January 12, 2015

BY ELECTRONIC DELIVERY

Kevin Counihan
Director and Marketplace Chief Executive Officer (CEO)
Center for Consumer and Information and Insurance Oversight
Centers for Medicare and Medicaid Services
7501 Wisconsin Avenue
Bethesda, M.D. 20814

RE: DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Director Counihan:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments regarding the Center for Medicare and Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight's (CCIIO's) "Draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces" published on December 19, 2014 (the "Draft Letter").[1] While we acknowledge that CMS is working diligently to provide meaningful guidance to stakeholders, we find that the Agency's reliance on a public comment period that is less than 30 days does not allow for thorough consideration by the public of all the proposals contained in this guidance. Thus, we ask that CMS return to at least a 30-day comment period in future years.

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, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO represents an industry that is devoted to discovering, and ensuring patient access to, innovative treatments. With the passage of the ACA, and the beginning of the operation of the health insurance Exchanges on January 1, 2014, millions more Americans have the opportunity to obtain health insurance. Yet insurance does not necessarily translate to access to healthcare, as we are increasingly seeing is the case for many individuals enrolled in Qualified Health Plans (QHPs). In fact, BIO previously has raised concerns to CMS specifically regarding timely access to prescription drugs and appropriate in-network providers.[2] Moreover, data are increasingly emerging that support these concerns on a

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[1] Centers for Medicare and Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight (CCIIO). 2014 (December 19). *DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces*, available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016DraftLettertoIssuers12-19-2014.pdf.

[2] Biotechnology Industry Organization (BIO). 2012. *Comments in Response to the Essential Health Benefits Proposed Rule [CMS–9880–P]*, available at: https://www.bio.org/sites/default/files/EHB%20Proposed%20Rule_Comment%20Letter%20FINAL_21%20Dec%202012.pdf; BIO. 2013. *Comments in Response to the Draft 2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges*, available at: https://www.bio.org/advocacy/letters/bio-submits-comments-centers-

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broad scale: according to a June 2014 study of 123 silver-level Exchange plan formularies, in seven drug classes, more than 20 percent of the plans require coinsurance of 40 percent or more for all medicines in the class.[3] Such policies often disproportionately impact patients with complex or life-threatening conditions like cancer and multiple sclerosis. Patients with rare diseases also face high hurdles to obtaining the care they need through Exchange plans. A separate study, published in September 2014, found that even when a rare disease therapy is robustly covered by a plan's formulary, utilization management policies can delay patient access to the therapy.[4]

In light of this mounting evidence, BIO submitted comments to the Department of Health and Human Services (HHS) and CMS on the Notice of Benefit and Payment Parameters for 2016 Proposed Rule (the "Proposed Rule") on December 22, 2014.[5] We note that the Draft Letter consistently references the Proposed Rule, and many of the proposals, if finalized, will directly impact issuers in the FFMs. Given the overlap between the Draft Letter and the Proposed Rule, we are including BIO's comments in response to the Proposed Rule as an Appendix to this letter as we feel they may be useful in contextualizing and providing additional detail to the comments we make on the Draft Letter herein. BIO's comments in response to the Proposed Rule also address issues that are not addressed by CMS in the current Draft Letter, but have been included in this guidance process in past years, such as the treatment of cost-sharing on services obtained out-of-network and the minimum inclusion standard for prescription drugs within QHPs' formularies. While BIO has not repeated our comments on such issues in response to the Draft Letter, we strongly urge CMS to review our comments to the Proposed Rule on these issues and to work closely with HHS broadly as the Proposed Rule is finalized to ensure consistency across QHP requirements within and outside of the FFMs.

As CMS suggests, we have arranged on comments by section of the Draft Letter, below.

I. Network Adequacy Standards (Ch. 2 § 3(i))

A. CMS should put in place specific standards to ensure patients enrolled in QHPs operating in the FFMs have access to expert, individualized care.

