Biotechnology Industry Organization

March 15, 2013

Ms. Marilyn Tavenner, B.S.N., M.H.A.
Acting Administrator
Centers for Medicare & Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Affordable Exchanges Guidance: Letter to Issuers on Federally-facilitated and State Partnership Exchanges

Dear Ms. Tavenner:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the draft Letter related to the Patient Protection and Affordable Care Act's (PPACA) health insurance Exchanges that the Centers for Medicare & Medicaid Services (CMS) issued on March 1, 2013, entitled "Letter to Issuers on Federally-facilitated and State Partnership Exchanges" (the "Letter").[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 case. 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 health care expenditures due to fewer physician office visits, hospitalizations and surgical interventions.

Thanks to PPACA, many uninsured individuals will be able to purchase more affordable health insurance through the Exchanges, and thus for the first time, will have access to the treatments that they need. BIO firmly believes that to fulfill the goals of PPACA, the standards for the qualified health plans (QHPs) that are made available to these individuals through the Exchanges must ensure meaningful coverage for medically necessary care, including emerging innovative technologies, and must guard against the possibility that any health plan designs its covered benefits or markets those benefits in a manner that discriminates against individuals with serious health conditions and the most complex treatment needs.

BIO appreciates CMS' efforts to provide additional operational and technical details to issuers of QHPs regarding the standards and process that CMS will apply to determine whether plans comply with the requirements established in PPACA and to certify those plans

[1] Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, Letter to Issuers on Federally-facilitated and State Partnership Exchanges (Mar. 1, 2013). Available at: http://cciio.cms.gov/resources/files/issuer-letter-3-1-2013.pdf (hereinafter "Letter to Issuers").

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as QHPs on the Federally-facilitated exchange (FFE) and on those State Partnership Exchanges for which CMS will perform the plan management functions. We commend CMS for its ongoing commitment to prohibiting plans from designing covered benefits or implementing cost-sharing for those benefits in a manner that discriminates against the most vulnerable individuals. However, we still have concerns that the standards and review procedures described in the draft Letter leave enrollees vulnerable in critical ways, and therefore we urge CMS to consider the following comments, discussed in more detail below.

- CMS should provide more detailed guidance to plan issuers regarding the number and types of providers that must be included in plan networks to ensure that enrollees have adequate access to a variety of specialists and providers of preventive services.
- CMS should strengthen its review process for certifying QHPs, and in particular, expand its review of plans' prescription drug benefits, by providing a specific time frame in which CMS will complete these reviews, analyzing other utilization management techniques in addition to cost-sharing, reviewing plans' coverage of prescription drugs that are included as part of the medical benefit as well as the pharmacy benefit, and scrutinizing plans' use of specialty tiers.
- CMS should explain more fully its methodology for determining whether two QHPs offered by the same issuer are "meaningfully different," and thus present a valuable choice for consumers.
- CMS should clarify its approach to counting "chemically distinct" prescription drugs for purposes of determining whether a plan's formulary complies with the essential health benefits (EHB) standards and should specifically state that the approach does not apply to biologics.
- CMS should emphasize that it expects issuers of any plan that must offer EHB to have exceptions processes in place that at a *minimum*, include the procedures specified in the Letter.

I. Broad Provider Networks Are Critical to Ensure Access to Care (Ch. 1 § 1)

As we have repeatedly emphasized in our comments to the guidance and regulations implementing PPACA's EHB provisions, to ensure that access to affordable health insurance through the Exchanges actually provides meaningful access to care, it is critical that plans contract with a broad network of health care providers that includes a wide range of both health care professionals and health care settings that are conveniently located throughout the plans' service areas. BIO believes that a comprehensive network of providers must include not only a variety of specialists, which will be crucial to preserve access for enrollees with complex or rare conditions who may need multiple types of specialized care, but also, a broad range of immunization providers and other providers of preventive services. Reducing barriers to access for immunizations by making it possible for all individuals to obtain such services within their communities at a clinic or other site of their choice is a key component to realizing both the health benefits to patients and the cost-savings to the health care system as a whole for these types of preventive services.

A. Access to Immunizations

One of the hallmark tenets of PPACA is the requirement that health plans cover all vaccines recommended by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) for all ages without cost sharing when administered by an in-network provider. The intent of this provision was to increase access to immunizations for covered individuals. To fulfill this intent, BIO recommends that the guidance clarify that a network of providers for immunization services must include those health care providers and locations allowed by state law to provide such services and should not be limited to physician office settings. The services should be delivered in these complementary settings under the same first dollar coverage provisions as applicable in physician offices.

