Biotechnology Industry Organization

February 25, 2013

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

Re: Draft 2015 Letter to Issuers on Federally-facilitated Marketplaces

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 (ACA) health insurance Marketplaces that the Centers for Medicare & Medicaid Services (CMS) issued on February 4, 2014, entitled "Draft 2015 Letter to Issuers on Federally-facilitated Marketplaces" (the "Draft Letter").[1]

BIO represents more than 1,000 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 health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

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

BIO appreciates CMS's efforts to provide additional operational and technical details to issuers of QHPs regarding the standards and processes that CMS will apply to determine

[1] Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces (FFM) (Feb. 4, 2014). Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf (hereinafter "Draft Letter to Issuers").

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whether plans comply with the requirements established by the ACA and to certify those plans as QHPs offered on the Federally-facilitated Marketplaces (FFM). 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. We also recognize the important steps CMS is taking to improve standards and processes to protect these enrollees. Nonetheless, 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, including complementary immunizers.
- CMS should strengthen its review process for certifying QHPs and, in particular, expand its review of plans' prescription drug benefits by: providing a specific timeframe in which CMS will complete these reviews; analyzing other utilization-management techniques in addition to cost-sharing; and scrutinizing plans' use of specialty tiers.
- While CMS must ensure the robust inclusion of medical benefit drugs by QHPs, the Essential Health Benefits (EHB) minimum inclusion standard for prescription drug formularies can be appropriately applied only to reviews of pharmacy benefits, and is ill-suited to assess the comprehensiveness of a plan's medical benefit coverage of prescription drugs.
- CMS should move forward with its proposal to require transition fills to minimize interruptions in patients' access to care.
- CMS should ensure that patients have access to meaningful information about the differences between issuers' QHP offerings to be able to choose a plan that meets their needs and is affordable.
- CMS should consider requiring issuers to allow coverage of prescription drugs before full payment of the plan's deductible.
- CMS must institute routine, timely, and consistent monitoring of QHP compliance with antidiscrimination requirements to ensure patients have timely access to complex or high-cost care when needed.
- CMS should emphasize that it expects issuers of any plan that must offer EHB—including QHPs offered through the FFM—to have exceptions and appeals processes in place that meet a minimum standard to ensure that patients can obtain access to needed therapies.

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 the ACA's EHB provisions: to ensure that access to affordable health insurance through the Marketplaces actually provides meaningful access to care, it is critical that plans contract with a broad network of healthcare providers that includes a wide range of both healthcare professionals and healthcare 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 healthcare system as a whole from these types of preventive services.

We believe that CMS has taken steps in the right direction to ensure that QHPs offered through the FFM maintain robust provider networks. For instance, we would like to express our strong support for CMS's proposal to abandon its reliance on issuer accreditation status and state review processes as a proxy for plan compliance with the ACA's network adequacy requirements. Instead, we believe that it is important for CMS to establish new standards and review processes against which all QHPs are judged to make sure that patients—especially those in need of complex care, such as oncology patients and patients with rare diseases—are able to access the care and services they need no matter where they live. Such robust standards will better ensure that QHPs fulfill the requirement to "maintain a network that is sufficient in number and types of providers . . . to assure that all services will be accessible without unreasonable delay."[2] There remains work to be done, however, to ensure that patients have access to immunizations and medical specialists.

A. Access to Immunizations

One of the hallmark tenets of the ACA 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, referred to as the "immunization coverage standard." The intent of this provision was to increase access to immunizations for covered individuals. However, we continue to have concerns that the standards and review procedures described in the Draft Letter may leave enrollees without access to critical immunization services, contrary to the intent of the ACA. Thus, to fulfill the ACA's original 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.

Notably, immunization services have a unique set of providers. In addition to traditional immunizers, such as pediatricians and other primary care providers, "complementary immunizers," like pharmacies, public health department clinics, and school-based clinicians provide many vaccines. The inclusion of these complementary immunizers in provider networks will improve vaccination rates, thereby reducing medical care costs, morbidity, and mortality.

