November 22, 2017

Eric Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

BY ELECTRONIC DELIVERY

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019 (CMS-9930-P)

Dear Acting Secretary Hargan and Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS's or the Department's) Proposed Notice of Benefit and Payment Parameters for 2019.[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

In its annual update of standards and requirements related to the exchanges and the health plans offered on them, HHS should strive for a policy framework that ensure access to health insurance also means access to appropriate care. We appreciate the work undertaken by HHS to develop and refine this framework since the inception of the Exchanges in 2014. But we believe more can and should be done. In this Notice, the Department proposes a number of modifications to foundational elements of the Exchanges – including significant changes to the ways States craft their essential health benefits (EHB) packages. We encourage the Department to carefully consider how these and other changes could impact the patient experience for those enrolled in health plans through the Exchanges.

Below, we provide detailed feedback on a number of proposed changes that could impact patient access that have been included in this year's Notice.

[1] 82 FR 51052, November 2, 2017

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I. Essential Health Benefits Package – National Prescription Drug Benefit Standard (81 FR 51102)

While not proposing such an approach in this Notice, the Department seeks feedback on the potential to establish a national benchmark plan standard for prescription drugs in conjunction with the establishment of a federal default definition of EHB.

Recommendation:

- **Prescription drugs are a critical component of many patients' treatment regimens, making it essential for patients to have access to a comprehensive prescription drug benefit.** These therapies can improve patients' lives by preventing disease in the first place, mitigating disease symptoms, halting disease progression, or curing disease altogether. Appropriate utilization of these therapies can also help to decrease overall healthcare costs by decreasing the need for hospitalizations, provider office visits, and even surgical interventions. Thus, access to these vital therapies should be prioritized. Yet emerging data suggest that patients are increasingly facing barriers in obtaining needed medicines. Although more information is needed to determine how a national benchmark plan standard for prescription drugs would be utilized before such a plan is developed, we nonetheless highlight several key considerations if such a proposal were to be developed by HHS.

  Any attempt to develop a national benchmark plan standard for prescription drugs must take into account the diverse population represented by the individuals enrolled in exchange plans across the country. Specifically, it is critical that patients with chronic or complex diseases are not disadvantaged from the exclusion of any given category and class from a standard benchmark, or an insufficient number of options available in any category and class. The different mechanisms of action, potential side effects, and disparate indications that exist for drugs of the same category and class must be taken into consideration in order to ensure that patients have access to the most appropriate treatment for a given condition. This is especially critical for patients who have complex healthcare needs due to rare diseases, which often has only one or very few approved therapeutic options. Any of these factors can have a negative impact on patient access to critical therapies and/or adherence, which can be detrimental for health outcomes, leading to greater healthcare costs in the long term.

  However, as previously noted, until more information regarding the intended use of such a national prescription drug benefit standard is explained in more detail, it is difficult to comment in full on the appropriate application and development of HHS's approach. To that end, BIO appreciates that the Department intends to publish further details on such an approach and gather stakeholder input before considering any longer-term changes.

II. Essential Health Benefits Package – State Selection of EHB-Benchmark Plan for Plan Years After January 1, 2019 (§156.111)

In implementing Section 1302 of the Affordable Care Act (ACA), HHS previously adopted an approach where States selected from among several popular plan options within their State to determine the scope of EHB. These benchmark plans serve as the basis for issuers to design

health plans that cover the statutorily-required 10 benefit categories and resemble a "typical" employer plan.

HHS now proposes to provide States with additional options in selecting their benchmark plans for 2019 and beyond. The Notice would provide for three new options:

1) Selecting another State's benchmark plan that was used in 2017;
2) Replacing entire benefit categories in the State's 2017 benchmark plan with the same categories used by another State in 2017; and
3) Selecting a set of benefits that would become the benchmark plan, provided the set of benefits does not exceed the generosity of a set of comparison plans.

States would be required to demonstrate that their benchmark plan selection contains an appropriate balance between the 10 benefit categories and provides benefits equal in scope to a typical employer plan, which HHS here defines as a produce with substantial enrollment of at least 5,000 individuals in the small or large group markets, or a self-insured group health plan with the same enrollment threshold.

A State that does not make a new selection under this framework would continue to use its benchmark plan from 2017.