The inclusion of complementary immunizers in provider networks will improve vaccination rates, thereby reducing medical care costs, morbidity, and mortality. Adults have demonstrated a preference to be vaccinated outside their medical home, where and when it is convenient for them, and the system has evolved to support that access. More than 185,000 pharmacists are currently trained to administer most vaccines in the U.S.,[2] and according to data from the CDC, during the 2010-2011 influenza season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[3] If a health plan's provider network is inadequate and the plan denies first dollar coverage of pharmacy-administered vaccines, an immunization opportunity may be lost. Or, alternatively, the individual may still receive a pharmacy-administered vaccine but pay out-of-pocket entirely for it, with none of this cost counting toward meeting the deductible or annual out-of-pocket limit.

In addition to supporting the inclusion of retail pharmacies in provider networks, BIO and many other public health stakeholders have supported efforts underway at the CDC to include other complementary immunization sites, such as public health and school-based clinics, in provider networks. The most significant CDC initiative, known as the Billing Project, works with state health departments, public health clinics and health insurers to include public health clinics in provider networks. To date, 35 states or large cities are currently planning or implementing the Billing Project, which will allow them to directly bill insurers for immunization services provided to insured persons of all ages.

CMS should use the final Letter as an opportunity to clarify that provider networks for immunization services should include those health care providers and locations allowed by state law to provide such services. The final Letter should include the three most common types of complementary community immunizers—public health clinics, school-based clinics, and pharmacies—in the list of "Other ECP Providers" in Table 1.1. Furthermore, "immunizations" should be included, along with the current mention of "mental health and substance use disorder services," in the first sentence of the network

[2] *See* Rothholz M. Opportunities for Collaboration to Advance Progress towards 'the Immunization Neighborhood': Recognition and Compensation of Pharmacists. Presentation. American Pharmacists Association. August 30, 2012.
[3] CDC. Place of influenza vaccination among adults – United States, 2010-11 influenza season. *MMWR Morb Mortal Wkly Rep*. 2011;60(23):781-785.

adequacy section (Section 1(i)) that defines the requirement for QHP issuers "to maintain a network that is sufficient in number and types of providers."[4] Finally, BIO urges CMS to clarify in the final Letter that these services should be administered without cost-sharing or point-of-care, out-of-pocket charges.

B. Access for Patients with Rare Diseases

Broad provider networks are essential to reducing non-financial barriers to care and to ensuring that medically necessary care is affordable for enrollees. In the final rule implementing PPACA's EHB requirements ("the EHB Final Rule"), CMS finalized its policy that out-of-network costs will not count towards the annual cost-sharing limits established by PPACA or the cost-sharing reductions that must be made available to certain low-income individuals.[5] Given this CMS policy decision, it will be particularly critical to ensure that individuals with rare or complex diseases have meaningful access to a wide range of in-network providers for their care. These patients are most likely to need the care of a particular specialist; they also are likely to incur significant out-of-pocket costs over the course of the year and to reach the statutory limit on such expenditures. In the final Letter CMS should delineate a provider exceptions process—much like the model it proposes in Appendix C of this Letter for medicines—to allow patients with rare diseases to request and have access to out-of-network providers as if they were in-network. If the exceptions process results in an approval, it should cover and apply in-network costs incurred from the date of the exception request rather than the date of the approval. Establishing minimum standards that all QHPs must have in place such provider exception processes will help to ensure that these patients have access to the appropriate specialists.

C. Essential Community Providers

The Establishment of Exchanges and Qualified Health Plans Final Rule requires that each QHP provider network include a sufficient number of essential community providers (ECPs) who serve low-income and medically-underserved populations. This Letter defines the approach CMS will use to evaluate whether QHPs have met this ECP inclusion requirement: both the Safe Harbor and Minimum Expectation standard require a QHP to demonstrate that a certain percentage (20 and 10, respectively) of available ECPs in a plan's service area participate in the issuer's provider network(s). The Safe Harbor standard also requires the issuer to offer contracts to at least one ECP in each ECP category—Federally Qualified Health Center (FQHC), Ryan White Provider, Family Planning Provider, Indian Provider, Hospital, and Other ECP Provider—in each county (assuming availability) in the service area during the coverage year. However, to ensure patient access and choice while maintaining issuer flexibility, BIO urges CMS to include in all of its approaches a review of each issuer's balance of contracts between the different ECP types. This will help to ensure a variety of sites of care are available to patients and that they can access care at facilities best suited to address their healthcare needs.