[2] 45 C.F.R. § 156.230.

These complementary immunizers are particularly important for the hard-to-reach adolescent and adult populations. Indeed, adults have demonstrated a preference to be vaccinated outside of their medical home, where and when it is convenient for them, and the system has evolved to support that access. For instance, more than 230,000 pharmacists are currently trained to administer vaccines in the United States,[3] and according to data from the CDC, during the 2011-2012 influenza season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[4]

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 department and school-based clinics, in provider networks. The most significant CDC initiative, known as the Third Party Billing Project, works with state health departments, public health clinics and health insurers to include public health department clinics in provider networks.[5] 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. Data from the Billing Project underscore the sheer volume of immunizations furnished by these complementary immunizers: in 2010 local health units billed private insurance for $1,964,267 in immunization-related costs in North Dakota alone. [6]

To the extent a health plan's provider network fails to include these complementary immunizers and the plan thus denies first-dollar coverage for vaccines administered in these settings, 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.

CMS should therefore use the final Letter to Issuers 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, including complementary immunizers. Where complementary immunizers are not included in a QHP's network, we further urge CMS to issue general guidance requiring QHPs to cover all ACIP-recommended immunizations without cost-sharing, regardless of whether they are furnished by in-network providers.

B. Essential Community Providers

A further opportunity for expanding access to immunization services lies in the requirement that each QHP provider network include a sufficient number of essential

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[3] Rothholz M. Opportunities for Collaboration to Advance Progress towards "The Immunization Neighborhood:" Recognition and Compensation of Pharmacists. Presentation. American Pharmacists Association. August 30, 2012.

[4] CDC, March Flu Vaccination Coverage United States, 2011-12 Influenza Season (March 2012), available at: http://www.cdc.gov/flu/pdf/fluvaxview/national-flu-survey-mar2012.pdf

[5] CDC, Billing Project Success Stories, http://www.cdc.gov/vaccines/programs/billables-project/success-stories.html (last accessed Feb. 6, 2014).

[6] Sander M. Lessons Learned: Billing Insurance at Local Health Units in North Dakota (PowerPoint). March 30, 2011. North Dakota Department of Health. Available at: https://cdc.confex.com/cdc/nic2011/webprogram/Paper25418.html.

community providers (ECPs) who serve low-income and medically-underserved populations.[7] BIO appreciates the steps CMS has taken in this Draft Letter to strengthen the ECP standard for 2015, which seeks to improve access to ECPs for some of the country's most vulnerable patients. For instance, CMS has proposed to eliminate the "minimum expectation" and will instead now require all QHPs to include at least 30 percent of the ECPs in their service area (an increase from 20 percent from last year). Moreover, all QHPs will now be required to include at least one ECP from each provider type, subject to certain exceptions. However, we believe that, in order to ensure meaningful network adequacy standards, CMS should add certain additional provider types that predominately serve low-income and medically-underserved populations to its list of "Other ECPs." Specifically, we urge CMS to include complementary immunizers in that list, such that QHPs will be required to include pharmacies, public health department clinics, school-based clinics, and other community sites in their provider networks. We believe that this change will greatly expand access to immunizations for hard-to-reach populations, including adults and adolescents. BIO also urges CMS to review each QHP issuer's balance of contracts between the different ECP types to help 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.

BIO remains concerned about the ambiguity that persists in the Draft Letter around how issuers can meet the proposed ECP minimum inclusion standard (i.e., at least 30 percent of the ECPs in a service area). Specifically, we are concerned that issuers will inappropriately count "child sites" of Disproportionate Share Hospitals (DSH), an identified ECP, to fulfill this requirement to the detriment of the overarching goal of creating broad provider networks to improve patients' accessibility to care. CMS should instead specify that the numerator and denominator of ECPs are those with unique Medicare Provider Numbers (MPN).

