by enrollees in plans subject to EHB.

BIO is concerned that the Draft Model Guidelines' categories and classes do not sufficiently reflect the entire range of drugs that are needed by and appropriate for the patient population that will be covered by insurance plans subject to the EHB (including those served by health insurance Exchanges or those in the Medicaid expansion population covered through Alternative Benefit Plans). We do recognize that the Draft Model Guidelines make important progress on this point by including a new class for drugs that treat the cause of cystic fibrosis, one of the most common lung diseases in children and young adults, but not prevalent in the Medicare population. However, many issues persist. For example, prescription contraceptives are not included as a specific class in the Draft Model Guidelines, yet the impact of limiting patient access to these drugs is most significant in, and almost exclusive to, the young and middle-aged adult population. Similarly, though diabetic macular edema is the most frequent cause of blindness for the young and middle-aged adult population, there is no category or class for the vascular endothelial growth factor (VEGF) products that have approved indications to treat the most serious causes of blindness. By using the USP categories and classes to define the floor for the EHB drug coverage standard, CMS may inadvertently leave individuals who require therapies that are disproportionately needed by the non-Medicare population, like prescription contraceptives and VEGF products, highly vulnerable.

Not only will more categories and classes of drugs and biologicals be required to meet the needs of an EHB population, but more granularity is necessary to account for distinct therapies with clinically relevant differences, such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). Although listed in the same USP class, extensive clinical evidence exists on the differences between SSRIs and SNRIs in the treatment of depression. Two separate pharmacological classes for these agents would better ensure that patients suffering from depression have access to the treatment most appropriate for them. Particularly when used as the formulary classification system for a benefit without protected classes, such as the EHB, it is critical that the therapeutic classes provide greater granularity.

Additionally, drugs used to treat certain conditions, such as agents when used for weight loss or agents when used to promote fertility, are excluded from Medicare Part D coverage under the Medicare statute,[20] and thus excluded from the USP categories and classes. This is troubling because one out of every eight deaths in America is caused by an illness directly related to obesity, leaving millions of Americans at risk from a preventable and treatable disease.[21] Yet despite the prevalence of this epidemic and the significant medical advances that have been made in the development of obesity drugs, specific categories and classes for obesity therapies are excluded from the Model Guidelines because

[20] Social Security Act § 1860D-2(e); *id.* § 1927(d)(2).
[21] Carmona, R. H. 2003. *The Obesity Crisis in America*. U.S. Surgeon General Testimony Before the Subcommittee on Education Reform Committee on Education and the Workforce United States House of Representatives. Washington, DC. Available at: http://www.surgeongeneral.gov/news/testimony/obesity07162003.html.

of a CMS interpretation of the Medicare Part D statute's limitation on coverage of weight loss drugs. This has the effect of limiting the EHB patient population's access to these therapies because of a Medicare Part D coverage rule that has no relevance in the commercial or Exchange marketplace. Even if certain commercial and Medicaid Alternative Benefit Plans choose to cover these therapies, without inclusion as a category or class for which all EHB plans must offer coverage, many enrollees will be denied access to therapies that can significantly mitigate their risks from this serious health condition.

BIO believes that increasing the comprehensiveness and granularity of the Model Guidelines will improve access to needed therapies for patients who are covered by plans subject to EHB because it will broaden the number of covered drugs under the EHB's "one drug per USP category and class" minimum coverage standard. This is crucial to ensuring that plans do not discourage enrollment of certain patients by excluding needed therapies from plan formularies. BIO reiterates its concern that even with expanded coverage, patient access is threatened by the imposition of stringent utilization management techniques, such as specialty tier cost-sharing, prior authorization, and step therapy/fail-first protocols. Therefore, not only must USP categories and classes, as a part of the EHB minimum coverage standard, accurately reflect the treatments needed by the exchange population, but CMS must require meaningful oversight of plans' prescription drug benefit designs as well.

B. <u>The USP Model Guidelines should be relied upon only to determine the robustness of an insurance plan's coverage of drugs and biologicals within a plan's pharmacy benefit.</u>

BIO urges the Expert Committee, potentially in conjunction with CMS or CCIIO, to clarify that the use of the Model Guidelines for EHB is for purposes of evaluating a plan's pharmacy benefit only. Because the Model Guidelines were developed for the Medicare Part D prescription drug benefit, the list of categories and classes represents therapies covered under a pharmacy benefit. The Model Guidelines are not designed to capture medical benefit drugs—such as biologicals used to treat cancer or autoimmune conditions—nor can the Model Guidelines adequately do so. The USP categories and classes do not reflect clinically meaningful differences between the mechanisms of action or methods of administration for drugs that are typically administered by a physician. Similarly, the Guidelines are not conducive to physician/patient decision-making that must take into account multiple clinical factors—including the patient's diagnosis and co-morbidities and the need to monitor the patient after administration of the drug—when determining how to utilize these therapies for complex and life-threatening conditions. Therefore, the Model Guidelines should only be used to evaluate the pharmacy benefits of plans subject to EHB.

USP, in conjunction with CMS and CCIIO, should further clarify how the minimum formulary drug counts, required by EHB, will be applied to Qualified Health Plans (QHPs).

The drug counts per class[22] presently utilize the Version 5.0 Model Guidelines—but could utilize Version 6.0 in the future—to count the number of therapies reimbursed only through the pharmacy benefit of state benchmark plans. In order to meet the minimum drug coverage standard under the EHB, QHPs must cover at least the greater of the same number of drugs per class as the state benchmark plan or at least one drug per USP category and class. Thus, the categories and classes developed for an EHB population must reflect the drugs that are covered under a pharmacy benefit in the commercial market. This is crucial to ensuring that the drugs counted by the QHPs and the state benchmark plans represent comparable pharmacy benefit structures (e.g., to prevent against some QHPs counting drugs that are covered by a medical benefit in other QHPs or in the state benchmark plan). Such an apples-to-apples comparison is necessary not only for robust oversight of QHPs' compliance with the EHB antidiscrimination requirements, but also to better inform patients enrolling in health insurance plans through the Exchanges and in Medicaid Alternative Benefit Plans under the Medicaid expansion.

In sum, the structure and use of the Model Guidelines will have an immediate and dramatic impact on patient access to drugs and biologicals covered under a pharmacy benefit. A formulary classification system that is sufficiently granular and comprehensive, along with transparency regarding how it will be used, will help to ensure that the EHB nondiscrimination requirements are met. This is particularly critical in the absence of adequate guidance, oversight, or enforcement frameworks that would facilitate compliance with nondiscrimination requirements.

III. Conclusion

We appreciate your attention to these concerns as you finalize the Version 6.0 Model Guidelines Version 6.0. We look forward to working with the Expert Committee to ensure that Version 6.0 reflects all of the innovative therapies needed by the Medicare Part D population, including those that have emerged since December 31, 2010, as well as takes into consideration its role in ensuring that individuals enrolled in health plans subject to the EHB have access to the full range of drugs and biologicals they need. Please feel free to contact me if you have any questions or if we can be of further assistance.

Sincerely,

/s/

Laurel L. Todd
Managing Director,
Reimbursement and Health Policy

[22] The methodology for which is stated in: CMS. 2013. *Letter to Issues on Federally Facilitated and State Partnership Exchanges*, Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.