[4] CCIIO Letter to Issuers on Federally-facilitated and State Partnership Exchanges, at 6.
[5] 78 Fed. Reg. 12,834, 12,848 (Feb. 25, 2013); *see also* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 15,410, 15,480 (Mar. 11, 2013).

D. Need for Improved Oversight

We applaud CMS' clear recognition of the need for QHPs to have provider networks that are "sufficient in number and types of providers ... to assure that all services will be accessible without unreasonable delay,"[6] and we appreciate that in this draft Letter, CMS reiterates that the standards set out the in federal regulations are the *minimum* requirements for QHPs. However, BIO also believes that clear guidelines and meaningful oversight though the QHP certification process will be crucial to ensure that QHPs do in fact have sufficiently robust provider networks. While BIO understands that it may make sense for CMS to rely on states' analyses of plans' network adequacy, as many states' insurance regulators already engage in similar network adequacy reviews and may have substantial expertise and resources to do so, BIO urges CMS to provide more detailed guidance regarding the number and types of providers that must be included in a plan's network in order to satisfy the federal requirements for QHPs. BIO believes that more specific standards will help ensure that all QHPs have sufficiently broad networks for both specialists and providers of immunizations and other preventive services. That, in turn, will protect QHP enrollees' access to needed care with affordable cost-sharing.

II. Review of Plans' Benefit Designs Must Be Even More Thorough (Ch. 2 § 4)

BIO supports the Letter's reiteration of the broad prohibitions against discrimination in plan benefit design that were codified in the final rule establishing standards for QHPs (the "Exchange Final Rule") and the EHB Final Rule.[7] We also endorse CMS' proposed approach to review plans for QHP certification by performing an outlier analysis of QHPs with comparable cost-sharing structures and focusing those outlier analyses on specific benefits, including the prescription drug benefit. We believe that a close comparison of QHPs' cost-sharing structures is a critical safeguard against benefit designs that use cost-sharing to undermine coverage of certain benefits in order to discourage enrollment by individuals with significant health care needs. However, we remain concerned that the review framework described in the Letter may not be sufficiently robust to prevent discriminatory benefit designs from reaching the marketplace. To better enforce the regulatory prohibitions against discrimination, in particular with respect to plans' design of their prescription drug benefits, we recommend that CMS strengthen its review process in several ways.

First, CMS should specify the timeframe in which it will conduct and complete its review analyses to ensure that potentially discriminatory benefit designs are identified quickly and that issuers have time to make any required adjustments before October 1, 2013. We believe that prompt and robust review of issuers' planned benefit designs for QHPs is critical to ensure that all individuals, including those with significant health care needs, are able to choose among a number of different plans for 2014 through the Exchange in their states.

[6] 45 C.F.R. § 156.230(a)(2).
[7] 45 C.F.R. § 156.225; *id.* § 156.125.

Second, in addition to performing an outlier analysis of QHP cost-sharing structures for the prescription drug benefit, CMS should review plans' other utilization management techniques as well. As we explained in our comments to the EHB guidance and regulations, certain prescription drug utilization management techniques discriminate against individuals with complex or chronic health conditions, who may need highly targeted drug therapies or multiple therapies at once. Not only do these types of utilization management techniques decrease medication adherence and thereby have a detrimental impact on patients' health outcomes, but also these techniques may even increase overall costs by leading to increased hospitalizations, physicians' office visits, and surgical interventions for patients. BIO remains concerned about the lack of strict guidelines for health plans' design and application of utilization management techniques. We strongly urge CMS to include in its final Letter a review of plans' other utilization management techniques, even including those techniques that are already commonly used by plans in the private insurance market, to ensure they are not discriminatory and do not prevent patient access to necessary medications.

Third, CMS should expand its review of QHPs' cost-sharing structures and utilization management techniques for the prescription drug benefit to specifically examine the cost-sharing and other utilization management techniques applied to prescription drugs offered as part of the medical, as well as the pharmacy, benefit. This is especially important because the EHB Final Rule retained the United States Pharmacopeia (USP) classification system for determining whether QHP formularies include the minimum number of drugs to satisfy the EHB standard.[8] As BIO has previously stated, the USP categories and classes were designed for Medicare Part D drugs, and thus are not sufficient to ensure that plans offer meaningful, robust coverage of medical benefit drugs. Medical benefit drugs, such as physician-administered drugs, are increasingly distinct and personalized and are often used to treat the most vulnerable patients in need of complex care. Thus, BIO urges CMS to meaningfully compare and evaluate whether a particular plan's coverage of medical benefit drugs is substantially equal to the EHB-benchmark plan, and more specifically, whether any of the cost-sharing or other utilization management techniques applied to such drugs have the effect of discriminating against individuals with more significant health care needs, in its review of plan benefit designs.