As CCIIO is aware, hospitals meeting certain criteria related to the number of Medicare and Medicaid patients who are admitted as inpatients are granted DSH status, which allows the hospital to qualify for certain federal programs, including the 340B Drug Discount Program. The DSH "parent" facility may register certain off-site clinics, such as outpatient oncology clinics, as "child sites," since these sites are an integral part of the broader institution even though they are located off-site. These child sites bill under the same MPN as the parent hospital. BIO believes that counting each child site separately toward the proposed ECP minimum inclusion threshold percentage would undermine the intent of ECP requirements in QHP networks. This is because it would practically diminish the number of ECPs that QHPs are required to include, in particular replacing the broad variety of safety-net providers with mostly sites from the same in-network hospital a QHP may have already decided to include. It also countermands the nature of a child site as simply part of the broader institution, not a separate entity. Moreover, allowing child sites to count toward the proposed 30 percent minimum inclusion standard may disincentivize the inclusion of other providers—such as for-profit community practices, federally-qualified health centers (FQHCs), and FQHC-look-alikes—in QHP networks. This would decrease overall accessibility to care and potentially increase overall costs, since DSH entities and their outpatient departments are more costly to the Medicare program and patients than

[7] See ACA § 1311(c)(1)(C); 45 C.F.R. § 156.235.

for-profit community practices[8] and FQHCs. Therefore, to ensure sufficient QHP network adequacy while maintaining incentives to provide efficient care, CMS should clarify in the Final Letter that the 30 percent ECP minimum inclusion standard be calculated on the basis of distinct MPNs.

C. 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. Given that out-of-network costs do not count towards the annual cost-sharing limits established by ACA or the cost-sharing reductions that must be made available to certain low-income individuals,[9] it is 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. BIO is encouraged that, in the Draft Letter, CMS begins to address the issue of access to specialists, for example, though considering how to create "a search engine function for consumers to search for particular providers and provider types."[10] Such a tool would give patients, especially those with rare diseases, more information about the breadth of a QHP's provider network when choosing a plan to best fits their healthcare needs. Thus, we urge CMS to expand upon the potential process and standards for such a tool in future rulemaking.

However, additional measures are needed to ensure that these patients have access to the care they need. In the final Letter to Issuers, CMS should take the Office of Personnel Management's (OPM) lead and require QHPs to "have in place a process to provide timely exceptions to ensure that consumers who need care from out-of-network providers (because of rare or complex medical conditions or lack of in-network providers in a geographic area) can receive it with reasonable cost-sharing, applying enrollee costs to the in-network out-of-pocket maximum, and protection from balance billing."[11] Moreover, to the extent this exceptions process results in an approval, the plan should be required to 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 require all QHPs to have in place such provider exception processes will help to ensure that these patients have access to the appropriate specialists.

D. Need for Improved Oversight

BIO continues to believe that clear guidelines and meaningful oversight through the QHP certification process and beyond will be crucial to ensure that QHPs do in fact have

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[8] Milliman, inc. 2011 (October 19). *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy*. Commissioned by McKesson Specialty Health. Available at: http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf.

[9] 78 Fed. Reg. 12,834, 12,848 (Feb. 25, 2013); HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 15,410, 15,480 (Mar. 11, 2013).

[10] Draft Letter at 20.

[11] Office of Personnel Management, Multi-State Program Issuer Letter No. 2014-002 (Feb. 4, 2014), available at: http://www.opm.gov/media/4517978/2014-002_dms_.pdf.

sufficiently robust provider networks. To achieve this, 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 network adequacy 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, as promised by the ACA.