For Calendar Year (CY) 2016, CMS proposes to continue with the requirement that all QHPs applying for certification or recertification attest that they meet the "reasonable access" standard, such that they "maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay."[6] 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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medicare-and-medicaid-services-cms-regarding-center--0; BIO. 2014. *Comments in Response to the Draft 2015 Letter to Issuers on Federally-facilitated Marketplaces*, available at: https://www.bio.org/advocacy/letters/bio-submits-comments-centers-medicare-and-medicaid-services-cms-regarding-draft-201; BIO. 2014. *Comments in Response to the Multi-State Plan Program Call Letter No. 2014-002*.

[3] Avalere. 2014. *An Analysis of Exchange Plan Benefits for Certain Medicines*. Washington, DC: Avalere, http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines.

[4] Robinson, S. W., K. Brantley, C. Liow, and J. R. Teagarden. 2014. An Early Examination of Access to Select Orphan Drugs Treating Rare Diseases in Health Insurance Exchange Plans. *Journal of Managed Care and Specialty Pharmacy* 20(10):997-1004.

[5] BIO. 2014. Comments Regarding HHS Notice of Benefit and Payment Parameters for 2016 Proposed Rule, p. 8-9, available at: https://www.bio.org/advocacy/letters/bio-submits-comments-regarding-hhs-notice-benefit-and-payment-parameters-2016-propo.

[6] 45 C.F.R. 156.230(1)(2).

sufficiently robust provider networks. To achieve this, BIO urges CMS to provide more detailed guidance regarding the 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 specialists, subspecialists, and providers of immunizations and other preventive services. That, in turn, will protect QHP enrollees' access to needed care with affordable cost-sharing, as envisioned by the ACA.

As in 2015, in 2016 CMS will analyze the data submitted by QHPs to assess compliance with the reasonable access standard, specifically with regard to "those areas which have historically raised network adequacy concerns."[7] BIO supports CMS's inclusion of oncology providers on this list for special scrutiny, given the importance of timely and convenient access to this type of specialist for those with cancer. However, not all cancers are the same, and thus we ask that CMS also consider assessing the extent of patient access to subspecialists within a QHP's network, as access to subspecialists can be crucial to ensuring patients obtain expert and individualized care. For example, CMS could assess the inclusion of subspecialists for the five most prevalent cancers by incidence—breast, prostate, lung, colorectal, and melanoma.[8]

Additionally, we ask that CMS consider including rare disease specialists in their analysis of individual QHP provider networks. 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 CMS is not currently counting out-of-network costs toward 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. Thus, additional measures are needed to ensure that these patients have access to the care they need. For example, CMS should develop a process for timely exceptions to ensure that consumers who need care from out-of-network providers can receive it with reasonable cost-sharing, applying enrollee costs toward the annual out-of-pocket maximum. In fact, such a proposal was made by the Office of Personnel Management (OPM) for multi-state plans in 2014.[10] Establishing minimum standards that require all QHPs to have in place such provider exception processes will help to ensure that these patients have timely access to the appropriate specialists.

B. <u>CMS should require QHPs operating in the FFMs to include all types of complementary immunizers in their provider networks.</u>

BIO reiterates our concern, expressed in previous communications with CMS, that complementary immunizers are not required to be included in QHPs' provider networks, since they often predominantly serve low-income and medically-underserved populations. Specifically, BIO believes that requiring all complementary immunizers—including those

[7] Draft Letter at 22.
[8] National Cancer Institute, National Institutes of Health. 2014. Common Cancer Types. Available at: http://www.cancer.gov/cancertopics/types/commoncancers (last viewed 9/4/2014).
[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] 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.

providing immunizations in pharmacies, public health department clinics, school-based clinics, and other community sites—to be included in QHP provider networks will greatly expand access to immunizations for hard-to-reach populations.

Complementary immunizers are particularly important for the hard-to-reach adolescent and adult populations. 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 have been trained to administer vaccines in the United States,[11] and nearly all Americans (94 percent) live within five miles of a community pharmacy.[12] All 50 states allow pharmacists to administer influenza, pneumococcal, and zoster vaccines, and many adults seek these vaccines in the pharmacy setting.[13] During the current 2014-15 influenza season, 25 percent of adult influenza vaccines have been administered in pharmacies.[14]

Complementary immunizers also serve low-income, medically underserved populations, mitigating the barriers these vulnerable patients have long faced with respect to access to care. For instance, community pharmacies provide patient access to important immunizations against vaccine-preventable diseases, including for individuals residing in medically underserved areas (MUAs). One nationwide community pharmacy corporation, Walgreens, indicated that over one-third of their influenza vaccines administered last year were in pharmacies located in MUAs; in states with the largest MUAs, they provided up to 77.1 percent of their influenza vaccines in these areas. Moreover, of all influenza vaccinations Walgreens delivered last flu season, 31 percent were during off-peak times (59 percent on weekends and 31 percent in the evenings), and approximately 31 percent of patients during off-peak times were age 65 or older, and 36 percent had underlying medical conditions. Notably, pharmacies' efforts to provide immunizations other than influenza have often been complicated by their lack of recognition as in-network providers.

Many public health stakeholders have supported efforts underway at the CDC to include additional complementary immunization sites, such as public health and school-based clinics, in provider networks. The most significant such CDC initiative, known as the "Third Party Billing Project," works with state health departments, public health clinics, and health insurers to include public health clinics in provider networks.[15] Thirty-five states and large cities are currently planning or implementing the Billing Project, which will allow them to 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.[16] Other states such as

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[11] Rothholz M. Opportunities for Collaboration to Advance Progress towards "The Immunization Neighborhood:" Recognition and Compensation of Pharmacists. Presentation. American Pharmacists Association. August 30, 2012.
[12] NCPDP Pharmacy File, ArcGIS Census Tract File, National Association of Chain Drug Stores Economics Department.
[13] See American Pharmacists Association, Pharmacist Authority to Immunize, available at: http://www.pharmacist.com/sites/default/files/PharmacistIZAuthority.pdf.
[14] CDC, National Early Season Flu Vaccination Coverage, United States, November 2014, available at: http://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2014.htm#place .
[15] CDC, Billing Project Success Stories, http://www.cdc.gov/vaccines/programs/billables-project/success-stories.html (last accessed Feb. 6, 2014).
[16] 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.

Arizona, California, Arkansas, Georgia, and Montana experienced success with the Billing Project.[17]

In spite of these efforts, when a health insurance plan does not include complementary immunization sites in its provider network, the ACA's intent of expanding access to immunizations is compromised. For instance, a plan enrollee who seeks to be immunized at a public health clinic or pharmacy that has been excluded from a plan's provider network would be denied first dollar coverage (or coverage at all) for that service. In turn, the patient may decide not to receive the vaccine due to cost and an immunization opportunity would be lost. Alternatively, a more affluent patient could elect to pay the bill, but none of these costs would count toward the patient's deductible, and the patient would understandably be upset and confused as to why he/she did not receive the benefits he/she were promised.[18]

It has been observed that complementary immunizers are currently being excluded from provider networks across the country. For example, in Nevada, school-based clinics in Carson City have been excluded from the network of a major health insurer. As acknowledged by the National Vaccine Advisory Committee in the updated Standards for Adult Immunization Practice, "there is an increased recognition of community vaccinators and pharmacists as integral to achieving higher adult vaccination rates."[19] Therefore, BIO urges CMS to require QHPs operating in the FFMs to include all types of complementary immunizers in their provider networks, as expanded access to immunization services will improve vaccination rates and thereby reduce morbidity, mortality, and overall medical care costs for enrollees.

While we believe it is essential for providers of immunization services to be included in QHP networks, and therefore urge CMS to take all available steps to ensure that this happens, we understand that universal inclusion of complementary immunizers may not be possible initially or immediately. Thus, in the interim, we urge CMS to require QHPs in the FFMs to cover all ACIP-recommended immunizations without cost sharing, regardless of whether they are furnished by in-network providers. We also ask that CMS work with HHS broadly as the Proposed Rule is finalized to coordinate requirements for all plans subject to EHB that improve access to immunizations. In doing so, we urge the Agency to adopt an approach similar to the standard implemented for emergency room services pursuant to section 2719A of the Public Health Service Act.[20] Together with ensuring that immunization providers are included in QHP provider networks, adopting an across-the-board policy ensuring that all QHPs extend access to ACIP-recommended immunization services with no cost sharing will ensure that beneficiaries have robust access to these services in accordance with section 2713 of the ACA.

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[17] Kilgus D. Billing Program Final Plans. February 2012. CDC. Available at: http://www.cdc.gov/vaccines/programs/billables-project/downloads/billing-final-plans-from-stkhldr-mtg-slides.pdf.
[18] Andrews M. Consumers Expecting Free "Preventive Care" Sometimes Surprised by Charges (Jan. 21, 2014), available at: http://www.kaiserhealthnews.org/Stories/2014/January/21/Michelle-Andrews-Consumers-Expecting-Free-Preventive-Care.aspx.
[19] National Vaccine Advisory Committee. Standards for Adult Immunization Practice. Available at: http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/adult_immunization_update-sept2013.pdf.
[20] 42 U.S.C. § 300gg-19a; 45 C.F.R. § 147.138(b).

C. CMS should establish more robust network adequacy standards to better ensure individuals have access to the most appropriate provider for their condition.

In the Draft Letter, CMS references the NAIC process to develop a *Managed Care Network Adequacy Model Act*, stating that the Agency "intends to evaluate the results of this workgroup for future rulemaking."[21] As noted in our comments in response to the Proposed Rule, BIO appreciates the opportunities NAIC has provided for public comment on its process, but we caution CMS that the final product of this process is still likely to be modified, perhaps significantly, as it is introduced in 50 state legislatures. Thus, the NAIC process also does not obviate the need for robust federal network adequacy standards for QHPs, especially standards that ensure patients who require out-of-network services (e.g., rare disease patients who require specialty care available in only a few places in the entire country) do not face discriminatory cost sharing that renders them effectively unable to access care in a timely manner. Thus, we urge the Agency to work with HHS more broadly to bolster minimum standards for network adequacy beyond those that are already in place,[22] so that enrollees have reasonable access to necessary providers no matter where they live.

Specifically, BIO continues to urges that QHPs should be required:

- To allow new enrollees to continue to receive care from a provider—even if that provider is outside of the plan's network—with whom the enrollee is under an ongoing course of treatment in the 90 days prior to the effective date of coverage for up to 30 days after the effective date of coverage;
- To put a process in place to allow enrollees to request and receive access to services provided by out-of-network providers at no greater cost than if those services were provided by in-network providers in cases where the insurer has an insufficient number or type of in-network providers, and to count the cost sharing for these services toward an enrollee's annual out-of-pocket maximum;[23] and,
- To allow patients receiving active treatment or are monitored under maintenance regimens from a provider whose network contract is terminated, for reasons unrelated to the quality of the care they provide, to continue to receive services from that provider through the conclusion of the benefit year.

II. Provider Directory Links (Ch. 2 § 3(ii))

CMS should work with HHS more broadly to improve the information contained in, and availability of, provider directories maintained by QHPs.

In the Draft Letter, CMS also notes that the Agency will require QHPs to make their provider directories available to the FFMs for publication online by providing the URL link to their network directory. CMS then goes on to reiterate the proposed requirements for provider directories—including that issuers publish a current, accurate, and complete provider directory, including information regarding which providers are accepting new patients—from the Proposed Rule. BIO strongly urges CMS to finalize this proposal to make detailed information on providers publicly available, as we believe consumers should have the best

[21] Draft Letter at 23.
[22] 45 C.F.R. § 156.230.
[23] This proposal aligns with recent proposed revisions to the National Association of Insurance Commissioners (NAIC) Network Adequacy Model Act: NAIC. 2014 (November). *Health Benefit Plan Network Access and Adequacy Model Act*, Model #74, Draft 11/12/14, Section 5, p. 6, available at: http://www.naic.org/documents/committees_b_rftf_namr_sg_exposure_draft_proposed_revisions_mcpna_model_act.pdf.

information at hand when choosing an insurance plan to meet their healthcare needs. In addition to the proposed requirements, BIO asks CMS to consider requiring plans to update the directory within a certain time period (e.g., 72 hours) in cases where an in-network provider becomes out-of-network for any reason.

III. Evaluation of Network Adequacy with respect to all Essential Community Providers (ECPs) (Ch. 2 § 4(i))

CMS should clarify its intent with regard to the proposal that multiple providers at a single location count as a single ECP.

Though CMS does not propose any major changes to the ECP inclusion standard for QHPs operating in the FFMs, the Draft Letter does note that for the purpose of both the general and alternative ECP standard, "multiple providers at a single location will count as a single ECP toward the issuer's satisfaction of the proposed ECP participation standard."[24] On this issue, as we did in response to the same proposal in the Proposed Rule, BIO urges CMS to clarify its intent in making such a proposal. Specifically, we ask that the Agency address concerns that not counting multiple providers at a single location as multiple ECPs may overlook the availability of distinct services provided at the same facility or group of facilities (e.g., in the case of large hospital systems that offer off-site outpatient clinics, which nonetheless function as part of the larger entity). We also are concerned that this current proposal would disadvantage the inclusion of varied types of entities and providers in-network, shifting more care to more costly hospital-based outpatient departments.[25] Thus instead, we ask that CMS count multiple providers at a single location as multiple ECPs to satisfy both general and alternative ECP standard.

IV. Discriminatory Benefit Design (Ch. 2 § 9)

CMS should establish a more robust framework for ensuring QHP compliance with the ACA's prohibition on discrimination.

In the Draft Letter, CMS reiterates its view that enforcement of the nondiscrimination standard for EHB benefit design is "largely conducted by the states."[26] BIO, too, acknowledges the important role of states in ensuring that nondiscrimination requirements are met by plans operating within and outside of the FFMs. However, since many issuers offer plans both within and outside of the FFMs, CMS's role in setting nondiscrimination 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 nondiscrimination 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. Thus, to better uphold this important patient protection, BIO urges the Agency to: (1) bolster its existing assessment framework to better identify instances of noncompliance; (2) finalize the proposed out-of-pocket-costs-based analysis; and (3) work

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[24] Draft Letter at 26.

[25] Several studies have found that the cost of care for patients treated in hospital outpatient settings is higher—both for the Medicare program and for patients individually—than when treated in the provider office setting. For example, *See* The Moran Company. 2013 (August). *Cost Differences in Cancer Care Across Settings*, available at: https://media.qractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/adebd67d-dcb6-46e0-afc3-7f410de24657.pdf; Fitch, K., and B. Pyenson. 2011 (October 19). Site of service cost differences for Medicare patients receiving chemotherapy. Milliman, Inc., available at: http://us.milliman.com/uploadedFiles/insight/health-published/site-of-service-cost-differences.pdf.

[26] Draft Letter at 34.

with HHS more broadly as the Proposed Rule is finalized to establish a more robust framework for ensuring QHP compliance with the ACA's prohibition on discrimination.

A. CMS should bolster the existing assessment framework for identifying instances of noncompliance.

BIO continues to support CMS's efforts to analyze the information contained in the Plans and Benefits Template with the objective of identifying discriminatory features or wording, especially those that involve a "reduction in the generosity of a benefit for subsets of individuals for reasons not clearly based on common medical management practices."[27] However, as we did in response to this proposed analysis in the CY 2015 Draft Letter, in undertaking this assessment, we urge CMS to judge a "reduction in generosity" by whether it introduces a delay in timely access to care for certain subsets of individuals, not just in terms of whether it reduces the amount of coverage or introduces discriminatory changes in cost sharing. This is an important facet of CMS's analysis because we 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. We also ask that CMS provide more information on how the Agency will proceed when this analysis identifies an instance of noncompliance. While the Draft Letter notes that issuers "may be asked to submit justification with supporting document to CMS explain how the plan design is not discriminatory[,]"[28] it is unclear how CMS evaluates that justification, if there are further rounds of adjudication, and what final action options are available. The timeline for this process also is not specified.

Additionally, with respect to their current role, we appreciate that CMS continues to include an outlier analysis in its assessment of compliance with the nondiscrimination requirement. However, in addition to including QHP cost sharing—such as copayments and coinsurance—in this analysis, we urge CMS to include an assessment of a QHP's use of specialty tiers and utilization management techniques to determine whether a particular benefit design limits access to needed care. This is important because 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. Moreover, there is a clear link between higher cost-sharing and decreased adherence to necessary medical treatment, which can lead to poor patient health outcomes.[29]

B. CMS should finalize the proposed out-of-pocket-costs-based analysis with the addition of four conditions for specific inclusion: multiple sclerosis, hemophilia, rare diseases, and cancer.

BIO strongly supports CMS's proposal to conduct a review of each QHP to identify outliers based on estimated out-of-pocket costs for beneficiaries associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines. We encourage CMS to provide more details about its methodology (e.g., which guidelines will be referenced, how estimated out-of-pocket costs will be calculated) and allow stakeholder

[27] Draft Letter at 35.
[28] Id. at 35.
[29] 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).

input on the methodology itself as this new analysis tool is implemented and evolves. Additionally, BIO urges CMS to adapt the outlier analysis to assess whether patients have meaningful access to the therapies they need, whether covered through inclusion on a plan's drug formulary or through a plan's comprehensive medical benefit. In general, the outlier analyses should help CMS ensure that the structure of plans' benefits are not incentivizing the choice of a therapy based on factors other than what is the most clinically appropriate for an individual patient (additional discussion of this concern is included in section V(B) below). Furthermore, these assessments can offer insights into each QHP's coverage of innovative or newly-approved therapies aligned with clinical guidelines and best practices (e.g., use of therapies in first-line or only in second- or third-line cancer cases).

In the Draft Letter, CMS identifies five potential conditions for inclusion in this outlier analysis: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia. While BIO supports this initial proposed list of conditions, we urge CMS to specifically include four additional conditions in 2016: multiple sclerosis, hemophilia, rare diseases, and cancer. Patients with these conditions rely on access to therapies as a vital part of their treatment regimen, and as the literature has shown, high out-of-pocket costs can adversely impact, not only access to therapies, but patient adherence to medication regimens.[30] Additionally, evidence is emerging that patients with these conditions already may have trouble accessing needed therapies: the 2014 Avalere analysis referenced in the introduction of this letter found that 50 percent of the 123 silver plans offered through the Exchanges require coinsurance of at least 30 percent for all multiple sclerosis therapies.[31] Concerns around the potential difficulties that hemophilia patients face in gaining access to needed therapies—due to the out-of-pocket costs associated with the formulary tiers on which these therapies are often placed—have been documented over time as well.[32] Similarly, recent analysis has shown that certain rare disease therapies are most likely to be placed on plans' highest formulary tiers and subject patients to coinsurance of up to 50 percent.[33] Additional Avalere analysis found similar practices for therapies treating certain types of cancer covered under plans' pharmacy benefits. Moreover, concerns have been raised with regard to the adequacy of QHPs' inclusion of innovative drugs and biologicals used to treat cancer as part of a comprehensive medical benefit: a 2014 American Cancer Society analysis raised concerns about potential gaps in formulary coverage of anti-cancer therapies that are administered intravenously (since these are often included as part of plan's medical benefit, but federal oversight of plans' compliance with prescription drug requirements generally focuses on the structure of plans' pharmacy benefit).[34] Thus, to better understand whether plans operating in the FFMs are providing adequate access to the therapies these vulnerable patients need, we strongly urge CMS to include multiple sclerosis, hemophilia, rare diseases, and cancer to the proposed outlier analysis in 2016.

In addition to supporting the inclusion of additional conditions in the proposed outlier analysis, we encourage the Agency to provide more detail on what criteria and timelines will

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[30] Ibid.
[31] Avalere. 2014. *An Analysis of Exchange Plan Benefits for Certain Medicines*. Washington, DC: Avalere, http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines.
[32] For example, *see* Hemophilia Federation of America. 2013. Issue Brief: Specialty Tiers, available at: http://www.hemophiliafed.org/uploads/Specialty-Tiers_Issue-Brief_HFA_2013_FINAL.pdf.
[33] Robinson, S. W., K. Brantley, C. Liow, and J. R. Teagarden. 2014. An Early Examination of Access to Select Orphan Drugs Treating Rare Diseases in Health Insurance Exchange Plans. *Journal of Managed Care and Specialty Pharmacy* 0(10):997-1004.
[34] American Cancer Society-Cancer Action Network. 2014 (March). Cancer Drug Coverage in Health Insurance Marketplace Plans, available at: http://www.acscan.org/content/wp-content/uploads/2014/03/Marketplace_formularies_whitepaper.pdf.

be used to update this list of specific conditions in the future and ensure that stakeholders have an opportunity to comment on any such amendments before they are finalized. We also encourage CMS to consider compiling and releasing to the public a general summary of the Agency's findings based on this type of analysis. This would be helpful in evaluating the utility of such an analysis in ensuring QHP compliance with nondiscrimination standards for future years.

C. CMS should work with HHS more broadly as the Proposed Rule is finalized to establish a more robust framework for ensuring QHP compliance with the ACA's prohibition on discrimination.

While we appreciate that the Draft Letter contains the most specific examples to-date of benefit designs that CMS considers to violate the nondiscrimination requirements, we continue to maintain that more active federal oversight of plans' compliance with the prohibition on discrimination is needed. The Draft Letter's examples of plans that CMS considers to violate this prohibition, in turn, suggest a concerning ability of plans with clearly discriminatory benefit designs to come to the marketplace. In our comments in response to the Proposed Rule, BIO urged HHS to: (1) identify criteria based on which the Department will assess plans subject to EHB for compliance with the nondiscrimination requirement; (2) proactively review plan offerings to better ensure plans with discriminatory benefit designs are not offered in the marketplace in the first place; and (3) consider providing states with more specific guidance on reviewing plans for compliance with the federal prohibition on discrimination to standardize the criteria against which plans are being judged. Thus, as the Proposed Rule and Draft Letter are finalized, we urge CMS to work with HHS more broadly to improve robust, proactive oversight of this critical patient protection both within and outside of the FFMs.

V. Prescription Drugs (Ch. 2 § 10)

A. CMS should finalize the proposed provisions on improved formulary transparency, robust exceptions processes, and sustained access to needed therapies during transitions in insurance coverage that are reiterated in the Draft Letter and were originally proposed in the Proposed Rule.

CMS notes that several changes proposed in the Proposed Rule around prescription drugs, if finalized, would become requirements in 2016 for all QHPs. First, the Draft Letter reiterates the proposed requirements around issuers' formulary drug lists. Namely, QHPs would need to provide URL links to formulary drug lists that are up-to-date, accurate, and include a complete list of the covered drugs, among many other requirements. BIO strongly supports all of these crucial transparency provisions and reiterates our support to further require that cost-sharing requirements be made available in addition to the other aspects of a plan's prescription drug formulary described. Making cost-sharing information readily available is critical in helping patients anticipate their annual out-of-pocket costs. Moreover, all of this information—including on cost-sharing—is necessary for individuals to make informed decisions about which plan best meets their anticipated healthcare needs. BIO also reiterates our support for requiring that this information be made publicly available on plan websites in a machine-readable file and format to allow third parties to create resources that aggregate information on different plans to help enrollees better understand plans' formulary drug lists. We support the opportunity for third parties to create consumer-friendly resources on available plan options as another tool to improve the information available to patients at the time they are making decisions about healthcare insurance.

Second, CMS also references the exceptions standards and timelines proposed in the Proposed Rule. BIO reiterates our strong support of this proposal, which, if finalized, would require plans to put in place a process and timelines for responding to exceptions requests made through a "standard" rather than an "expedited" channel. Specifically, HHS proposed to require plans to establish a standard exceptions process and make a coverage determination on a standard exception request and notify the enrollee of the determination no later than 72 hours after receiving the request. This requirement is in addition to existing requirements that plans have in place a process for expedited exceptions and make a coverage determination and notify the enrollee of the determination no later than 24 hours after receipt of the request. We also support the proposal that plans be required to establish an external review process conducted by an independent review organization if the issuer denies an exceptions request. We direct CMS to our comments in response to the Proposed Rule for a more detailed discussion on the importance of finalizing these proposals, including the need to codified additional, related patient protections.[35]

Third, in the Draft Letter, CMS "continues to encourage issuers to temporarily cover non-formulary drugs (including drugs that are on an issuer's formulary but require prior authority or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage when an enrollee is transitioning to a new plan."[36] As BIO noted in our comments in response to the Proposed Rule, given the importance of sustaining access to needed therapies during insurance transitions, BIO urges CMS to require issuers to have such a temporary process in place during the first 90 days of new coverage to ensure that patients transitioning between plans are able to maintain adherence to the therapies on which they are already stable. We note that this is similar to transition policies in Medicare Part D.[37] CMS also should require plans to provide all of the necessary information on exceptions processes and prior authorization requirements to patients upon new enrollment, especially if a patient's medical history includes the use of a therapy subject to non-coverage or utilization management requirements.

B. <u>CMS should finalize the two review analyses proposed to apply to the 2016 QHP certification process: an outlier analysis of drugs subject to prior authorization and/or step therapy requirements; and an analysis of the availability of covered drugs recommended by nationally-recognized clinical guidelines.</u>

In the Draft Letter, CMS identifies two review processes it will apply to the 2016 QHP certification process to ensure plans comply with all prescription drug-related regulations. First, the Agency notes that it will perform an outlier analysis to identify QHPs that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class. We strongly support this review and ask that CMS include "or are subject to the highest cost-sharing tier" to this list of criteria based on emerging reports that patients with certain chronic diseases have experienced delayed access to needed therapies because all or substantially all have been placed on the highest cost-sharing formulary tier.[38]

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[35] BIO. 2014. Comments Regarding HHS Notice of Benefit and Payment Parameters for 2016 Proposed Rule, p. 8-9, available at: https://www.bio.org/advocacy/letters/bio-submits-comments-regarding-hhs-notice-benefit-and-payment-parameters-2016-propo.

[36] Draft Letter at 36.

[37] Medicare Prescription Drug Benefit Manual, Chapter 6 § 30.4.4, Rev. 10, 02-19-10, available at: https://www.HHS.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

[38] For example, *See* Andrews, M. 2014 (July 8). *Some Plans Skew Drug Benefits To Drive Away Patients, Advocates Warn*. Kaiser Health News, available at: http://kaiserhealthnews.org/news/some-plans-skew-drug-benefits-to-drive-away-patients-advocates-warn/.

Second, for 2016, CMS also proposes to review each QHP to analyze the availability of covered drugs recommended by nationally-recognized clinical guidelines used in four specific medical conditions: bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. Specifically, CMS notes that the purpose of these reviews is to determine whether QHPs are offering a sufficient number and type of needed therapies, including an assessment of whether access to certain medically necessary therapies is being restricted through the use of utilization management techniques. BIO strongly supports this type of review as we believe it will offer a more detailed perspective on how certain benefit designs are implemented and their potential impact on patient access to crucial therapies. As we did in section IV(B) above, we urge CMS to include four additional conditions in this proposed analysis: multiple sclerosis, hemophilia, rare diseases, and cancer. We believe that emerging evidence suggests that therapies treating these conditions are often subject to the highest cost-sharing requirements, which can impact whether patients are able to access the therapies they need in a timely manner.[39] Thus, including these additional conditions in the proposed analysis will strengthen CMS's perspective on whether some of the most vulnerable patients enrolled in plans operating in the FFMs are able to gain access to the most appropriate therapies for them.

In conducting such an availability analysis, we also strongly urge CMS to consider patient access to the standard of care whether through a plan's prescription drug formulary or through its comprehensive medical benefit. Additionally, in conducting such an analysis, CMS should aim to identify benefit designs that attempt to incentivize the choice of therapy based on factors other than what is the most clinically appropriate for an individual patient (e.g., a benefit design that uses variations in cost sharing that may influence the choice of one therapy over another). We also encourage CMS to pilot test this analysis methodology in advance of the 2016 QHP certification process to better understand what data are needed for a comprehensive assessment in these eight disease areas. Additionally, the Agency should provide more details around this review methodology as well work with stakeholders to identify additional appropriate diseases and conditions for inclusion as this analysis is implemented and evolves.

VI. 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

[39] For example, *see* references cited in footnotes 30-33 above.