Fourth, BIO reiterates its particular concerns about the discriminatory impact of excessive cost-sharing imposed through specialty tiers on the most vulnerable patients with the most complex treatment needs. Specifically in the case of cancer patient populations, higher cost-sharing has been demonstrated to reduce adherence to necessary medical treatment, leading to poor patient health outcomes.[9] While BIO recognizes that the EHB Final Rule does not prohibit plans from using specialty tiers in their prescription drug benefits, we urge CMS to specifically consider the impact of plans' use of specialty tier cost-sharing in CMS' review of QHP cost-sharing structures to prevent plans from using such specialty tiers to discriminate against patients with chronic, complex, or life-threatening diseases.

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[8] 78 Fed. Reg. at 12,845–46 (codified at 45 C.F.R. § 156.122).
[9] Eaddy, M, et. al., "How Patient Cost-Sharing Trends Affect Adherence and Outcomes", Literature Review, P&T, 37(1): 45-55, (2012). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/ (Confirmed March 13, 2013).

BIO also recommends that CMS provide additional guidance to QHP issuers about its proposed "meaningful difference" review of potential QHPs. The Letter states that in order to support informed consumer choice, CMS will analyze whether there is a "meaningful difference" between QHPs offered by the same issuer and with the same plan characteristics. Specifically, CMS proposes to consider the extent to which each potential QHP is "substantially different" from other QHPs of its plan type (e.g., preferred provider organization (PPO), health maintenance organization (HMO)) "with respect to key characteristics such as metal level (that is, bronze, silver, gold or platinum), service areas covered, provider networks, premiums, cost-sharing, benefits offered, or formulary structure."[10] While BIO appreciates that the Letter provides examples of QHPs that CMS would flag for follow-up because they do not appear to be meaningfully different, we recommend that CMS thoroughly describe the methodology it will use to perform these analyses in order to promote transparency for both plan issuers and consumers. Furthermore, BIO urges CMS to ensure that the methodology it uses to determine whether two QHPs are "meaningfully different" does not inadvertently create incentives for plan issuers to design differences in covered benefits or in cost-sharing structures that undermine coverage of the EHB or discriminate against individuals with the most significant health care needs.

III. Relying on "Chemically Distinct" Standard Does Not Ensure Adequate Coverage of Biologics (Appendix C)

The Letter reiterates the approach set out in the EHB final rule to count the number of "chemically distinct" drugs covered in each USP category or class to compare plans' prescription drug coverage to the coverage offered under the applicable EHB-benchmark plan.[11] CMS confirms that to calculate the number of drugs covered under each state's EHB-benchmark plan, it applied a definition of "chemically distinct" drugs that did not include different dosages of the same drug, different concentrations of the same active ingredient, brands and their generic equivalents, extended release and non-extended release formulations, and different delivery methods of the same drug.[12]

However, BIO remains concerned that the term "chemically distinct" cannot be applied to biologics because of the fundamentally different scientific principles on which the manufacture of biologics is based, which are wholly distinct from the principles and processes used to develop small molecule drugs. BIO strongly believes that the concept of "chemically distinct" products applies only to those small molecule drugs. CMS should not use this antiquated standard to limit the number of biologics that plans must cover to offer EHB. Instead, BIO urges CMS to count QHPs' inclusion of biologics through a mechanism that accurately captures the important clinical differences between different biologics.

We are especially concerned about the inadequacy of the concept of "chemically distinct" drugs to describe biologics because CMS proposes to allow states to use CMS'

[10] Letter to Issuers, at 15–16.
[11] 78 Fed. Reg. at 12,845.
[12] Letter to Issuers, at 53–54.

automated "drug count service" to review plan formularies.[13] We urge CMS to provide a much more complete description of how this drug counting service will work, including in particular how it applies to combination products, to ensure that there is adequate transparency of plan formularies to allow consumers to make a meaningful choice between plans. We further urge CMS to confirm that the drug counting service does not apply to medical benefit drugs, like physician-administered drugs and biologics. The methodology CMS used to calculate the number of drugs covered by each state's EHB benchmark plan relied on matching USP categories and classes to drugs covered on plans' formularies.[14] This method would not have produced a comprehensive list of drugs offered through the medical benefit, which do not necessarily appear on plans' formularies. Therefore, it is inappropriate to count medical benefit drugs when determining whether a QHP's formulary meets the minimum number of drugs required standard established in the EHB Final Rule.[15] CMS should clarify in the final Letter that the Exchanges will not count medical benefit drugs when evaluating QHPs' formularies against states' benchmark plans' formularies, and thus, avoid creating an asymmetric comparison that could limit patient access to needed therapies.

BIO also suggests that CMS expand its guidance regarding the treatment of combination products. We note that one of the examples of "chemically distinct" drugs in Table 1.1 of Appendix C includes a single drug product and a combination product including the same drug (Epivir (lamivudine) oral tablet and Epzicom (abacavir and lamivudine) oral tablet are counted as two drugs). Since the example only provides clarity on how Exchanges should count this specific combination product, we respectfully request that CMS provide more detailed information of how the concept of "chemically distinct" should be applied to count combination products in the final Letter.

In sum, a more detailed understanding of CMS' approach to counting "chemically distinct" drugs will be important to ensure consistency and transparency in plan formularies in all states, whether a state opts to use CMS' drug counting service or to conduct its own formulary reviews. We recommend that CMS provide a much more detailed explanation of its approach in the final Letter.

IV. Exceptions Process Is Critical For Access to Innovative Technologies (Appendix C)

BIO strongly supports CMS' efforts to ensure patients are able to access, not just request, clinically appropriate drugs that are not covered by their health plan. We appreciate that CMS revised the regulatory text in the EHB final rule to make clear CMS' intent,[16] and we similarly appreciate that this Letter underscores that commitment by providing QHP issuers with additional information about the prescription drug exceptions process that CMS expects to be in place.[17] We firmly believe that a robust exceptions

[13] *Id.* at 54.
[14] CMS. Essential Health Benefits (EHB) Rx Crosswalk Methodology. Available at: http://cciio.cms.gov/resources/EHBBenchmark/ehb-rx-crosswalk.pdf.
[15] 78 Fed. Reg. at 12,867.
[16] 78 Fed. Reg. at 12,846 (codified at 42 C.F.R. § 156.122(c)).
[17] Letter to Issuers, at 54–55.

process, that requires timely decision-making by the plan and includes the right to independent review, is vital to ensure that enrollees have access to innovative treatments and technologies that become available during the course of a plan or policy year. The protection offered by the exceptions process will be even more important because CMS finalized its proposal that states' selected EHB-benchmark plans will apply for both the 2014 and 2015 plan years, and in the EHB Final Rule, CMS declined to establish specific requirements or processes for updating the EHB.[18] Thus, the only way that an enrollee may be able to gain access to new, life-saving treatments that become available partway through the plan year may be through the exceptions processes that his or her plan has in place.

We therefore recommend that CMS revise the Letter to clearly state that the two-step exceptions process described in Appendix C is the *minimum* procedure a plan should have in place to ensure access to clinically appropriate prescription drugs and to urge the Exchanges, states, or the Office of Personnel Management (OPM) to ensure that any plan offering EHB, especially plans that propose to rely on their current exceptions processes, meet *at least* the requirements specified in the Letter.

BIO also strongly supports CMS' instruction that plans should allow an enrollee to have the medication in dispute during the entire exceptions review process and that if an exception is granted, to allow an enrollee to have access to that medication in subsequent plan or policy years should enrollment continue without interruption. Indeed, we believe that such access should be required—not simply encouraged—of all issuers of plans that must offer EHB, as these two protections are critical to protect enrollees' access to life-saving medical treatments and to guard against any disruptions in treatment. We recommend that CMS specifically encourage the Exchanges, states or OPM to ensure that any plan offering EHB also meets these requirements.

V. Conclusion

BIO appreciates the opportunity to comment on this draft Letter. We look forward to continuing to work with CMS and interested partners in designing and implementing QHPs and the EHB package to ensure that plans offer meaningful coverage of the EHB and that plans do not discriminate against the most vulnerable individuals with serious, complex medical conditions and significant health care needs. 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,

Laurel L. Todd
Managing Director
Reimbursement and Health Policy

[18] 78 Fed. Reg. at 12,842.