II. Review of Plans' Benefit Designs Must Be Even More Thorough (Ch. 3 § 1)

BIO understands that the Essential Health Benefits (EHB) non-discrimination requirements are a protection that applies both within and outside of the Marketplaces. However, since many issuers offer plans both within and outside of the Marketplaces, CMS' role in setting non-discrimination standards for purposes of the FFM may be useful as a minimum benchmark for all issuers. In this regard, we are concerned that CMS's application of its non-discrimination requirements is currently insufficient. Specifically, we are concerned that CMS's general approach—to require an attestation of compliance by issuers and then assess compliance by retrospective review—will not be sufficiently timely to ensure that certain patient groups, especially the most vulnerable (e.g., those depending on high-cost treatments, those with complex chronic diseases), are able to obtain access to appropriate providers and treatments. Moreover, while we continue to endorse CMS's use of an outlier analysis of specific benefits, including the prescription drug benefit and specialists visits, to identify potential noncompliance, we remain concerned that the review framework described in the Draft Letter may not be sufficiently robust to prevent discriminatory benefit designs from affecting patient care. 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 three key ways.

First, we continue to urge CMS to 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 the start of the next plan year. 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 healthcare needs, are able to choose among a number of different plans for 2015 through the FFM.

Second, BIO continues to be concerned that 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, these techniques may even increase overall costs by leading to increased hospitalizations, physicians' office visits, and surgical interventions for patients. We therefore applaud CMS's addition of the excessive use of prior authorization and/or step therapy as a measure in its planned outlier review of QHPs, as well as its focus on discriminatory cost-sharing language, for compliance with non-discrimination requirements. That said, BIO continues to believe that any measure that delays or denies patients' timely access to needed providers and/or treatments falls

within the prohibition on discrimination on the basis of health status. Thus, in assessing whether there has been a "reduction in the generosity of a benefit in some manner for subsets of individuals,"[12] we ask that CMS look for not just reductions in the amount of coverage or discriminatory changes in cost-sharing, but also judge a "reduction in generosity" by whether it introduces a delay in timely access to care for certain subsets of individuals.

BIO also remains concerned about the lack of strict guidelines with respect to the design and application of other benefit design techniques, including other utilization-management techniques, which may negatively impact patient access to needed care and treatment. For example, while the Draft Letter "encourages" the analysis of the information plans enter into the "explanations" and "exclusions" fields of the QHP Plans and Benefits Template as part of a compliance assessment strategy, we believe that more detailed guidance is necessary to direct oversight activities at the state and federal level.[13] We therefore strongly urge CMS to include in the final Letter to Issuers criteria for the review of plans' other benefit design techniques, even including those utilization-management 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 medically necessary medications.

Third, 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.[14] 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, rare, or life-threatening diseases.

III. Robust Benefit Design Must Include Comprehensive Access to Prescription Drugs and Minimize Interruptions in Care (Chapter 3 § 2)

In the Draft Letter, CMS makes several proposals related to the provision of prescriptions drugs within the federal EHB standards. While BIO appreciates the Agency's continued efforts to improve compliance with EHB, and thus improve patients' timely access to the most appropriate care, we are concerned that these proposals will not ultimately achieve this goal and may instead result in discrimination against patients in need of complex care.

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[12] Draft Letter to Issuers, p.31.
[13] Draft Letter to Issuers, p.30.
[14] 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).

A. Assessment of the Inclusion of Medical Benefit Drugs (Chapter 3 § 2)

BIO has three important concerns with CMS' proposal that issuers have the ability to indicate how a specific drug is covered, through the medical or retail pharmacy benefit, on the prescription drug benefit section of the 2015 QHP Application.

First, while BIO supports this proposal to the extent that it offers CMS the transparency into plans' benefit designs needed to ensure that plans' provide robust coverage of drugs typically covered within a comprehensive medical benefit, CMS should clarify how it will use this information to ensure sufficient inclusion of medical benefit drugs, particularly since it is unlikely that all issuers will report this information (the proposal just gives them the ability to do so), making it difficult to compare and contrast across plans.

