Biotechnology Industry Organization

December 22, 2014

Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 [CMS-9944-P]

Dear Secretary Burwell and Director Counihan:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments regarding the Department of Health and Human Services' (HHS's or the Department's) Proposed Rule entitled "Notice of Benefit and Payment Parameters for 2016" published on December 8, 2014 (the "Proposed Rule").[1] While we acknowledge that HHS is working diligently to provide meaningful guidance to states and other stakeholders, we find that the Department's reliance on a 30-day period provided to the public does not allow for thorough consideration by the public of all the proposals contained in this rule. The proposals contained in this rule have significant and far-reaching implications for patients, the health care industry, and public health. As established by Executive Order 12866, 60 days is the standard comment period for major rules.[2] We urge HHS to follow the standard comment period in the future for rules continuing to implement the Affordable Care Act's (ACA's) requirements.

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

[1] 79 Fed. Reg. 70, 674 (December 8, 2014).
[2] 58 Fed. Reg. 51735, (October 4, 1993).

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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 HHS specifically regarding timely access to prescription drugs and appropriate in-network providers.[3] Moreover, data are increasingly emerging that support these concerns on a 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.[4] 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.[5] In light of this mounting evidence, we believe the Proposed Rule is an opportunity to substantively address many of these issues.

In general, BIO appreciates that the Department is proposing changes that aim to improve the beneficiary's experience with obtaining and using healthcare coverage through QHPs. For example, BIO supports the proposed change to the open enrollment period such that, regardless of when a plan is selected, coverage begins on January 1.[6] We agree with HHS that this should reduce confusion among enrollees and has the potential to streamline the provision of coverage. However, we also believe that HHS can further strengthen some of the existing and proposed patient protections, and thus ask HHS to:

- Replace the current drug count methodology with a hybrid system such that plans' Pharmacy and Therapeutic (P&T) Committees are responsible for developing a prescription drug formulary based on minimum federal inclusion standards;
- Finalize the proposal to require plans to establish a process and timelines for standard exception requests;
- Finalize the proposal to require plans to establish an external exceptions review process;
- Finalize requirements that will improve patients' access to information on a plan's formulary before, during, and after enrollment;
- Clarify that the proposed requirements around retail pharmacies are meant to expand, not limit, patients' timely access to needed therapies;
- Require, rather than just encourage, plans to temporarily cover non-formulary drugs during the first 90 days after a coverage transition;
- Ensure that drug coverage as part of a comprehensive medical benefit is sufficiently robust to meet the needs of enrollees;

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[3] 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-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*.

[4] 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.

[5] 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.

[6] 79 Fed. Reg. 70, 674 (December 8, 2014) at 70,708.

- Take a more active oversight role of plans' compliance with the prohibition on discrimination;
- Finalize the proposed clarifications in cost-sharing policies regarding calculating the annual out-of-pocket maximum;
- Require plans to count all cost-sharing on Essential Health Benefits (EHB) toward the annual out-of-pocket maximum;
- Require plans to treat cost sharing on products or services obtained through an exceptions process the same as if those products or services were covered without the need for an exception;
- Consider alternative out-of-pocket-cost limits for individuals with incomes between 250 and 400 percent of the Federal Poverty Line (FPL);
- Further clarify the policy on applying a plan's annual limitation on cost-sharing between individuals within a plan other than self-only;
- Bolster network adequacy standards to better ensure individuals have access to the most appropriate provider for their condition;
- Finalize the proposals to improve provider network information and the availability of provider directories maintained by plans subject to EHB;
- Require plans to include all types of complementary immunizers in their provider networks;
- Provide more details on how the proposed re-enrollment options will be communicated to enrollees at the time of initial enrollment and when reassignment occurs;
- Clarify its intent with regard to the proposal that multiple providers at a single location count as a single ECP;
- Address concerns that an ever-increasing maximum annual cost-sharing limitation will nullify this critical patient protection over time; and,
- Require QHPs to include robust quality measures and appropriate attribution methodologies in the development and implementation of a Quality Improvement Strategy (QIS).

More detail on each of these issues is provided below.

I. Essential Health Benefits Package: Prescription Drug Benefits

A. HHS should replace the current drug count methodology with a hybrid system in which plans subject to EHB are required to establish P&T Committees to develop drug formularies and formularies must be based on a federal minimum inclusion standard.

In the Proposed Rule, HHS proposes to replace the current minimum inclusion standard for prescription drugs, which requires plans subject to EHB to cover "at least the greater of: (i) one drug per United States Pharmacopeia (USP) [Medicare Model Guidelines (MMG)] category and class; or (ii) the same number of prescription drugs in each category and class as the EHB-benchmark plan."[7] We appreciate HHS's recognition of and attention to the issues associated with continuing to employ the USP-MMG-based standard (e.g., USP MMG was established for a different population, namely Medicare, than the population covered by EHB), and commend the Department's willingness to work with stakeholders to improve access to needed therapies for enrollees in EHB plans. Additionally, we agree that whatever replacement standard is finalized should correct the shortcomings of the existing system. This includes, as HHS notes, that the current system does not encourage the inclusion of

[7] 45 C.F.R. § 156.122(a)(1).

newly-approved drugs and does not provide an incentive for issuers to cover innovative products. BIO has voiced similar concerns in our communications with HHS since the standard was implemented and appreciates the opportunity in the Proposed Rule to work toward robust coverage of the prescription drugs that reflect the clinical needs of patients.

The Department proposes to replace the current drug count methodology with one of three alternatives: (1) establishing requirements for plans to utilize a P&T Committee to develop drug formularies; (2) maintaining a similar structure to the current drug count methodology but replacing the USP MMG with a classification system—such as the American Hospital Formulary Service (AHFS)—more reflective of the full breadth of therapies needed by the EHB population; and, (3) establishing a hybrid in which there is a federal minimum inclusion standard for prescriptions drugs and plans are required to use a P&T Committee to develop drug formularies. BIO urges HHS to pursue this hybrid model as an alternative to the current drug count standard, and, in the remainder of this section, we expand on the necessity of this hybrid model and propose additional provisions we believe are needed to further strengthen the model.

i. *Additional requirements for P&T Committees are needed to ensure patient access to a broad range of necessary therapies*.