Recommendations:

- **We are concerned that the additional flexibility provided to States under the proposed §156.111 could reduce patient access to prescription drugs in certain situations.** We strongly support HHS' decision to maintain the current language at §156.122 – which requires health plans to provide the greater of (1) one drug in every United States Pharmacopeia (USP) category and class or (2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. This important standard ensures that patients have access to a robust set of medicines. It is our understanding that many current EHB-benchmark plans cover drugs in excess of the one per category and class floor established in §156.122. In allowing States to seek out other States' benefit categories or craft a package of benefits out of whole cloth, the revised §156.111 could result in State benchmark plans that still technically meet the requirements of §156.122, but with much less-robust coverage than existed generally in the State prior to the selection of the new benchmark plan. We encourage HHS to examine how this proposed flexibility could erode coverage of prescription drugs, as well as guardrails the Department could adopt to prevent a "race to the bottom" for this and other categories of benefits.

- **The Department should develop a process to ensure that newly-selected State benchmark plans meet the ACA's non-discrimination and outlier requirements.** The breadth of new options for selection as a benchmark raises significant concerns that a State may select a benchmark plan that does not conform to the ACA's prohibition on discriminatory plan design or reference what would be considered a non-compliant product. For example, HHS proposes a change to the definition of "typical employer plan" for purposes of comparing the scope of benefits in the benchmark. Under the revised definition, a State could reference *any* small or large group market health plan or self-insured group health plan with enrollment of at least 5,000 as the "typical employer plan" to which its benchmark selection is compared for purposes of complying with the scope of benefits requirement at §156.111(b)(2). HHS should establish procedures and criteria to evaluate these

selections and the selection of the new benchmark itself to ensure that EHB-compliant coverage offered in a State is, in fact, typical of employer coverage offered in that State. Absent such protections, a State could select a reference plan that is itself an outlier based on the Department's non-discrimination tests or whose scope of benefits differs substantially from what most individuals would consider "typical" coverage. As a part of this process, the Department could also develop criteria and guidelines for State insurance commissioners to use in their development and selection of new benchmark plans.

- **We strongly encourage HHS to establish more definitive and robust requirements regarding the timing and public comment process when a State chooses to adopt a new EHB-benchmark plan.** If finalized as proposed, these new options could result in much more frequent – possibly even yearly – changes to a State's benchmark plan. Such changes could have significant impacts on the scope of covered services in a State and major implications for how patients covered under these health plans receive care. HHS should define in regulation a more detailed timeline around when States must submit to HHS and publish the documents necessary to change the EHB-benchmark plans, including sufficient time for the receipt of and response to public comments. HHS should also take care to require this process well in advance of the plan year in which the new benchmark would be effective so that patients have enough time to understand changes in their coverage.

III. Provision of EHB – Benefit Substitution (§156.115(b)(1)(ii))

HHS proposed to modify the requirements at §156.115 that permit benefit substitution within, but not between, the 10 categories of EHB. Under the revised requirements, health plans would be permitted to make substitutions between categories, provided that the substitution is actuarially equivalent and that it is not the prescription drug benefit.

Recommendation:

- **We support the restriction on making benefit substitutions in the prescription drug benefit category.** Allowing those types of substitutions could significantly hinder patient access to medically-necessary therapies.

IV. Functions of an Exchange – Network Adequacy (§155.200)

For 2019, HHS proposes to eliminate requirements for State-based Exchanges on the federal platform (SBE-FPs) to enforce standards for network adequacy and essential community providers, and provide SBE-FPs with the flexibility to determine how to implement network adequacy and essential community provider standards. Additionally, HHS proposes, for 2019 plan years and later, the federally-facilitated exchanges (FFEs) would rely on State reviews of network adequacy standards where the States have been determined to have an "adequate review process." However, HHS fails to define what would be considered an "adequate review process" for purposes of determining a State's network adequacy standards.

Recommendations:

- **An adequate provider network, and access to essential community providers, are critical components of health insurance coverage.** A narrow or

insufficient provider network may cause patients to delay needed care or treatment, causing undue harm. BIO is a consistent advocate that more must be done to ensure that all forms of insurance coverage provide timely, accessible, and reliable access to care. For example, patients must be able to access the providers most appropriate for them, namely, those with the expertise to provide highly-specialized care, those in sufficient proximity, and those who can provide essential care in a timely manner in settings where patients may already seek care. We firmly believe that standards for network adequacy must ensure meaningful coverage for all medically necessary care.