Second, we strongly object to the application of the retail pharmacy minimum formulary inclusion standard, as specified by 45 C.F.R. § 156.122, to plans' coverage of medical benefit drugs. As CMS is aware, the minimum inclusion standard is benchmarked to the greater of one drug per U.S. Pharmacopeia (USP) category and class, or the same number of drugs per category and class as the state-selected benchmark plan. As BIO has noted in several previous communications with the Agency, neither of these components of the minimum inclusion standard are appropriate to judge the inclusion of medical benefit drugs. The USP Medicare Model Guidelines (MMG) categories and classes are ill-suited for this purpose because they were specifically developed for the Medicare Part D drug benefit. This means that USP's list of categories and classes does not, and has never attempted to, capture all of drugs covered under a comprehensive medical benefit (e.g., Medicare Part B). In addition, the USP MMG categories and classes are not meant to reflect clinically meaningful differences between the mechanisms of action or methods of administration for drugs that are typically administered by a physician. Such therapies are often used for complex and life-threatening conditions, and the decision to use a particular drug is often based on multiple clinical factors, including the patient's diagnosis and co-morbidities and the need to monitor the patient after administration of the drug.

Meanwhile, comparison to the state-selected benchmark is similarly inappropriate because 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. Thus, this method would not have produced a comprehensive list of drugs offered through the benchmark plan's medical benefit. BIO urges CMS to further consider how it will assess QHPs' coverage of medical benefit drugs to avoid establishing an inadequate method—such as a comparison to a pharmacy benefit-based benchmark—that will result in discrimination against patients who rely on the life-saving treatments often covered only under a comprehensive medical benefit. While CMS intends to provide more detailed information on this issue in the 2015 Prescription Drug Template, BIO strongly urges the Agency to provide further clarity around, and allow stakeholders to provide meaningful input into, how it will use plans' reporting of which drugs are covered as part of the medical benefit to assess the robustness of coverage for these drugs *before* finalizing the Draft Letter.

Third, BIO is concerned that the CMS policy allowing QHPs to count drugs covered by a plan's medical benefit toward meeting the pharmacy benefit minimum inclusion standard will result in more limited drug coverage overall. As explained above, the EHB standard set forth in section 156.122 is based on comparisons with each state's benchmark retail pharmacy formulary. Yet it remains unclear whether the formularies of states-selected benchmark plans counted any of the prescription drugs covered under their medical benefit for this purpose. Allowing QHPs to use medical benefit drugs to fulfill pharmacy benefit formulary requirements sets up an unequal comparison to state benchmarks in those states that only counted pharmacy benefit drugs, thereby permitting QHPs to *appear* to meet the minimum inclusion standard for their pharmacy benefits while *actually* offering less comprehensive coverage than the state benchmark plan. Therefore, BIO urges CMS to clarify in the Final Letter that plans' retail pharmacy drug benefits must meet the EHB minimum standard on their own, without considering the plans' other benefits.

B. Additional Limitations of the USP Medical Model Guidelines (MMG) and the Need for an Alternative Mechanism to Meet Antidiscrimination Requirements (Chapter 3 § 2)

BIO echoes more general concerns voiced to CMS by participants in its Pharmacy Stakeholder Working Group with the USP-benchmark methodology itself, as described in the prescription drugs section of the Draft Letter. As we have noted in previous communication with the Agency, because the USP MMG was created for use with drugs provided through the Part D benefit, as noted above, it does not reflect the full range of drugs that may be needed by patients enrolling in the QHPs. This failure can impede access to therapeutic interventions for those patients suffering from life-threatening and debilitating rare diseases and complex chronic conditions. As just one example, currently, the USP does not include a category for anti-obesity therapies, despite the fact that many commercial plans offer such coverage. Obesity is a significant risk factor for chronic diseases like diabetes and heart disease, and is estimated to cost the United States health care system $147 billion a year.[15] In cases where a state's benchmark plan does not include anti-obesity drugs, patients could be denied access to these crucial therapies, and the health care system could lose an opportunity to improve patient outcomes while decreasing long-term costs. Thus, multiple stakeholders, including BIO, have recognized the need to consider a potential replacement for the USP benchmark to be implemented after 2015. BIO firmly believes that any potential replacement mechanism—including the use of an alternative benchmark such as the American Hospital Formulary Service (AHFS) system—must represent a comprehensive classification system that is sufficiently detailed to reflect the needs of the evolving Marketplace population.