As HHS points out in the preamble, other federal healthcare programs—including Medicare Part D—require participating plans to utilize a P&T Committee to establish and update prescription drug formularies. BIO supports the use of a P&T Committee as part of ensuring robust formularies. However, BIO notes that the Medicare Part D program additionally includes patient protections—such as the six protected classes and a requirement that a formulary include at least two drugs per therapeutic category or class—that do not exist in the EHB standard. Thus, to achieve comprehensive coverage of the therapies enrollees need under EHB, HHS also must establish a minimum inclusion standard for the prescription drug formularies developed by P&T Committees. BIO has addressed specific recommendations for P&T Committee operations and formulary classification and counting requirements below.

P&T Committee Requirements. BIO appreciates that the proposed requirements for a plan's P&T Committee—with regard to membership, conflict of interest, meeting standards, and formulary drug list establishment and management—closely reflect the requirements in place for such Committees within the Medicare Part D program.[8] As part of a hybrid alternative to the current drug standard, the requirements governing P&T Committees will determine their ability to foster improved access to needed therapies for EHB plan enrollees. Thus, to further strengthen the P&T Committee structure and operation, we urge HHS to include several additional provisions, similar to counterpart requirements in Medicare Part D, described below.

Membership of P&T Committees. We note that one discipline not explicitly included in the P&T Committee membership requirements is 'health outcomes.' Given the perspective that an individual with such expertise might lend a P&T Committee—including on issues of patient adherence—we ask HHS to consider encouraging the inclusion of this discipline among Committee membership.

[8] Medicare Prescription Drug Benefit Manual, Chapter 6 § 30.1, Rev. 10, 02-19-10, available at: https://www.HHS.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

Timeframe for review of new therapies. In the draft regulatory text, HHS should include a timeliness requirement, such that the P&T Committee must "develop and document procedures to ensure appropriate and timely drug review and inclusion."[9] This requirement is especially important if an alternative prescription drug standard is to meet HHS's stated goal of better encouraging the inclusion of newly-approved innovative therapies. Specifically, HHS should require that P&T Committees make coverage decisions within 90 days after a new product, or a new indication of an existing product, is approved by the U.S. Food and Drug Administration (FDA). HHS also should require that, if a patient requests and receives access to the new product through a plan's exceptions process while the product is undergoing the P&T Committee review, the enrollee will be allowed continued access to the product after the P&T Committee's coverage determination is made on terms that are no more restrictive than those in place under the exceptions process.[10]

Standards for P&T Committee Review. HHS should require additional operational elements of a P&T Committee's work. Specifically, BIO asks HHS to include the following additional provisions since we feel these provisions are similarly crucial to the ability of P&T Committees to better ensure that enrollees can access needed therapies: the P&T Committee should be required to review for clinical appropriateness the practices and policies for formulary management activities that affect access (e.g., prior authorizations, step therapies, quantity limitations, generic substitutions); P&T Committee recommendations regarding which prescription drugs are placed on a plan's formulary should be binding on the plan; the P&T Committee should evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually; and documentation on decisions and the Committee's annual review should be posted publicly and in a timely manner.

Conflicts of Interest. HHS should consider setting a single definition of "conflict of interest" as it pertains to P&T Committee membership to ensure consistent requirements across plans. This is important because the decisions of the P&T Committees will be heavily influenced by their membership. Thus, standardizing certain requirements for membership is more likely to ensure that patients are able to access needed therapies no matter under what plan they are insured. Similar to the Medicare Part D standard, BIO believes this definition should consider P&T Committee members who may have certain non-employee relationships with pharmaceutical manufacturers that do not constitute significant sources of income as independent and free of conflict with regard to such a relationship.[11]

Accreditation. BIO urges HHS to consider the important role accreditation—either by HHS or a designated third party/parties—can play in ensuring the processes and procedures a P&T Committee uses to make inclusion decisions. We ask that HHS strongly encourage accreditation to review at least: compliance with federal nondiscrimination requirements; that decisions are based on evidence-based medicine; and that the resulting formulary is inclusive of all therapies considered the standard of care for a given disease or condition.

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[9] 79 Fed. Reg. at 70,756, draft regulation §156.11(a)(2)(iii)(A).

[10] E.g., An enrollee in this scenario would not be subject to a prior authorization requirement that was part of the P&T Committee's recommendation if he/she obtained the product through an exceptions process that did not include the prior authorization requirement prior to the Committee's coverage determination; if a new-to-market product is included on the plan's formulary, an enrollee in this scenario would not be subject to higher cost-sharing for the product once it is included on the formulary than to what he/she was subject under the terms of the exceptions process.

[11] Medicare Prescription Drug Benefit Manual, Chapter 6 § 30.1.1, Rev. 10, 02-19-10, available at: https://www.HHS.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

Begin P&T Committee process in 2016. Finally, BIO asks HHS to allow and encourage plans to begin to use P&T Committees—subject to the requirements specified above—to expand formularies as soon as benefit year 2016.

ii. HHS should develop a prescription drug classification system specifically to use as a benchmark for a federal EHB minimum inclusion standard that sufficiently reflects the healthcare needs of patients enrolled in EHB plans.

While BIO supports P&T Committees as part of an alternative to the current drug count standard, we firmly believe that a federal minimum inclusion standard is crucial to any such alternative. Thus, as we stated previously, BIO recommends a hybrid model in which a minimum inclusion standard serves as the basis for formulary development by P&T Committees. However, the USP MMG as the benchmark for the minimum inclusion of prescription drugs, as we have noted in previously communications, is not an adequate standard for many of the reasons HHS recognizes in the preamble to the Proposed Rule. For example, because the USP MMG was created for use with drugs provided through the Part D benefit, it does not reflect the full range of drugs that may be needed by patients enrolling in plans subject to EHB. While the size of the commercial market subject to EHB requirements is large and projected to continue growing through 2018, failure to develop an EHB-specific drug classification tool could impede access to therapeutic interventions for those patients suffering from a wide range of life-threatening and debilitating rare diseases, complex chronic conditions, and multiple chronic illnesses. In cases where a state's benchmark plan narrowly covers drugs in a specific therapeutic area, 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, we appreciate HHS's willingness to consider a potential replacement for the USP MMG benchmark to be implemented in the future.