- **Given the importance of ensuring health insurance plans in each State offer a robust provider network to ensure that patients are able to access to the most appropriate provider in a timely fashion, BIO recommends HHS more thoroughly elaborate upon which State reviews will be deemed "adequate" and therefore, relied upon by the FFEs.**

V. Qualified Health Plan Minimum Certification Standards – Other Considerations (82 FR 51111)

BIO appreciates and supports HHS' interest in finding ways to encourage value-based insurance design within the individual and small group markets. Removing barriers to patient access to drugs and therapies is extremely important to ensuring patient adherence to needed medications. Increasingly, consumers are faced with higher cost-sharing access hurdles due to restrictive plan benefit designs. For example, the Kaiser Family Foundation's 2017 Employer Health Benefits Survey found that 83 percent of covered workers are in a plan with three, four, or more, tiers of cost sharing for prescription drugs.[2] Plans often impose coinsurance requirements of therapies placed on the highest cost-sharing tier that can exceed 33 percent. Additionally, large employers use a variety of mechanisms to restrict access to certain types of therapies (e.g., those that treat complex, chronic diseases), including utilization management (UM) programs (70%), step therapy (68%), and prior authorization (82%).[3] Although there are benefits to making individuals engaged consumers in their healthcare decisions, access restrictions placed on a given treatment must be thoroughly considered so as not to cause undue delay in needed therapies. To that end, it is critical that treatments are assessed based on value, as implementing restrictive mechanisms based on cost alone is shortsighted and detrimental to patients in the long run.

When considering value, a number of factors must be appropriately accounted for—including, but not limited to—other healthcare interventions avoided, patient outcomes and preferences, and overall savings to the healthcare system. Studies have established a clear relationship between out-of-pocket costs and access and adherence to treatment regimens.[4] Thus, any attempt to implement value-based insurance design into plans on the Exchanges must recognize the value of biopharmaceuticals and apply appropriate levels of cost-sharing to ensure that patients are able to access these life-saving medications. Furthermore, consistent access to prescription drugs can be the reason that patients with chronic diseases are able to maintain their condition and avoid costly and uncomfortable complications. Imposing unduly

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[2] Kaiser Family Foundation. 2017 (September 19). 2017 Employer Health Benefits Survey, available at: http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.

[3] Kaiser Family Foundation. 2016 (September 14). 2016 Employer Health Benefits Survey, available at: http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey.

[4] 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

burdensome access restrictions through high levels of cost-sharing or other utilization management techniques only deters patients from adhering to their providers' prescribed regimen. The result is not only detrimental to patient health outcomes, but also to the overall healthcare system which must then incur additional costs through the increase of otherwise avoidable hospitalizations and surgeries. The Department should assess and ensure flexibility to apply reduced cost-sharing to all therapies that may be clinically appropriate for an individual patient, including ensuring access to immunization services and interventions that mitigate, but do not necessarily prevent disease progression. BIO supports efforts that reduce beneficiary cost-sharing, while maintaining or improving access to necessary treatments.

Although distinct from value-based insurance design, our members are also interested in working with payors and other stakeholders to establish innovative value-based contracting arrangements that take into account a wide variety of factors and appropriately reimburse for the value of innovative therapies and interventions. However, several existing laws and regulations for Medicare Average Sales Price, Medicaid Best Price, and other government pricing calculations, currently impede the ability of manufacturers and insurers to enter into value-based arrangements. As currently written, these regulations can result in uncertain and potentially disproportionate negative impact for certain types of contracting strategies. In order to allow for the flexibility needed in the evolving value-based contracting space, regulatory changes that implement carve-outs for Best Price and all other government pricing calculations and requirements as they relate to products sold or transferred under value-based contracts should be considered. HHS should work with stakeholders—including industry, providers, patient and caregiver representatives, and payors—to establish parameters through notice-and-comment rulemaking for contracts that meet this statutory exemption (e.g., value-based contracts that financially incentivize measurable quality of care or positive health outcomes).

VI. Conclusion

BIO appreciates the opportunity to comment on the proposed Notice. We look forward to continuing to work with HHS to ensure that plans offer meaningful coverage of the EHB package and do not discriminate against the most vulnerable individuals, including those with serious, complex medical conditions and other significant healthcare needs. Please feel free to contact me at (202) 962-9200 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/

Crystal Kuntz
Vice President
Healthcare Policy and Research