C. Minimizing Interruptions in Care During Transitions into and between QHPs (Chapter 3 § 2)

In the past, CMS has issued both regulations and guidance that aim to protect beneficiaries from interruptions in access to ongoing care when switching between plans (e.g., in the Medicare Part D program) and BIO supports instituting similar protections for

[15] CDC (Centers for Disease Control and Prevention). 2012 (April 27). *Causes and Consequences: What Causes Overweight and Obesity?* Atlanta, GA: CDC, http://www.cdc.gov/obesity/adult/causes/index.html (accessed December 20, 2012).

those switching into and between QHPs. In particular, we believe that CMS should require QHPs on the FFM and state partnership Marketplaces to implement transition-fill policies that apply to the first 30 days of coverage, beginning the first day of coverage after the annual or any special enrollment period, to ensure continuity of access to prescription drugs and specialists, rather than allowing each Marketplace to individually decide whether to require inclusion and implementation of these provisions. To better ensure continuous access, QHPs should be required to cover these services at favorable cost-sharing (e.g., in-network cost-sharing for patients' specialist providers who may otherwise be out-of-network). Moreover, CMS should specifically address the need for continued access after a transition period has lapsed, and ensure that patients are made aware of the need to obtain an exception or begin an appeal with sufficient time to do so without risking an interruption in care. We look forward to further detail on these policies.

IV. Patients Must Have Access to Sufficient Information to Choose a Plan that Fits Their Needs and is Affordable (Chapter 3 § 2-3)

BIO strongly supports CMS's focus on the need for improved information to aid patients in choosing between QHPs. We, therefore, urge CMS to finalize the requirement that issuers make their formularies—as well as their medical benefit drug coverage—available online to patients directly, without the need to provide detailed, or a burdensome level of, personal information or navigate the issuer's website to access these details. We strongly agree that "tiering and cost sharing"[16] information must be included in the details issuers provide about a QHP's formulary. This requirement moves toward the standard set by the Medicare Part D Plan Finder tool, allowing patients to easily access the information needed to understand the relevance of the benefits a plan provides to their medical needs, or the needs of their families. To ensure that plans implement this requirement in a meaningful manner, BIO also asks CMS to verify that patients are able to access this information, that the information is kept up-to-date, and that it is presented in a format that is meaningful and intelligible for all patient populations.

We also agree that patients' ability to make informed decisions benefits from information on the meaningful difference between issuers' offerings and appreciate the specifics CMS provides on its proposed approach to reviewing meaningful difference between QHPs for 2015. That said, BIO urges CMS to continuously assess the methodology it proposes to use to determine whether two QHPs are "meaningfully different"[17] to ensure it 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.

V. Patients Should Be Able to Access Prescription Drugs Prior to Meeting an Annual Deductible (Chapter 3 § 7)

BIO appreciates CMS' attention to the need for patients to access care prior to meeting a deductible, evidenced by the contemplation of requiring issuers in the FFM to cover three primary care office visits prior to meeting any deductible. We note that such a

[16] Draft Letter to Issuers, p. 33.
[17] Id.

requirement would reflect benefits currently available to those with employer-based insurance: the 2013 Kaiser Employer Benefit Survey found that "[l]arge majorities of covered workers (77% in HMOs, 78% in PPOs, and 72% in POS plans) with general plan deductibles are enrolled in plans where the deductible does not have to be met before physician office visits for primary care are covered."[18] In fact, BIO believes that this approach also is appropriate with respect to access to prescription drugs, especially for those patients requiring high-cost therapies. Ensuring affordable access to these therapies without having to meet the deductible can minimize any interruption in a patient's care. Moreover, as with the proposed requirement for physician office visits, requiring access to prescription drugs before meeting an annual deductible also aligns with current employer-based insurance benefits: the same Kaiser survey also found that "among workers with a general annual deductible, large shares of covered workers in HMOs (95%), PPOs (91%), and POS plans (87%) are enrolled in plans where the general annual deductible does not have to be met before prescription drugs are covered."[19] Particularly with regard to Bronze plans with high deductibles and coinsurance benefit designs for specialty drugs, a patient could face a significant out-of-pocket cost burden to obtain their first prescription and immediately meet their annual deductible. Therefore, we ask CMS to consider requiring issuers to allow coverage of prescription drugs before full payment of the plan's deductible for all plans, or at a minimum, for one plan per metal level per issuer. Additionally, we urge CMS to explore varied approaches to reducing up-front out-of-pocket burdens on patients with complex medical conditions who need access to specialty medications.