In the Proposed Rule, HHS identifies a potential alternative to the USP MMG: the AHFS Drug Information classification system. BIO reiterates our appreciation for the Department's attention to the crucial issue of a robust benchmark for the federal minimum inclusion standard, including consideration of AHFS as an alternative. However, given the increasing experience over the past several years with the use of AHFS in other segments of the market, it is not clear that replacing the USP MMG with AHFS as a benchmark would fully achieve the Department's aim of improving patient access to needed therapies. This is because, while the AHFS classification system can include greater breadth and depth than the USP MMG—AHFS has the potential for four tiers of drug classification while the USP MMG only has two—as currently structured, that depth is not universal across drug categories. For example, AHFS lists only the first tier category of "antineoplastics" without any further specificity for the drug targets, mechanisms of action, or disease stage, despite the fact that an anti-cancer drug may be more or less appropriate for a patient given the type of cancer they have. Thus, a standard that relies on AHFS to identify the minimum number of antineoplastics an EHB plan must include on formulary is likely to result in a severely under-representative formulary for cancer patients.

The use of AHFS also presents additional concerns. For example, AHFS is not publicly available. Thus, it is difficult for stakeholders who do not hold an AHFS license to determine how utilizing this classification standard as an alternative may impact patient access to needed innovative therapies. Additionally, it is unclear how AHFS makes classification decisions, its process for including updates, and whether and how stakeholders can provide input into this process. While AHFS is touted as being in widespread use, there is little-to-no

publicly available information analyzing the ability of this classification system to provide for robust prescription drug formularies.[12]

Since the current structure of the USP MMG is not sufficiently inclusive of the prescription drugs enrollees may need, but AHFS is not an ideal replacement given the concerns just discussed, BIO urges HHS to work with stakeholders to develop a drug classification system specific to this EHB population and use the newly developed system as the benchmark for a minimum drug inclusion standard in the hybrid model described above. We note that a similar process was undertaken for the Medicare Part D population: HHS worked with USP to develop a drug classification system for the express purpose of being used by Part D plans in formulary development. We believe that there is an important parallel in terms of the need for a classification system that characterizes the prescription drugs likely to be needed by a specific population, in this case, EHB plan enrollees. Moreover, the development and implementation of a novel classification system to be used as a benchmark for a minimum inclusion standard could address the other concerns identified around the use of the USP MMG or AHFS, described above. To do this, BIO strongly urges HHS to utilize the following principles in the development of a novel prescription drug classification system to serve as a benchmark for plans' drug formularies:

- **Transparency**: The prescription drug classification system must be developed, implemented, and updated in a transparent, evidence-based manner with clearly defined opportunities to seek and include stakeholder input, and should be publicly available in its entirety.
- **Reflect the standard of care**: In order to reflect the current standard of care, the novel classification system must be updated annually, with a simultaneous requirement that EHB plans update their formularies accordingly, and have in place a process for incorporating new-to-market products (and newly approved indications of existing products) in a timely manner.
- **Retain sufficient breadth and depth within and across categories**: There must be a sufficient number of drug categories to represent the existing therapies that may be covered under a pharmacy benefit, and the subcategories used must be sufficiently specific if the novel classification system is to support broadly inclusive formulary structures, and in turn, to better ensure robust coverage of the therapies EHB plan enrollees may need. Where applicable, products should be listed under all relevant categories and subcategories (i.e., class overlap should be permitted) to reflect the wide range of clinically appropriate uses for which a product may be approved.
- **Appropriateness for the EHB population**: HHS must work with a diversity of stakeholders to understand the current and evolving healthcare needs of the EHB population in developing a novel prescription drug classification system to ensure it can specifically meet the needs of this population. As an aspect of appropriateness for the EHB population, HHS also should take into account the broader need to ensure that plans subject to EHB are robustly inclusive of prescription drugs, regardless whether covered as part of a medical benefit, a subject we discuss in more detail in subsection G below.

BIO recommends that HHS develop the specific minimum inclusion standard based on this novel classification system through notice-and-comment rulemaking so that stakeholders have the opportunity to provide meaningful feedback. Nevertheless, we also recommend—

[12] AHFS Drug Information. 2014. *About the Classification*, available at: http://www.ahfsdruginformation.com/pt-classification-system.aspx.

as we have historically—that HHS consider a similarly inclusive standard as that in Medicare Part D: at least two drugs per category and subcategory/subcategories of the benchmark classification system.

In addition to these principles, as the Department considers how to structure the minimum inclusion standard for plans' formularies, BIO urges HHS to reconsider its existing use of the term "chemically distinct" in the description of the drug count methodology for determining that a plan has met the EHB minimum inclusion standard. Our concern with the existing use of this term is based on the fact that, fundamentally, this term cannot be applied to biologics given the difference between the scientific principles on which they are manufactured and those used to produce small molecule drugs (for which the term was originally coined). Thus, in transition to an alternative minimum inclusion standard, HHS should not use this antiquated definition as it may inappropriately limit the number of biologics EHB plans cover.

Finally, HHS proposes an effective date for an alternative to the current drug count standard of January 1, 2017. We agree that such a regulatory change requires sufficient lead time for stakeholders to develop and execute processes to comply with an alternative framework, and believe HHS should engage with stakeholders meaningfully in the interim to develop and work to implement the hybrid model based on a novel prescription drug classification system that serves as the basis for P&T Committees to develop a formulary. Given the proposed effective date and the text of the Proposed Rule, it appears that HHS intends to continue to use the USP benchmark through benefit year 2016. If this is the case, we urge HHS to specify that the most recent published version of the USP MMG will be used until a new classification system has been developed and implemented, per the principles defined above, since earlier USP MMG versions no longer reflect the standard of care.

B. <u>HHS should finalize its proposal to require plans to establish a process and timelines for standard exception requests.</u>

BIO strongly supports HHS's proposal to 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 proposes 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 it receives the request. In urging HHS to finalize this proposal, BIO also asks that HHS strengthen existing patient protections by including requirements that plans:

- Provide beneficiaries with the initial coverage determination, including the reasons for a denial, and information describing how to appeal the decision, including relevant timelines, at the time and place the denial is made (e.g., pharmacy counter, via mail in the case of mail-order pharmacies);
- Send copies of all materials used to arrive at a denial decision to the beneficiary and, as applicable, to the independent review entity evaluating the appeal; and
- Enhance Department monitoring and enforcement activities around how plans subject to EHB manage appeals requests, including scrutinizing the rationale for coverage denials.

HHS further proposes that if a plan grants such an exception under the standard review process, it must provide coverage for the non-formulary drug for the duration of the prescription, including refills, and any cost-sharing requirements would count toward an enrollee's annual out-of-pocket maximum. This patient protection is crucial since there is a robust literature base that supports the link between higher out-of-pocket costs and decreased medication adherence.[13] Adherence, in turn, can impact short- and longer-term health outcomes and overall healthcare costs. Thus, BIO urges HHS to finalize these proposed requirements to ensure patients are able to gain timely, sustained access to needed prescription drugs. We also urge HHS to clarify that a plan cover the non-formulary drug and count cost-sharing toward the out of-pocket maximum regardless of whether a request is made pursuant to standard or expedited review. The Department also should ensure that the exceptions process is not overly onerous such that it prevents enrollees from gaining access to needed therapies.

C. HHS should finalize the proposal to require plans to establish an external exceptions review process.

BIO strongly supports, and urges HHS to finalize, the proposal to require plans to establish an external exceptions review process such that an enrollee, whose initial exceptions request has been denied, can request a secondary review of the request and the plan's denial by an independent organization. The same timelines for the review and enrollee notification of a determination would apply as those governing the proposed standard exceptions review process and the existing expedited review process, described above. An external, independent, review process to assess the merits on which a request was denied is a critical patient protection required by the ACA that is necessary to ensure coverage decisions are made based on a clinical assessment of an individual patient's circumstances.

In fact, BIO asks HHS to consider the feasibility of requiring plans to establish an additional tier in the external exceptions review process, such that if an independent organization, as described in the Proposed Rule, renders a decision against the patient's exception request, the individual has the option to make a final appeal. There are several ways that such an additional tier could be established. For example, in the Medicare Part D program, this additional appeal tier involves review by the HHS Office of Medicare Hearings and Appeals.[14] We also note that in other segments of the market, such a final review of an exceptions request can involve the state insurance commissioner.[15] Thus, we ask HHS to work collaboratively with stakeholders through a notice-and-comment process to explore the feasibility of a final exceptions review tier as an added safeguard for patients and providers. If considered, this final tier should be subject to the same enrollee notification requirements and timelines as identified for the second-tier exceptions review by an independent organization, just described.

Finally, we urge HHS to require that plans provide patients access to the product requested by the exception for the duration of the exception and appeals processes. This is an important patient protection to minimize delays and disruption in treatment that could negatively impact health outcomes in the short- and longer-term.

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[13] For example, *see* Eaddy, M. T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How patient cost-sharing trends affect adherence and outcomes: a literature review. *Pharmacy & Therapeutics* 37(1):45-55.
[14] Centers for Medicare and Medicaid Services (CMS). 2014. *Medicare Prescription Drug Appeals & Grievances; Flow Chart: Medicare Part D Appeals Process*, available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdappealsflowchart.pdf.
[15] For example, *see* Maryland Insurance Administration. *How the Appeals and Grievances Process Works*, available at: http://www.mdinsurance.state.md.us/sa/consumer/appeals-and-grievances.html.

D. HHS should finalize requirements that will improve patients' access to information on a plan's formulary before, during, and after enrollment.

HHS proposes to require EHB plans to publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained. As described in the Proposed Rule, this list must be easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and the Office of Personnel Management (OPM), and the general public. BIO strongly supports this crucial transparency provision and urges HHS to further require that cost-sharing requirements be made available in addition to the other aspects of a plan's prescription drug formulary described in the Proposed Rule. 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.

HHS also is considering requiring issuers to make this information publicly available on their 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.

E. HHS should clarify that the proposed requirements around retail pharmacies are meant to expand, not limit, patients' timely access to needed therapies.

Current policy allows EHB plans to only include mail-order pharmacies in-network, effectively requiring patients to obtain all prescription drugs through this distribution channel. In the preamble of the Proposed Rule, HHS notes the growing awareness that obtaining prescription drugs through a mail-order pharmacy in a timely manner is not always viable (e.g., some patients may not have a consistent mailing address or may need access to certain therapies more quickly than a mail-order pharmacy can provide them). In response, the Department proposes to require plans to provide enrollees the option to access their prescription drug benefit through retail (brick-and-mortar) pharmacies. As part of this proposal, plans would still be permitted to charge a higher cost-sharing amount when obtaining the drug at an in-network retail pharmacy (versus a mail-order pharmacy), but all cost-sharing amounts would be counted toward a patient's annual out-of-pocket maximum. HHS also proposes an exception to the proposed requirement that plans include an in-network retail pharmacy, such that: plans can restrict access to a particular drug when (1) the FDA has restricted distribution of the drug to certain facilities or practitioners, or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. As part of this proposed exception, HHS would require plans to publicly disclose such restricted access as part of the formulary transparency proposal described earlier.

BIO appreciates HHS's recognition of the need for patients to be able to access needed prescription drugs in the most timely, efficient, and convenient manner. We support the Department's proposals described above, as we believe it will improve patient access.

However, BIO is concerned that the proposed exception will unnecessarily hinder patient access. First, we urge HHS to clarify that this exception—allowing plans to restrict access to

a particular drug if one of two criteria is met—applies only to restricting the distribution channel through which a patient can obtain the product (i.e., that a patient would only be able to obtain the product through a mail-order pharmacy, rather than retail pharmacy) and does not restrict access to the product in general. Additionally, we believe that the second criterion is unduly broad as drafted, and therefore could undermine the impact of HHS's initial proposal to improve patients' timely access to prescription drugs and lead to clinically unreasonable restrictions on where a patient can access certain therapies. Thus, in finalizing this proposal, we urge HHS to remove the second criterion entirely, or at the very least require that plans notify HHS of any products they think meet this second exception criterion and that such notification include a written rationale for how a product meets the exception. HHS, in turn, should put in place a process to review and object to any such restrictions. The Department also should review the ability of such a process to limit the number of products restricted to mail-order pharmacy channels only in the first place.

F. HHS should require, rather than just encourage, plans to temporarily cover non-formulary drugs during the first 90 days after a coverage transition.

In the Proposed Rule, HHS encourages, but does not propose to require, plans to temporarily cover non-formulary drugs as if they were on formulary to allow new enrollees the opportunity to learn about and file exceptions requests and/or go through any prior authorization processes otherwise required. However, given the importance of sustaining access to needed therapies during insurance transitions, BIO urges HHS 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.[16] HHS 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.

G. HHS should ensure drug coverage as part of a comprehensive medical benefit is sufficiently robust to meet the needs of EHB plan enrollees.

HHS does not address the need to ensure the adequacy of plans' medical benefits in the Proposed Rule. However, patient access to such therapies is critical, and these therapies are often used to treat some of the sickest, most vulnerable individuals (e.g., those with cancer, multiple sclerosis, rare diseases, and multiple chronic illnesses). Thus, BIO asks that HHS specify that plans must offer robust coverage of drugs that are included as part of a comprehensive medical benefit and include a wide range of therapies. Also, plans' coverage should include physician-administered drugs and biologics for which a specialty pharmacy has accepted an assignment of benefits (AOB) for the product. To achieve this, review of a plan's medical benefit should be part of States, HHS's, and OPM's assessment of whether a plan is in compliance with the federal nondiscrimination requirement. Specifically, BIO urges the Department—and all other relevant authorities (e.g., OPM, states)—to ensure EHB plans comply with federal nondiscrimination requirements with regard to the structure of their medical benefit (including the use of utilization management techniques and cost-sharing requirements), similar to BIO's recommendations around ensuring nondiscrimination in the structure of plans' pharmacy benefits and provider networks (discussed throughout this letter).

[16] 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.

II. Essential Health Benefits Package: Prohibition on Discrimination

HHS Should Take an Active Oversight Role of EHB Plans' Compliance with the Prohibition on Discrimination.

In the Proposed Rule, HHS reiterates the Department's interpretation of the statutory prohibition on discrimination, such that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. HHS goes on to identify several examples of benefit designs that violate this prohibition, including: those in which an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen; and where an issuer places most or all drugs that treat a specific condition on the highest cost tiers, effectively discriminating against, or discouraging enrollment by, individuals who have those chronic conditions. BIO believes that the specificity of these examples is important, and asks that HHS consider updating the regulatory language around compliance with the prohibition on discrimination in a manner consistent with the increased specificity of these examples. Since there are multiple entities responsible for ensuring plans' compliance (e.g., HHS, OPM, states), this specificity would be practically helpful to ensure a similar standard of compliance is observed throughout the broader marketplace. However, we also ask that HHS note in the preamble that these examples are not comprehensive. For example, BIO is aware of similar discriminatory practices that can negatively impact patient access to therapies with biomarker targets.

HHS notes that when a Department examination identifies an instance in which a plan reduces benefits for a particular group—based on factors other than clinically-indicated reasonable medical management practices—the Department will notify the issuer. The issuer then may be asked to submit justification with supporting documentation to HHS or the State explaining how the plan design is not discriminatory. Where enforcement actions are taken against plans, presumably based on the sufficiency of the justification offered, BIO asks that HHS consider making such actions public to ensure patients are aware of the potential impact of their ability to access EHB and to encourage broader compliance in the marketplace (i.e., via the sentinel effect).

BIO continues to maintain that more active federal oversight of plans' compliance with the prohibition on discrimination is needed. The Proposed Rule's examples of plans that HHS considers to violate this prohibition, in turn, suggest a concerning ability of plans with clearly discriminatory benefit designs to come to the marketplace. To address this, HHS should consider specifically identifying criteria based on which it will assess plans subject to EHB for compliance with the nondiscrimination requirement. HHS also should proactively review plan offerings to better ensure plans with discriminatory benefit designs are not offered in the marketplace in the first place. For state-based Exchanges, HHS should 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. These actions, taken in concert, would better ensure that patients have equitable access to covered services and products no matter in what state they live. Finally, BIO urges HHS to provide more details on the Department's process and criteria for reviewing plan justifications where a plan has been identified as potentially employing a discriminatory benefit design, as described by example in the Proposed Rule.

III. Essential Health Benefits Package: Cost-Sharing

A. HHS should finalize the clarifications in cost-sharing policies made in the Proposed Rule with regard to calculating the annual out-of-pocket maximum.

BIO supports the clarifications HHS proposes around how beneficiary cost sharing is calculated, and urges HHS to finalize them. Namely, HHS proposes to require plans that operate on a non-calendar year to adhere to the annual limitation on cost sharing that is specific to the calendar year in which the plan begins. HHS notes that this clarification may better ensure that enrollees are only required to accumulate cost-sharing that applies to one annual limit per plan year. HHS also propose to clarify that issuers have the option to count the cost sharing for out-of-network services towards the annual limitation on cost sharing, but are not required to do so.

In particular, BIO supports the second proposal since it aims to clarify existing regulatory text that may be misinterpreted to mean that plans do not have the option to count the cost-sharing for out-of-network services toward the annual cost-sharing limitation. However, this provision, in general, raises concerns BIO expresses in more detail below that existing cost-sharing policies, including how cost-sharing for out-of-network services is treated by plans, are likely to have negative effects on continuity of care, access to physician specialists, and adherence to treatment plans (*See* the next section (B) and Section IV).

B. HHS should require plans to count all cost sharing for EHB toward the annual out-of-pocket maximum.

Evidence is beginning to emerge that plans offered on the Exchanges are increasingly employing narrow provider networks. In fact, a June 2014 analysis of all silver-plan offerings found that narrow networks (defined as including 31 to 70 percent of all hospitals in a rating area) make up about half of all exchange networks and 60 percent of the networks in the largest cities.[17] While this study defined the narrowness of a network by hospital participation, individual accounts across the country suggest that this trend toward narrow networks on the Exchanges is even more pronounced in the case of individual or group provider practices. Narrower networks means that patients, especially those with complex or difficult-to-treat conditions, may need to access services outside of their plan's provider network to ensure their provider has the appropriate expertise and training. Yet under existing policy, cost sharing on these out-of-network services may not count toward a patient's annual out-of-pocket maximum, which can effectively delay or deny the most appropriate care to him/her, in turn, impacting their health outcomes.

To address this issue, BIO urges HHS to consider requiring all cost sharing on EHB, not just cost-sharing on in-network services, to count toward a patient's annual out-of-pocket maximum. Not only is this prudent policy to ensure patient access to covered services, but requiring cost-sharing on out-of-network services to count toward the annual out-of-pocket maximum aligns with the statutory definition of cost-sharing, which includes: "(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health

[17] Bauman, N., E. Coe, J. Ogden, and A. Parikh. 2014 (June). Hospital networks: Updated national view of configurations on the exchanges. *Center for U.S. Health System Reform*, available at: http://healthcare.mckinsey.com/hospital-networks-updated-national-view-configurations-exchanges.

benefits covered under the plan."[18] Notably, cost sharing does not exclude costs expended by a patient on EHB received out-of-network.[19]

C. HHS should require plans to treat cost sharing on products or services obtained through an exceptions process the same as if those products or services were covered without the need for an exception.

BIO is committed to helping to ensure that enrollees can access the most appropriate care for them, whether in the form of access to providers or access to needed therapies. To better accomplish this goal, we ask that HHS mirror requirements being proposed by the National Association of Insurance Commissioners (NAIC) (*see* BIO's comments in Section IV below) to treat cost sharing on products or services obtained through an exceptions process the same as cost sharing on products or services that are covered without the need for an exception (e.g., for prescription drugs obtained through an exceptions process, for covered services rendered by out-of-network providers). Specifically, HHS should require plans to impose no greater cost-sharing requirements on patients who obtain services and/or products through an exceptions process. Also, as stated in our recommendation in the immediately preceding section (Section III(B)), all cost sharing on covered services obtained out-of-network should be counted toward the patient's annual maximum limitation on out-of-pocket costs. HHS should make these requirements part of the final rule as an interim step to strengthening protections against prohibitively high cost sharing for patients enrolled in EHB plans.

Additionally, as more information about existing access to prescription drugs under EHB plans becomes available, HHS should consider whether additional requirements are necessary to protect patients from untenable cost-sharing. The Department should consider how it can contribute to existing efforts to make data available on the impact of cost-sharing on patients, including considering encouraging plans to share data on the number of patients, stratified by chronic conditions, who are subject to the highest levels of cost sharing for prescription drugs.

D. HHS should consider alternative out-of-pocket limits for individuals with incomes between 250 and 400 percent of the FPL.

BIO asks that HHS consider alternative out-of-pocket limits for enrollees with household incomes between 250 and 400 percent of FPL. Compliance with medication regimens and continuity of care can be disproportionately impacted by cost sharing in this population. As we understand, there have been concerns that alternative out-of-pocket limits for this population may impact actuarial value (AV) calculations. However, we believe there may be alternatives that accomplish the aim of better protecting these patients' access to covered services without impacting AV, and urge HHS to actively pursue study of such alternatives. As one example, HHS could require plans to design and offer plan variations that meet all of the statutorily defined parameters, recognizing that in some cases this will require increases in deductibles, coinsurance, or copayments in order to meet all of the statutory criteria.

In considering alternative out-of-pocket cost limits for this enrollee population and their impact on AV calculations, BIO cautions HHS to examine how reductions in cost-sharing are applied across different benefit categories. For example, one recent study examined plans that offer cost-sharing reductions (CSRs) for individuals and families enrolling in silver plans

[18] Affordable Care Act (ACA) § 1302(c)(3)(A).
[19] ACA § 1302(c)(3)(A).

with incomes between 100 and 250 percent of FPL. In the case of CSR plans, for each standard silver plan offered on the Exchange, issuers must offer three CSR plans with increasing AVs: 73, 87, and 94 percent. This study found that plans meeting different AV percentages offered CSRs differently across benefit categories, especially with regard to cost sharing on prescription drugs.[20] As one example, the study found that "over half of the 87 [percent] AV and two-thirds of 94 [percent] AV CSR plans reduce cost-sharing for tier one (generic) prescription drugs, while only 39 [percent] and 53 [percent] of such plans, respectively, reduce cost-sharing for tier four drugs."[21] This can result, the study notes, in diminished or delayed access to innovative therapies placed on higher formulary tiers. Thus, in considering how to provide alternative out-of-pocket limits for enrollees with incomes between 250 and 400 percent of FPL, HHS also must ensure that cost sharing on individual EHB services, including prescription drugs, is not negatively affected, which could countermand the aim of such an effort in the first place by limiting patients' access to needed care.

E. HHS should further clarify the policy on applying a plan's annual limitation on cost sharing between individuals within plans other than self-only.

In the Proposed Rule, HHS intends to provide clarification around existing treatment of the annual limitation on cost sharing for self-only and family coverage. BIO agrees that such clarification is needed since many stakeholders have voiced questions about how an individual's cost sharing can be counted toward the annual limitation when that individual is insured through self-only versus family coverage. While we appreciate HHS's acknowledgement of the need for more information, the description of the Department's policy offered in the Proposed Rule's preamble is not sufficiently clear, and may actually serve to further confuse stakeholders. Thus, to better meet the Department's goal in including this section, we ask that, in the final rule, HHS clarifies how the annual limitation on cost sharing for coverage other than self-only coverage (i.e., $13,700) applies to each covered individual for cost sharing on all covered EHB services. Moreover, a positive example of how an issuer might apply the plan's annual limitation on cost sharing between the individuals in such a plan would be helpful in further clarifying the Department's intent on this issue.

IV. Qualified Health Plan Minimum Certification Standards: Network Adequacy Standards

A. HHS should bolster network adequacy standards to better ensure individuals have access to the most appropriate provider for their condition no matter in what state they reside.

BIO reiterates our concern that without sufficiently robust network adequacy standards in place, 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) may face discriminatory cost sharing that renders them effectively unable to access care in a timely manner. However, in the Proposed Rule, HHS notes that the NAIC is working to draft a Model Act relative to network adequacy and that the Department will wait for the results of this initiative before proposing significant changes to federal network adequacy policy. BIO disagrees that HHS should defer further refinement of the QHP network adequacy standards

[20] Brantley, K., H. Bray, and C. Pearson. 2014 (June). *Analysis of Benefit Design in Silver Plan Variations*. Washington, DC: Avalere Health LLC.
[21] Id. at p.4.

until NAIC finalizes a revision to their Model Act. While BIO has been closely monitoring the NAIC process, and appreciates the opportunities NAIC has provided for public comment, the final product of this process is still likely to be modified, perhaps significantly, as it is introduced in 50 state legislatures. Thus, BIO urges HHS 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 urges the Department to:

- Require, rather than just recommend, that plans 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;
- Require plans 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,
- Require plans to allow patients receiving active treatment 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.

B. <u>HHS should finalize the proposals to improve the information contained in and availability of provider directories maintained by plans subject to EHB.</u>

HHS proposes to strengthen the provider directory requirements by insisting that QHPs publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM. HHS proposes to require QHPs to update this directory at least once per month and that the general public must be able to easily access the directory online through the plan's website without creating any form of a user account. HHS also is considering requiring issuers to make this information publicly available on their websites in a machine-readable file and format specified by HHS so that third parties can aggregate this information to further inform consumers. BIO strongly urges HHS to finalize this proposal to make detailed information on providers publicly available, as we believe consumers should have the best information at hand when choosing an insurance plan to meet their healthcare needs. In addition to the proposed requirements, BIO asks HHS 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.

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[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.

C. HHS should require EHB plans to include all types of complementary immunizers in their provider networks.

BIO reiterates our concern, expressed in previous communications with the Department, that complementary immunizers are not required to be included in EHB plans' provider networks, since they often predominantly serve low-income and medically-underserved populations. Specifically, BIO believes that requiring the inclusion of pharmacies, public health department clinics, school-based clinics, and other community sites 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,[24] and nearly all Americans (94 percent) live within five miles of a community pharmacy.[25] All 50 states allow pharmacists to administer influenza, pneumococcal, and zoster vaccines, and many adults seek these vaccines in the pharmacy setting.[26] During the current 2014-15 influenza season, 25 percent of adult influenza vaccines have been administered in pharmacies.[27]

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.[28] 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

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

$1,964,267 in immunization-related costs in North Dakota alone.[29] Other states such as Arizona, California, Arkansas, Georgia, and Montana experienced success with the Billing Project.[30]

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 they did not receive the benefits they were promised.[31]

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."[32] Therefore, BIO urges HHS to require EHB plans 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.

V. Annual Eligibility Redetermination

<u>HHS Should Provide More Details on How Re-Enrollment Options Will Be Communicated to Enrollees at the Time of Initial Enrollment and When Reassignment Occurs.</u>

HHS proposes to allow enrollees to designate one re-enrollment hierarchy from among several potential options. For example, currently the default re-enrollment option prioritizes re-enrollment with the same issuer in the same or a similar plan to maximize the goal of continuity of care between benefit years. A proposed alternative—for the 2017 re-enrollment process for the federally-facilitated exchanges and potentially the 2016 re-enrollment process for state-based Exchanges—is a hierarchy based on the cost of the monthly premium of a plan. If at the time of initial enrollment, a beneficiary were to choose this cost-based hierarchical option, at the time of re-enrollment, if their current plan's monthly premium was set to increase above a certain percentage threshold (e.g., five or ten percent above the previous year), the beneficiary would be re-enrolled in a plan with a lower premium in the same metal level.

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[29] 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.
[30] 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.
[31] 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.
[32] 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.

BIO is concerned that this cost-based option inappropriately focuses on only one aspect of patients' healthcare costs, and may provide a misleading sense that an individual who chooses this reassignment option will be paying the same-as or less for health care from one year to the next. However, in fact, the differences in plans at the same metal level—with regard to provider networks, cost-sharing requirements, and benefit structures—can lead to significantly higher costs despite a similar or lower monthly premium. Therefore, to ensure that such re-enrollment options do not result in disadvantaging patients in obtaining access to the care they need, BIO asks HHS not to finalize the premium-based re-enrollment option. However, if HHS nonetheless moves forward with this option, we urge the Department to provide further details on how it will communicate the differences between an individual's current plan and the potential reassignment option. For example, while the Proposed Rule includes additional transparency requirements around benefit structure and in-network providers, we do not believe that these requirements will be sufficient on their own to ensure patients who are being automatically re-enrolled in a different plan understand the changes in their coverage. To do this effectively, HHS should consider providing a version of a side-by-side comparison tool personalized for individual beneficiaries that subscribe to the proposed cost-based re-enrollment option. The benefit of this tool is that it would aggregate the information already available to the individual in one place. Part of this communication also should include clear guidelines to assist enrollees to opt into a different plan than the one to which they were re-assigned, if they choose to do so. HHS also should provide more details around how it will track beneficiary satisfaction with the proposed re-enrollment process to better understand and adapt its processes to meet beneficiary needs

VI. Qualified Health Plan Minimum Certification Standards: Essential Community Providers (ECP)

HHS Should Clarify Its Intent With Regard to the Proposal that Multiple Providers at a Single Location Count as a Single ECP.

In the Proposed Rule, HHS notes its intention to retain the general structure of the ECP inclusion standard for QHPs that seek certification to operate on a Federally-facilitated Exchange. Namely, these QHPs need to demonstrate that they meet the general or alternative standard for inclusion of ECPs available within the plan's service area within the plan's network. The Department goes on to note that the specific inclusion criteria, in terms of the percentage of available ECPs who need to be included in a plan's network to meet the general or alternative standard, will be set by the Department through annual guidance. HHS also proposes 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."[33] On this issue, BIO urges the Department to clarify its intent in making such a proposal. Specifically, we ask that HHS address concerns that not counting multiple providers at a single location as a 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 the Department's 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.[34] Thus instead, multiple providers at a single location should count as multiple ECPs to satisfy the 30 percent inclusion standard.

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[33] 79 Fed. Reg. 70,674 (November 26, 2014) at 70,727.

[34] 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:

VII. Premium Adjustment Percentage

HHS Should Address Concerns that an Ever-Increasing Maximum Annual Cost-sharing Limitation Will Nullify This Critical Patient Protection over Time.

In the Proposed Rule, HHS notes that based on the existing methodology for calculating the maximum annual limitation on cost sharing for a given calendar year, the 2016 maximum annual cost-sharing limitation will be $6,850 for self-only coverage and $13,700 for other than self-only coverage. BIO notes that this is a $500 increase over the 2014 maximum annual limitation on cost-sharing, and we express concern that an increase of a similar magnitude year-on-year effectively could nullify this important patient protection over time. Patients' adherence to treatment regimens can be quite sensitive to increases in cost sharing,[35] as can their willingness to seek treatment in the first place. This, in turn, can have a direct, negative impact on their health outcomes and on broader healthcare spending as well (e.g., due to the need for increased hospitalizations, physician offices visits, and/or surgical procedures resulting from a lack of preventive care or delayed treatment). Therefore, we urge HHS to address how it will maintain this important patient protection, including potential alternative options for the methodology and variables used to calculate the maximum annual cost-sharing limitation to better protect patients from ever-increasing out-of-pocket costs.

VIII. Quality Standards

HHS Should Include Two Additional Principles on the Inclusion of Robust Quality Measures and Appropriate Attribution Methodology in Standards for a QHP'S QIS.

BIO supports and shares the primary goal of the QIS that QHPs participating on an Exchange must implement, which is to use market-based incentives to: improve the health outcomes of plan enrollees; prevent hospital readmissions; improve patient safety and reduce medical errors; implement wellness and health promotion activities; and, reduce health and healthcare disparities.[36] However, we urge HHS to consider additional crucial principles to those already proposed to ensure that a QHP's QIS does not restrict patient access to necessary and medically appropriate care.

Our concern about the potential for the QIS to restrict access is borne from HHS's focus on QHPs using "increased reimbursement or other incentives" without equal attention to the metrics that will access the quality of care patients receive. BIO believes that any quality measures used in the context of a QIS must meaningfully evaluate whether the patient is receiving the most appropriate course of treatment, and serve as a bulwark against the perverse incentives that can be brought about by a solitary focus on the costs of care (i.e., under-utilization of appropriate and medically necessary care). The sufficiency of a quality measure should be judged on whether it is specific to the type of care received and whether it has been demonstrated and tested to be valid and actionable as a measure of care for a specific population. In addition, it is critical that quality measures are targeted at those areas where the plans may be incented to stint on care and avoid the cost of treatments, resulting in larger public health implications. As just one example, diabetic macular edema

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https://media.gractions.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.

[35] For example, *see* Eaddy, M. T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How patient cost-sharing trends affect adherence and outcomes: a literature review. *Pharmacy & Therapeutics* 37(1):45-55.

[36] *See* ACA § 1311(g)(1).

(DME) screening is critical to avoiding blindness and disability, and as such should be included as a key quality measure.

Additionally, HHS does not address the need to ensure that QIS measures evaluate—and provide incentives to—a provider based on the variations in patients' overall care that are within a practitioner's control. Accounting for external factors (e.g., underlying health of a patient population, patient adherence, care and services received from other providers) is crucial to ensure that changes in provider reimbursement, for example, do not inappropriately penalize providers for treating sicker patients. Thus, to ensure QHPs' QIS accurately reflect the appropriateness of the care patients are receiving, we urge HHS to include the following two principles in the final rule:

- The QHP's QIS will employ robust quality measures that are disease-specific, capture the impact of care on patients, are actionable by providers, and are developed by a consensus-based organization that employs sophisticated and transparent processes for developing and endorsing measures; and
- If a QHP's QIS targets provider reimbursement within its QIS to achieve one of the give stated goals in the first principle, it will establish an attribution and risk-adjustment methodology that accurately captures, to the extent possible, variations in health, or other, outcomes that are within the provider's control.

Furthermore, in an effort to reduce administrative burdens for QHPs and providers, who provide care for patients with multiple types of insurance, HHS sets as the second principle the alignment of QIS standards and data collection with existing public and private quality improvement systems. While BIO also is sensitive to the administrative burdens of these stakeholders, we caution HHS in aligning the QHP QIS system with existing systems like those employed by Medicare. This is because there can be significant differences in the demographics and healthcare needs of the Exchange population, and existing programs in both the public and private sector may be flawed and thus inappropriate models for setting QHP QIS standards. For example, HHS identifies the Medicare Shared Savings Program (MSSP) and the Physician Value-Based Payment Modifier (VBPM) as examples of existing programs with which the QHP QIS standards should align. However, BIO notes our existing concerns with the MSSP that its selective attribution of some types of costs (e.g., the inclusion of Part B drugs costs, but the exclusion of Part D drug costs) to a provider's overall cost-of-care metric can inappropriately drive provider behavior based on economic factors rather than solely on what is most clinically appropriate for an individual patient. In addition, there is no mechanism to evaluate whether physicians are being penalized for providing the best quality of care. BIO has expressed similar concerns with the VBPM, but even more so notes that this program is still in its earliest implementation phases and should not serve as a model for nascent QIS standards given that there has been no analysis of the impact of the VBPM on patient care. Thus, we ask that HHS omit these examples and only seek to align QIS standards and timelines where there is an evidence-base for doing so.

Finally, we appreciate that HHS included a principle geared toward transparency in the development of QIS standards, and the inclusion of stakeholder feedback during development and implementation. In fact, we ask that HHS institute similar requirements around the public disclosure of the final QIS employed by each QHP and similar opportunities for public comment on the annual updates HHS proposes to require QHPs provide on the progress of QIS implementation activities, analysis of progress using proposed measures and targets, and any proposed modifications to the QIS process.

IX. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule, and reiterates our appreciation to the Department for its continued focus on improving access to needed healthcare services and therapies for patients enrolled in QHPs. We look forward to continuing to work with HHS and interested partners to ensure that QHPs 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 me 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