VI. QHP Issuer Compliance Reviews Must be Routine, Timely, and Consistent to Ensure Robust Patient Access to Necessary Care (Chapter 4 § 2-3)

BIO continues to urge CMS to proactively monitor and audit QHPs in the FFM and Partnership Marketplaces to ensure compliance with the EHB non-discrimination standards. We appreciate the need for coordination with other QHP-responsible agencies at the state and federal level, but urge CMS to standardize and streamline monitoring and enforcement processes to ensure the potential issues are recognized early and remedied in a timely manner, especially in cases that impact patients' access to timely care. While we agree that CMS' monitoring cannot be limited to reviews of compliant data, we ask that CMS provide more clarity on the other mechanisms it intends to use to identify potential instances of discrimination. Finally, CMS should be prepared to recognize patterns of potentially discriminatory practices employed by issuers and have in place mechanisms to rectify broader scale issues.

VII. Exceptions and Appeals Processes Are Critical For Access to Innovative Technologies (Chapter 6 § 3)

BIO firmly believes that a robust exceptions process—namely one 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 such an

[18] Kaiser Family Foundation and Health Resources and Educational Trust. 2013. *Employer Health Benefits: 2013 Annual Survey*. Exhibit 7.21, p.122. Available at: http://kaiserfamilyfoundation.files.wordpress.com/2013/08/8465-employer-health-benefits-20131.pdf.
[19] Id.

exceptions process is particularly important because there is no mechanism for updating the EHB to include new, innovative treatments partway through a plan year, or even between plan years 2014 and 2015.[20] 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 (or for plan year 2015) may be through the exceptions processes that his or her plan has in place.

In the Draft Letter, CMS does not address plans' exception processes and notes only that issuers must "implement an effective process for internal claims and appeals and external review."[21] While it references the need to comply with "any applicable guidance documents," BIO believes this is an insufficient level of detail to ensure all QHP issuers maintain robust coverage appeals and exceptions processes. We therefore reiterate our recommendation that CMS require that the example exceptions process included in the 2014 Final Letter to Issuers (2014 Final Letter)[22] be defined as a *minimum* standard that issuers' processes must meet to ensure access to clinically appropriate prescription drugs. This model exceptions process included descriptions and timelines for both an internal and external review process and outlines the Medicare Part D-consistent criteria for granting an exception based on a determination that the drug is clinically appropriate. Thus, in the 2015 Final Letter, BIO urges CMS, states, and 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 2014 Final Letter.

BIO also reiterates our strong support for CMS' instruction in the 2014 Final Letter that plans should allow an enrollee to have access to the medication in dispute during the entire exceptions review process and, if an exception is granted, that plans should allow an enrollee to have access to that medication in subsequent plan or policy years should enrollment continue without interruption.[23] 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 therefore recommend that CMS specifically require that the states or OPM to ensure that any plan offering EHB also meets these requirements.

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[20] Indeed, 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. 78 Fed. Reg. at 12,842.
[21] Draft Letter to Issuers, p. 48.
[22] CCIIO, CMS. 2013 (April 5). Letter to Issuers on Federally-facilitated and State Partnership Exchanges. pp.55-56. Baltimore, MD: CMS, Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.
[23] Id.

VIII. 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,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy