



December 21, 2015

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

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
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**BY ELECTRONIC DELIVERY**

**Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 [CMS-9937-P]**

Dear Secretary Burwell and Acting Administrator Slavitt:

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 2017" published in the *Federal Register* on November 20, 2015 (the "Proposed Rule").<sup>1</sup> While we acknowledge that HHS is working diligently to provide meaningful guidance to states and other stakeholders, we find that the Department's continued reliance on a 30-day public comment period 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 healthcare industry, and public health. As established by Executive Order 12,866, 60 days is the standard comment period for major rules.<sup>2</sup> We continue to urge HHS to follow the standard comment period in the future for rules implementing the Affordable Care Act's (ACA's) requirements, particularly those which contain new or significantly modified policy proposals.

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. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also

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<sup>1</sup> 80 Fed. Reg. 75,488 (December 2, 2015).

<sup>2</sup> 58 Fed. Reg. 51,735 (October 4, 1993).

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 health insurance does not necessarily translate to access to health care, 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 for enrollees of these plans.<sup>3</sup> In addition to the data cited by BIO in last year's comment letter,<sup>4</sup> new data continues to emerge that support these concerns on a broad scale: according to a February 2015 study of silver-metal level plans, some such plans operating on the Exchanges place all drugs used to treat complex diseases on the highest drug formulary cost-sharing tier.<sup>5</sup> The same study, conducted by *Avalere Health*, found that, for 8 of the 10 drug classes studied, 2015 Exchange plans were more likely than 2014 plans to assign all single-source branded drugs to the highest cost-sharing tier. Such policies often disproportionately impact patients with complex or life-threatening conditions like HIV, cancer, multiple sclerosis, and rare diseases.

The emergence of these data casts a brighter spotlight on the need for HHS to ensure that the policy framework that governs the Exchanges facilitates, rather than hinders, patient access to appropriate care, which is the principal theme underlying BIO's feedback on the Proposed Rule. For ease of reference, we have structured our input throughout the remainder of this letter in the same order as the Proposed Rule. In general, BIO appreciates that the Department is proposing changes that aim to improve the beneficiary's experience with obtaining and using health coverage through QHPs, including with regard to the proposal to strengthen network adequacy standards. However, BIO has serious concerns that, if finalized, several of HHS's proposals may result in delaying or effectively denying patient access to appropriate care, particularly those proposals related to:

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<sup>3</sup> 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](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*, available at: [https://www.bio.org/sites/default/files/Sign%20On%20Letter%20-%20OPM%202015%20Multi-State%20Plan%20Program%20Draft%20Call%20Letter%203\\_7\\_14\\_0.pdf](https://www.bio.org/sites/default/files/Sign%20On%20Letter%20-%20OPM%202015%20Multi-State%20Plan%20Program%20Draft%20Call%20Letter%203_7_14_0.pdf).

<sup>4</sup> BIO. 2014. *Comments in Response to Notice of Benefit and Payment Parameters for 2016 Proposed Rule [CMS-9944-P]*, available at: [https://www.bio.org/sites/default/files/BIO%20Final%20Comments\\_CY%202016%20Notice%20of%20Benefit%20&%20Payment%20Parameters\\_22%20Dec%202014.pdf](https://www.bio.org/sites/default/files/BIO%20Final%20Comments_CY%202016%20Notice%20of%20Benefit%20&%20Payment%20Parameters_22%20Dec%202014.pdf).

<sup>5</sup> Avalere. 2015. *Avalere Analysis: Exchange Benefit Designs Increasingly Place All Medications for Some Conditions on Specialty Drug Tier*, available at: <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication>.

- **Third Party Payment of Qualified Health Plan Premiums:** BIO strongly urges HHS to modify its policy such that patients enrolled in Exchange plans retain access to all patient assistance programs, at least until HHS can articulate a clear, statutorily supported rationale for limiting such access. Patients—especially those who suffer from complex, chronic conditions—depend on such assistance to obtain, and maintain, access to needed care. Accordingly, HHS should not allow QHPs to discriminate against patient assistance programs. Instead these plans should be directed to accept all such payments, regardless of the source of funding.
- **Annual Eligibility Redetermination:** BIO urges HHS to consider a patient’s total out-of-pocket costs and other aspects of plan benefit design in the process of its annual eligibility redetermination. Moreover, given the potential impact that differences in plan benefit designs may have on patients’ access to care and total out-of-pocket costs, we urge the Department not to finalize the proposal to establish a re-enrollment hierarchy based on a comparison of plan premium costs alone.
- **Standardized Options:** While BIO appreciates and supports HHS’s goal of simplifying the plan-selection process for consumers, we urge the Department to reconsider the structure of the proposed standardized options, especially the design elements related to prescription drug formularies, to ensure that patients who enroll in standardized options have access to the most appropriate therapies for them.

BIO provides detailed feedback on these issues, as well as on additional provisions of the Proposed Rule, in the balance of this letter.

**I. Provisions and Parameters for the Permanent Risk Adjustment Program: HHS should continue to explore mechanisms to improve the predictive capabilities of the existing risk-adjustment methodology, while working with stakeholders to identify a risk-adjustment methodology that more accurately predicts the relationship between patients’ underlying health risks and the comprehensive cost of care.**

Robust risk adjustment methods are crucial to mitigate existing disincentives that plans face to enrolling patients with highly complex, potentially costly-to-treat conditions (e.g., in the form of inappropriate payment). In the Proposed Rule, HHS makes several proposals related to the existing process for risk-adjusting patient populations, on which BIO offers comments in the following subsection (A).<sup>6</sup> Additionally, BIO reiterates our outstanding concerns with the HHS-Hierarchical Condition Categories (HHS-HCC) risk adjustment model, which are discussed in subsection (B). In sum, BIO urges HHS to continue to explore mechanisms to improve the predictive capabilities of the existing risk-adjustment methodology until an improved model can be developed and vetted, and to work with stakeholders to identify a risk-adjustment methodology that more accurately predicts the relationship between patients’ underlying health risks and the comprehensive cost of care than does the HHS-HCC model.

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<sup>6</sup> 80 Fed. Reg. at 75,499.

**A. Proposed Updates to the Risk Adjustment Model (§153.320)**

BIO supports several aspects of HHS's proposals to update the existing process for risk-adjusting patient populations. First, BIO supports HHS's proposal to update the risk factors in the risk-adjustment model for the 2017 benefit year. We agree that the more recent the data utilized by the model, the more likely the model will reflect real-world differences in treating patients with certain underlying health or risk factors. Relatedly, given the timeline for publishing the proposed and final rules, BIO also supports HHS's proposal to publish the updated factors in the CY 2017 Notice of Benefit and Payment Parameters (NBPP) Final Rule, but recommends that the Department issue the final rule with at least a 30-day comment period specific to the updated factors such that stakeholders can understand and provide feedback on the proposed updates.

Second, BIO supports the incorporation of preventive services into the recalibrated risk-adjustment models for 2017. We believe this is an important inclusion because it will take into account the cost of providing preventive services in the baseline cost-of-care measure to which risk-adjusted costs are compared. In turn, this will ensure that providers are not penalized for spending on preventive services, such as critical vaccinations, that have the potential to prevent or mitigate the impact of serious conditions and improve general public health.

Third, BIO supports any modifications to the HCC methodology that improve its predictive capability, which we believe is essential to help mitigate the existing perverse incentives in the market to avoid patients who suffer from complex, often difficult-to-treat chronic conditions. Along these lines, BIO supports HHS's proposal to incorporate prescription drug data as a supplement to diagnostic data, to serve as a severity indicator, or as a proxy for diagnoses in cases where diagnostic data are likely to be incomplete. We believe this proposed treatment of prescription drug data strikes a good balance by capitalizing on the predictive nature of these data, while addressing concerns raised in response to the CY 2015 NBPP Proposed Rule that the incorporation of prescription drugs in the HCC model to predict expenditures may have created adverse incentives to modify discretionary prescribing. BIO strongly agrees with these commenters that the risk-adjustment methodology should reflect, but not drive, prescribing patterns, which should be based solely on clinical considerations specific to each individual patient. However, utilizing prescription drug data as a proxy for severity, or in cases in which diagnostic data are incomplete, may provide HHS an opportunity to identify how these data can be utilized in a meaningful way to provide a more comprehensive, nuanced portrait of a patient's underlying health.

In considering how to improve the predictive value of the existing risk adjustment model using these data, HHS should work with stakeholders to refine the prescription drug data that would be utilized if this proposal is finalized. For example, while prescription drug event (PDE) data is likely to be most readily available, we also ask that the Department consider how to gather and incorporate data on prescription drug utilization collected by Electronic Health Records (EHRs). Additionally, HHS should consider that prescription drug utilization is likely to be more predictive of severity in certain diseases than others, and be

mindful that different characteristics of prescription drug utilization will be more or less predictive depending on the condition. For example, in some instances, the type of prescription drug will be more indicative of disease severity, while in others, metrics such as prescription drug dose, frequency of administration, or total number of prescription drugs prescribed for a condition will be more predictive of disease severity and/or diagnosis. HHS should ensure that the proposed use of prescription drug data takes into account at least all of the factors described here so that it is as reflective of the clinical realities of treating certain types of patients as possible and is a meaningful component of the risk-adjustment model.

Fourth and finally, BIO applauds HHS's attention to "more accurately account[ing] for high-cost conditions with new treatments that are not reflected in [the current] model due to lags in the data available to us for recalibration."<sup>7</sup> However, given the historical claims data on which the HHS-HCC model relies (discussed in more detail in the next section of this letter), reducing the lag time between the availability of a new treatment and the recalibration of the model will only go so far in terms of accounting for advances in standard of care, and may never be able to do so in real time. BIO nevertheless supports HHS's proposal to diminish this lag time to the greatest extent possible. We believe this will help ensure that the risk-adjustment methodology is updated to reflect changes in the standard of care as soon as possible, based on a combination of data availability and extrapolation from existing data. We also encourage HHS to explore additional mechanisms that eliminate existing disincentives for the use of new-to-market therapies in the future (e.g., HHS could analyze the potential to establish an update to the risk-adjustment process during a benefit year in the event that sufficient data were available to account for the introduction of a major advance in the standard of care, the uptake of which has a significant impact on the cost of treating patients).

#### **B. Additional Considerations With Regard to Improving the HHS-HCC Risk-Adjustment Model**

As HHS works to improve the HHS-HCC risk adjustment model, BIO notes several targets for improvements. Analyzed collectively, these issues with the model may describe why it explains only 11 percent of the variation in costs—just half of the variability that is thought to be predictable.<sup>8</sup> Specifically, BIO is concerned that:

1. The HHS-HCC system explicitly gives zero weight to many acute conditions. While these conditions are not always "predictive" of future health spending, they are nonetheless likely to result in a need for potentially expensive services—both in the year they occur, and potentially in subsequent years.
2. The HHS-HCC is a prospective risk-adjustment model; therefore, health problems in the current year are ignored. Consequently, risk scores calculated with the HHS-HCC tend to over- or under-predict scores in the payment year versus the base year used to calculate risk scores.

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<sup>7</sup> *Id.* at 75,500.

<sup>8</sup> MedPAC, *Issues for Risk Adjustment in Medicare Advantage* (June 2012).

3. On a related note, the HHS-HCC relies on data from only one year, which limits the ability of the model to take into account prior health conditions that may be predictive of future health costs. For instance, an initial stroke can increase the cumulative risk of recurrence even ten years after it occurs.<sup>9</sup>
4. The HHS-HCC relies on historical claims data, and thus inherits the limitations of diagnosis codes recorded on medical claims (e.g., inaccurate or missing coding information). For example, diagnosis codes do not always fully distinguish differences in patient conditions that can significantly influence the nature of services that patients should receive (e.g., stage of cancer). Moreover, claims forms only allow for a limited number of diagnosis codes to be recorded and providers may not report diagnosis codes for conditions that are currently well-controlled (but that could affect future healthcare costs).
5. There may not be standardized definitions of metrics within a given HHS-HCC category, which can impact a practice's risk score. For example, morbid obesity is known to be a predictor of healthcare spending, such that HHS included it in the 2014 HHS-HCC update.<sup>10</sup> However, while the ICD-10 Code Manual defines "morbid obesity" for adults to be a BMI  $\geq 40$ , under the Medicare program, HHS covers bariatric surgery for morbid obesity, defined as a BMI of  $\geq 35$  with comorbidity.<sup>11</sup>
6. While HHS-HCC risk scores may be more accurate in predicting risk over large populations (e.g., the 1.4 million enrollees, on average, enrolled in each of the top seven national Medicare Advantage issuers), such risk scores are less likely to average out when applied to smaller patient populations (e.g., of QHPs with smaller patient enrollment) as well as to patients with rare diseases (i.e., inherently small patient populations with potentially significant heterogeneity in the clinical manifestations of disease and disease progression).

BIO is interested in working with the Department and other stakeholders to further refine the HHS-HCC methodology to address these issues, or to help identify an alternative risk-adjustment methodology that more accurately predicts the relationship between patients' underlying health risks and the comprehensive cost of care than does the HHS-HCC model.

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<sup>9</sup> A 2011 meta-analysis of the risk of stroke recurrence found that the cumulative risk of recurrence at five years after initial stroke was 26.4 percent and was 39.2 percent at ten years after initial stroke. Mohan, et al., *Stroke* (2011).

<sup>10</sup> Health Alliance. 2014. *2014 CMS—HCC Model Updates*, available at: <http://codingcounts.com/2014/02/28/2014-cms-hcc-model-updates/>.

<sup>11</sup> CMS Transmittal 2641 (Jan. 29, 2013).

**II. General Functions of An Exchange: BIO supports HHS's proposals to strengthen standards applicable to state-based exchanges and Navigator programs.**

**A. Functions of an Exchange (§155.200)**

BIO commends HHS for two of its proposals related to the general functions of the exchanges. First, BIO would like to express our support for HHS's proposal to amend §155.200(a) to include reference to subpart M, which establishes oversight and program integrity standards for State Exchanges, and subpart O, which establishes quality reporting standards for Exchanges.<sup>12</sup> We agree that this proposal incorporates important consumer safeguards already applicable in the federal marketplace to the state-based exchanges, and thus urge HHS to finalize this proposal.

Second, we support HHS's proposals to formally recognize a new category of marketplaces: a state-based exchange using the federal platform (SBE-FP). BIO is aware of state-based exchanges in four states—Hawaii, Oregon, Nevada, and New Mexico—that currently use the FFE's Healthcare.gov functionality for purposes of their enrollment and eligibility functions. We support HHS's efforts to formally extend this option to all states, as it will permit state-based exchanges to leverage existing Federal assets and operations by relying on HHS services for performing certain Exchange functions.

Relatedly, BIO also strongly supports HHS's proposal to require the SBE-FP to require its QHP issuers to comply with certain Federally-facilitated Exchange (FFE) standards governing QHPs and issuers, including certain critical standards around network adequacy and formulary drug lists. We agree with HHS that "[a]pplying the formulary drug list, network adequacy, meaningful difference, and essential community providers standards will ensure that all QHPs on HealthCare.gov meet a consistent minimum standard and that consumers obtaining coverage as a result of applying through Healthcare.gov are guaranteed plans that meet these minimum standards."<sup>13</sup> In addition, while we support HHS's proposal that "[t]he States would conduct QHP certification reviews for these standards," we believe it is critical that HHS finalize its proposal "that HHS will work with SBE-FPs to enforce the FFE standards listed under §155.200(f)(2) directly against SBE-FP issuers or plans, when the SBE-FP is not substantially enforcing one or more of these requirements."<sup>14</sup>

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<sup>12</sup> 80 Fed. Reg. at 75,518.

<sup>13</sup> Id. at 75,519.

<sup>14</sup> Id.

**B. Standards Applicable to Navigators under §§155.210 and 155.215; Standards Applicable to Consumer Assistance Tools and Programs of an Exchange under §155.205(d) and (e); and Standards Applicable to Non-Navigator Assistance Personnel in an FFE and to Non-Navigator Assistance Personnel Funded through an Exchange Establishment Grant (§§155.205, 155.210 and 155.215)**

BIO generally supports HHS's proposed modifications to the standards applicable to Navigators that would improve the ability of patients to evaluate different plan options, as well as choose and enroll in the most appropriate plan based on their healthcare needs.

We have some concerns, however, with respect to HHS's proposal that all Navigators help consumers understand and apply for exemptions from the individual shared responsibility payment that are granted by the Exchange. Specifically, we are concerned with language in the preamble to the Proposed Rule, which proposes to clarify that "[t]his assistance with Exchange-granted exemptions would include . . . helping consumers understand and use the Exchange tool to find bronze plan premiums."<sup>15</sup> We are concerned that this language could be construed as suggesting that Navigators are encouraged to, or even limited to, identifying bronze plans for consumers—yet these plans are not necessarily the most appropriate plan type for all consumers. We therefore urge HHS to clarify that the purpose of this assistance is to identify the "lowest-cost bronze plan available in the individual market through the Exchange in the State in the rating area in which the individual resides" for purposes of determining whether an individual is eligible for an exemption as an "individual[] who cannot afford coverage" under section 5000A(e)(1) of the Internal Revenue Code. We also are concerned that Navigators' limited resources could be directed to helping people avoid enrolling in health insurance under HHS's proposal—which we believe would be contrary to their core function, as established by the ACA.<sup>16</sup> To these ends, we support HHS's proposal to limit a Navigator's duty to provide assistance with filing exemption applications and filing appeals of exemption application denials "to consumers who have applied for or have been denied coverage or financial assistance, or whether another limitation should apply." We believe that this limitation will help ensure that Navigator resources are appropriately directed primarily at enrolling people in the right plan for them.

Finally, with respect to HHS's invitation for comment regarding the need for additional specificity for Navigators related to the proposed duty to help consumers understand and use their coverage, we strongly urge the Department to require Navigators to assist consumers in understanding the newly developed out-of-pocket cost calculators and, once they are available, tools to determine whether specific physicians or particular drugs are covered by a given plan. Given the novelty of these tools, and the depth and complexity of the information they aim to distill, we believe that consumers would greatly benefit from assistance in this area. Also in response to HHS's request for comment, we would support HHS making explicit in regulation that Navigators should inform consumers

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<sup>15</sup> Id. at 75,551.

<sup>16</sup> See ACA § 1311(i)(3) ("[a]n entity that serves as a navigator under a grant under this subsection shall . . . facilitate enrollment in qualified health plans.").



regarding their rights as to applicable non-discrimination standards as a required post-enrollment duty.

**III. Annual Eligibility Redetermination (§155.335(j)): HHS must consider a patient's total out-of-pocket costs and other aspects of plans' benefit designs, including access to appropriate providers, in the annual eligibility redetermination process, and should not finalize the proposal to establish a re-enrollment hierarchy that re-enrolls patients by default into a low-cost plan for the subsequent benefit year.**

In the Proposed Rule, HHS establishes a goal to facilitate an operationally efficient way of maintaining continuity for enrollees in the event that their current QHP is not available in the subsequent benefit year, a goal that underlies the Department's proposals related to the annual eligibility redetermination process.<sup>17</sup> BIO shares this goal, and believes that the ability to structure a re-enrollment process to meet this goal hinges on how HHS defines "the most similar," with regard to comparing the product into which a patient will be re-enrolled with the patient's current product.

At a minimum, this determination of similarity must assess the similarity of the monthly premium, deductible, breadth of a plan's provider network, and the patient's likely cost-sharing for items and services that are likely to be needed in the upcoming benefit year (e.g., based on items and services utilized in the current year-to-date). For example, in the case of a patient with a chronic condition, to identify a product that is the most similar to the patient's current product, the re-enrollment determination must address, at a minimum: (1) the patient's cost sharing for his/her prescription drugs, which will depend on the formulary tier on which each therapy has been placed by a particular plan; and (2) the patient's cost sharing for visits to his/her current health care providers, including specialist(s), which will depend on whether these providers are considered in-network by a specific plan. A summary of the similarity analysis, including what aspects of a plan have been compared in making the re-enrollment choice, should be provided to the patient within a timeframe that allows him/her sufficient time to consider the proposed re-enrollment choice and assess other QHP offerings before open enrollment concludes (i.e., this information should be provided to the patient at least 60 days before the conclusion of open enrollment).

HHS also requests stakeholder feedback on whether, in considering the re-enrollment process, patients should be allowed to be automatically re-enrolled into a plan that is not available through an Exchange, in situations in which a patient's existing plan will not be offered in the subsequent benefit year. BIO urges HHS not to allow this. Plans operating on Exchanges, especially on a FFE, must abide by certain requirements—including in the provision of information about the benefits each plan offers and available in-network providers—that are not necessarily required of all plans offering Essential Health Benefits (EHB). Thus, automatically re-enrolling a patient in a non-Exchange plan may make it difficult for the patient to compare the benefits he/she can expect from the plan into which he/she has been re-enrolled with those of his/her current plan. This is

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<sup>17</sup> 80 Fed. Reg. at 75,531.

concerning because ease of comparison is critical to a patient's decision-making process. Moreover, HHS specifically identifies the patient's ability to distinguish between plans as the underlying motivation for its proposals with regard to standardized options, described later in this letter.

Finally, in the Proposed Rule, HHS also requests comments on the issue of offering patients enrolled in QHPs operating on a FFE a choice of re-enrollment hierarchies at the time of the initial enrollment, such that patients "could thereby opt into being re-enrolled by default for the subsequent year into a low-cost plan, rather than his or her current plan or the plan specified in the current re-enrollment hierarchy."<sup>18</sup> BIO urges HHS not to finalize this proposal, and reiterates the concerns that we noted in response to a similar proposal in the CY 2016 NBPP Proposed Rule. Namely, we are concerned that this cost-based option inappropriately focuses on only one aspect of patients' healthcare costs (i.e., the cost of premiums), and may provide a misleading sense that an individual who chooses this reassignment option will be paying the same or less for health care from one year to the next. However, 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 overall 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.

If the Department nonetheless moves forward with this proposal, we urge HHS to delay the implementation of any such process until the requirement that QHPs provide details about their provider networks in a format that is easily available to and understood by patients has been fully implemented and plans' compliance has been verified.<sup>19</sup> Access to providers with the appropriate expertise and training is an important aspect of a patient's care and may be subject to change if a patient is re-enrolled in a different plan in a subsequent benefit year. To facilitate patients' understanding of the impact of opting-in to this type of re-enrollment hierarchy, HHS also 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 this process to meet beneficiary needs.

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<sup>18</sup> Id.

<sup>19</sup> Note: CY 2016 is the first benefit year in which the current provider directory requirements will be in place. See HHS. 2015. FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces, available at: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf>.

**IV. Denial of Certification: HHS should finalize the proposed description of the Department's authority to non-certify plans that meet minimum QHP certification standards but do not provide quality coverage to consumers.**

In the preamble of the Proposed Rule, HHS notes that Section 1311(e)(1)(B) of the ACA provides Exchanges with "the discretion to deny certification of QHPs that meet minimum QHP certification standards, but are not ultimately in the interests of qualified individuals and qualified employers."<sup>20</sup> BIO strongly agrees with HHS's proposed implementation of this statutory requirement, which would permit an Exchange to deny certification of a QHP that does not provide "quality coverage to consumers."<sup>21</sup> We believe that such implementation is consistent with the broader goal of the ACA, which is to promote improved access to health insurance as a means to improve patient access to health care.

Specifically, BIO supports HHS's proposal to utilize the authority of non-certification in instances in which a plan's issuer has not complied with applicable requirements based on the Department's assessment of past performance, including with respect to oversight concerns raised through compliance reviews and consumer complaints received. This is a critical authority to ensure that the patient protections HHS has, and continues to, put into place to enforce the ACA's prohibition on discrimination on the basis of health status are meaningful. Unless HHS can non-certify plans that have failed to comply with these requirements, the ability of the Department to enforce these patient protections will be considerably diminished. Thus, BIO urges HHS to finalize this proposed description of the Department's authority in this respect. HHS also should include in the final rule a more thorough description of the existing adjudication process in situations in which an HHS compliance review identifies a potential instance of noncompliance. In doing so, HHS should identify a process, consistent with existing procedures and resources available during and between benefit years, to notify patients of the non-certification of a plan for reasons of non-compliance with existing requirements.

BIO also appreciates HHS's note in the preamble that "OPM has the sole discretion for contracting with multi-State plans and as such retains the authority to selectively contract with multi-State plans."<sup>22</sup> We urge HHS and OPM to work together to ensure consistent standards for non-certification and discontinuation of contracts, respectively, for reasons related to verified noncompliance with existing requirements, especially those meant to protect patients from discriminatory practices. We believe that HHS and OPM should both utilize clearly identified and measurable standards and adjudication processes that are as similar as practicably possible to minimize the burden on participating QHPs and ensure transparency and predictability.

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<sup>20</sup> 80 Fed. Reg. at 75,541.

<sup>21</sup> Id.

<sup>22</sup> Id. at 75,542.

**V. Standardized Options: HHS should address concerns with the standardized options before moving forward with this proposal.**

In the Proposed Rule, HHS proposes to establish standardized options to simplify the consumer plan-selection process.<sup>23</sup> BIO generally supports the underlying goal of this proposal, which we believe has the potential to improve the affordability of health coverage for patients across a range of services. We also support the voluntary nature of the proposal, such that issuers would not be required to offer standardized options in 2017 and would retain the flexibility to offer non-standardized plans. However, we are concerned that standardized options may confuse, rather than clarify, patients' understanding of the meaningful differences between plans and may be insufficient to support the healthcare needs of certain types of patients (e.g., those with complex, chronic conditions). Specifically, the proposed specialty tier coinsurance rates in the standardized options are onerously high and may result in delaying or effectively denying certain patients' access to appropriate therapies, undermining the very intent of this proposal in the first place. Moreover, we have significant concerns that HHS has not yet put into place sufficiently robust oversight mechanisms to protect patients—both those who opt-in to the proposed standardized options and those who choose non-standardized plans—from potentially discriminatory benefit designs. Thus, BIO urges HHS to address these concerns, detailed in the following subsections, before moving forward with the standardized options proposal.

**A. Standardized Option Definition: HHS should address concerns that the standardized options will not meet the needs of “non-average” patients and may confuse, rather than clarify, plan comparisons.**

BIO agrees that a balance must be struck between promoting a robust marketplace that offers a wide variety of consumer choice—to fit the variety of patients' healthcare needs—and providing patients with the tools to navigate such a marketplace effectively and efficiently. HHS has already taken steps to strike a better balance by requiring plans to provide information about provider networks and benefit structures in a machine-readable format to facilitate the creation of consumer-compare tools for patients, similar to those that currently exist in the Medicare Part D program. In the Proposed Rule, HHS goes further, proposing to certify standardized QHP options at the bronze, silver, and gold levels of coverage, and to define a standardized option as “a QHP with a standardized cost-sharing structure specified by HHS and that is offered for sale through an individual market FFE.”<sup>24</sup> The Department also proposes that “standardized options [will] include a single provider tier, a fixed in-network deductible, a fixed annual limitation on cost sharing, and standardized copayments and coinsurance for a key set of EHB that comprise a large percentage of the total allowable costs for an average enrollee.”<sup>25</sup>

BIO is concerned that, as proposed, the standardized options may oversimplify the comparison between QHP offerings to the disadvantage of patients who are not “the average patient.” These patients often utilize the healthcare system to a greater extent than “average,” in terms of frequency and/or intensity of resource use, and include, for

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<sup>23</sup> Id.

<sup>24</sup> Id. at 75,585 (Proposed 45 C.F.R. § 156.20).

<sup>25</sup> Id. at 75,542.

example, patients suffering from complex, chronic conditions like cancer, rheumatoid arthritis, mental illness, and/or rare diseases. Such patients may be significantly impacted by the differences between the provider networks and cost-sharing requirements imposed by different standardized options, but may not be aware that these differences exist given the proposed definition and presentation of these options, which could result in choosing a plan that does not meet their healthcare needs. Moreover, in considering how to improve patients' experience choosing the most appropriate QHP for their healthcare needs, HHS should avoid structuring the standardized options based only the "average patient," and instead consider design elements that promote quality coverage for a diversity of patients.

Furthermore, to assist stakeholders in considering the potential implications of offering these standardized options, HHS should provide additional information about how these options will be described to patients to ensure that "standardized" is not misinterpreted as "the same." For example, predicted out-of-pocket costs within a specific QHP are a major component of an individual patient's decision to choose one QHP over others. These include premiums, deductibles, and cost-sharing for items and services, including provider office visits and prescription drugs. However, these are not the only considerations. While the standardized options are proposed to have no more than one in-network provider tier, HHS would need to make clear to patients that the standardized options offered in a geographic location may not include the same providers in-network. Similarly, different standardized options may place therapies on different formulary tiers while still meeting certification requirements. In sum, ensuring that patients can easily understand the difference between QHP offerings will not be any less important in the case of comparing standardized options, and thus HHS must detail how that comparison will be facilitated.

**B. Standardized Option Design Principles: HHS should improve oversight of plans' compliance with the ACA's prohibition on discrimination before moving forward with prescription drug benefit design elements that may exacerbate existing challenges to patient access.**

BIO is concerned that the HHS proposal to define standardized options as plans with four drug tiers promotes the use of a specialty drug tier—which can have the effect of discriminating against some of the sickest, most vulnerable patients—in the absence of sufficient patient protections to prevent discrimination on the basis of health status. This concern is bolstered by emerging data: as noted previously, according to a February 2015 *Avalere* study of silver metal level plans, some plans operating on the Exchanges place all drugs used to treat complex diseases on the highest drug formulary cost-sharing tier.<sup>26</sup> This appears to be a rising trend: this same study found that, in 8 of 10 drug classes studied, 2015 exchange plans were more likely than 2014 plans to assign all single-source branded drugs to the highest cost-sharing tier. 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

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<sup>26</sup> Avalere. 2015. *Avalere Analysis: Exchange Benefit Designs Increasingly Place All Medications for Some Conditions on Specialty Drug Tier*, available at: <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication>.

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.<sup>27</sup>

Thus, if HHS moves forward with this proposed standardized options structure for prescription drug formularies, the Department must simultaneously improve the robustness of its oversight activities to ensure that QHPs' benefit designs—including the use of specialty tiers and utilization management techniques (e.g., prior authorization, step therapy)—do not violate the ACA's prohibition on discrimination based on health status. As BIO has communicated to HHS on several occasions, most recently in response to the Proposed Rule entitled "Nondiscrimination in Health Programs and Activities,"<sup>28</sup> existing oversight activities are insufficient to ensure QHPs' compliance with the ACA's nondiscrimination requirements.<sup>29</sup> In particular, BIO continues to express concerns with the potentially discriminatory nature of certain benefit designs, including, as just one example, placing all therapies indicated to treat a specific condition on a specialty tier and establishing a high coinsurance cost-sharing requirement. Without broader and more robust oversight at the federal level, this proposed design element of the standardized options may inadvertently subject greater numbers of patients to such discriminatory practices.

**C. Specific Standardized Option Designs: HHS should retain only those specific design proposals that promote patient access to appropriate care.**

- i. If the standardized options proposal is finalized, HHS should retain the deductible-related design elements as proposed.

BIO strongly supports HHS's proposal to exempt the following services from the deductible of silver and gold metal level standardized options plans: primary care visits, mental health/substance use outpatient services, specialist visits, urgent care visits, and all drug benefits.<sup>30</sup> We agree that this proposal would further the ACA's goal "to ensure that access to coverage translates into access to care for routine and chronic conditions and that enrollees receive some up-front value for their premium dollars."<sup>31</sup> Ensuring that all prescription drugs are available at first-dollar coverage will facilitate the patient/provider decision-making process such that the decision to prescribe a specific therapy for a patient is driven only by the clinical appropriateness of a therapy for the individual clinical circumstances of that patient. Accordingly, this proposal may help to improve patient access to the most appropriate therapy for him/her, and in doing so, improve patient health outcomes and decrease overall healthcare expenditures (e.g., through fewer

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<sup>27</sup> 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.

<sup>28</sup> 80 Fed. Reg. 54,172 (Sept. 8, 2015).

<sup>29</sup> BIO. 2015. *Comments Submitted in Response to Nondiscrimination in Health Programs and Activities Proposed Rule* (November 9, 2015), available at: <http://www.regulations.gov/#!documentDetail;D=HHS-OCR-2015-0006-0001>.

<sup>30</sup> 80 Fed. Reg. at 75,543.

<sup>31</sup> *Id.*

hospitalizations, provider office visits, surgical interventions). BIO therefore asks HHS to finalize this proposal to the extent that the Department moves forward with the standardized options proposal at all.

- ii. Before moving forward with the standardized options proposal, HHS should significantly reform the proposed pharmacy benefit design elements to ensure that patients have access to the therapies that are most appropriate for them.

As an initial matter, BIO notes that it is unclear why HHS is proposing a coinsurance-based cost-sharing requirement for prescription drug benefits but copayment-based cost sharing for other benefits. When used appropriately, prescription drugs can improve patients' short- and longer-term health outcomes and help prevent the need to utilize other healthcare services.<sup>32</sup> Specifically, BIO is concerned that the proposed structure of the pharmacy benefit under the standardized options proposal will incentivize QHPs to place therapies on the specialty tier and to require the highest allowable cost sharing (i.e., 40 percent coinsurance), since this would not prevent the QHP from being certified, and potentially promoted, as a standardized option. In such a case, patients who are enrolled in standardized options plans, and require a therapy that has been placed on the specialty tier, would face significant out-of-pocket costs. In fact, these patients would face a higher coinsurance percentage than the average patient enrolled in a 2015 silver metal level plan, according to a recent *Avalere* analysis.<sup>33</sup> Moreover, if HHS establishes a 40 percent coinsurance ceiling as a facet of the standardized options, this may "spill over" into the broader Exchange marketplace, effectively encouraging all participating plans (even non-standardized options) to raise coinsurance rates on the highest tier to at least 40 percent.

The increased cost-sharing burden to which HHS's proposal may expose patients is especially concerning in the current environment: recent data suggests that patients are already struggling to meet cost-sharing requirements, which, in turn, is impacting their ability to obtain appropriate care.<sup>34</sup> Moreover, studies have shown that increased out-of-pocket costs can negatively impact medication adherence,<sup>35</sup> which can increase overall healthcare expenditures (e.g., through an increase in hospitalizations, emergency department visits, and surgical interventions). In light of these considerations, BIO strongly urges HHS to reconsider this design element of the standardized options before moving forward with the broader proposal.

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<sup>32</sup> See Roebuck, M. C., J. N. Liberman, M. Gemmill-Toyama, and T. A. Brennan. 2011. Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. *Health Affairs* 30(1): 91-99.

<sup>33</sup> Avalere. 2014. *Exchange Plans Increase Costs of Specialty Drugs for Patients in 2015*, available at: [http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1417539841\\_20141202\\_Exchange\\_Coinsurance\\_FINAL.pdf](http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1417539841_20141202_Exchange_Coinsurance_FINAL.pdf).

<sup>34</sup> See Families USA. 2015. Non-group health insurance: many insured Americans with high out-of-pocket costs forgo needed health care, available at: [http://familiesusa.org/sites/default/files/product\\_documents/ACA\\_HRMSurvey%20Urban-Report\\_final\\_web.pdf](http://familiesusa.org/sites/default/files/product_documents/ACA_HRMSurvey%20Urban-Report_final_web.pdf).

<sup>35</sup> 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.

- iii. If the standardized options proposal is finalized, HHS should establish dedicated oversight mechanisms to ensure that the policy facilitates patient access to high-quality care.

While BIO supports the general goals of the standardized options proposal, we recognize that robust oversight of its implementation will be necessary to ensure that these options do not result in the increased utilization of discriminatory practices in other aspects of the benefit design (e.g., restricted formularies, increase use of utilization management techniques, higher cost-sharing). Specifically, BIO strongly urges HHS to propose specific oversight mechanisms in future rulemaking—including applicable timelines, processes, and metrics—to ensure that QHPs’ standardized options designs provide quality coverage for patients, discussed as a criterion for general QHP certification earlier in the Proposed Rule, and do not discriminate against patients based on health status, as described above.<sup>36</sup> The oversight mechanisms applied to standardized options are particularly critical, as the Department proposes to call patients’ attention specifically to these plans.<sup>37</sup>

**VI. Essential Health Benefits Package: Prescription Drug Benefit: HHS should collect and analyze additional information before considering whether plans can satisfy federal requirements for exceptions processes by complying with certain state laws or regulations.**

BIO is sensitive to the need to align state law and federal regulations with regard to plans’ exceptions processes to reduce the burden of compliance. However, we believe that any efforts to balance ensuring patient access to appropriate therapies with minimizing plans’ compliance burden should favor the former goal. In fact, a robust exceptions process should be considered a criterion of “quality coverage to consumers” necessary to avoid non-certification, as described in section (IV), above.<sup>38</sup> In response to concerns that issuers in certain States may have to satisfy two standards for granting exceptions to cover non-formulary drugs, HHS proposes to allow “a plan, in a State that has coverage appeals laws or regulations that are more stringent than or are in conflict with our exceptions process under section 156.122(c), and that include reviews for non-formulary drugs, satisfies section 156.122(c) if it complies with the State’s coverage appeals laws or regulations.”<sup>39</sup>

As an initial matter, BIO urges HHS not to finalize this proposal until the Department has had the opportunity to analyze the information it receives in response to its simultaneous request for comments on “the scope of application of State appeals laws or regulations that are allowing determinations for non-formulary drugs for this purpose,” and all accompanying, relevant information.<sup>40</sup> Finalizing any proposal before clearly defining the scope of the problem it is meant to address may lead to an imprecise solution that does not rectify the issue and/or may inadvertently create negative implications in other arenas (e.g., in terms of ensuring patients have a mechanism to request, and obtain, drugs not covered by their plan).

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<sup>36</sup> 80 Fed. Reg. at 75,541.

<sup>37</sup> In the Proposed Rule preamble, HHS notes the potential to make “modifications to our consumer-facing plan comparison features to readily allow consumers to identify standardized options.” See id. at 75,544.

<sup>38</sup> Id. at 75,541

<sup>39</sup> Id. at 75,546.

<sup>40</sup> Id.



Moreover, once HHS has analyzed this information, and allowed stakeholders the opportunity to provide additional comments on such an analysis, if the Department still proposes to move forward with this proposal, we recommend a more tailored approach to ensure the federal patient protections currently in place are maintained for all patients, regardless of the state in which they reside. Specifically, if such a need is identified, we recommend HHS consider the following, amended proposal: if a plan is operating in a state that has coverage appeals laws or regulations that govern coverage appeals requests (i.e., patient requests to obtain therapies not covered by the plan) and those laws or regulations are the same as or more stringent than existing federal exceptions process requirements, plans should be allowed to satisfy federal requirements by complying with such State laws or regulations. HHS should judge whether a State's coverage appeals laws or regulations are the same or more stringent based on, at a minimum: (1) the timeframes for the standard and expedited review process utilized (i.e., more stringent than 72 hours and 24 hours, respectively); and (2) whether the processes allow for a comparable or more rigorous internal and external review process of adverse determinations (i.e., as or more stringent than the adjudication process identified in section 155.122(c)).

BIO also urges HHS to exclude from further consideration the aspect of the current proposal that would allow plans to satisfy federal requirements by complying with State coverage appeals laws or regulations that are in conflict with the federal exceptions process requirements. This feature of the current proposal undermines current federal requirements because it does not guarantee at least the same degree of patient protection, and would therefore create a dual standard for patients requesting exceptions, dependent on the state in which they reside. No matter how HHS structures a proposal to allow plans to satisfy federal exceptions process requirements by complying with applicable state laws or regulations, HHS must clarify that patients' out-of-pocket costs for the non-formulary drug obtained through an exceptions process—whether a process established by HHS or a state—count toward the annual limitation on cost sharing in accordance with existing federal policy.

**VII. Maximum Annual Limitation: HHS should address concerns that an ever-increasing maximum annual cost-sharing limitation will nullify this patient protection over time.**

HHS proposes to increase the maximum annual limitation on cost sharing for CY 2017 for self-only coverage to \$7,150 and for other than self-only coverage to \$14,300. BIO notes that this is an \$800 increase over the 2014 maximum annual limitation for self-only coverage, a \$300 increase from CY 2016. While we understand that HHS's proposal is based on existing methodology, finalized in the CY 2015 NBPP Final Rule, we continue to 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,<sup>41</sup> as can their willingness to seek treatment in the first place. In fact, recent data suggest that patients enrolled in

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<sup>41</sup> 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.

Exchanges are foregoing needed care due to high cost-sharing requirements.<sup>42</sup> 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. At a minimum, HHS should meaningfully engage stakeholders on revisions to the methodology in advance of the Department's reconsideration of the methodology, to take place in 2017 (as noted by the 2015 Final Rule).<sup>43</sup>

### **VIII. Qualified Health Plan Minimum Certification Standards**

#### **A. General Network Adequacy Standards: HHS should finalize the proposed network adequacy standards to ensure patients have timely access to providers with the requisite expertise and training.**

BIO generally supports HHS's proposed approach to implementing network adequacy standards for Exchange plans, specifically to: allow a State to choose a network standard that is at least as inclusive as a federal default standard; approve the standard(s); and then, require the State to certify that plans meet this network adequacy standard.<sup>44</sup> We also support HHS's proposals that issuers still be required to submit provider data to HHS, as well as continue to comply with all other existing reporting standards with regard to benefit and provider network design. Given the diversity of patient populations in each state, including the population density differences between and within states, BIO believes that this structure is practical for the first year that these network adequacy standards are in effect because it relies on close coordination between HHS and States, and requires States to certify issuers' compliance annually. However, we urge HHS to devote organizational infrastructure to ensure these communications are efficient, comprehensive, and continue throughout the benefit year to monitor for and address potential noncompliance rapidly. Additionally, BIO asks HHS to make the "acceptable quantifiable network adequacy metric" described in section 156.230(d)(1) publicly available for each state.<sup>45</sup>

BIO also supports HHS's proposal that a FFE would conduct an independent review under a federal default standard in instances in which states do not review for network adequacy, or do not select a standard. We believe that the county level is appropriate for

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<sup>42</sup> See Families USA. 2015. Non-group health insurance: many insured Americans with high out-of-pocket costs forgo needed health care, available at: [http://familiesusa.org/sites/default/files/product\\_documents/ACA\\_HRMSurvey%20Urban-Report\\_final\\_web.pdf](http://familiesusa.org/sites/default/files/product_documents/ACA_HRMSurvey%20Urban-Report_final_web.pdf). See also Kaiser Family Foundation. 2015 (May 21). Survey of non-group health insurance enrollees, wave 2. Figure 24, available at: <http://kff.org/health-reform/poll-finding/survey-of-non-group-health-insurance-enrollees-wave-2/>.

<sup>43</sup> 79 Fed. Reg. 13,744 (March 11, 2014).

<sup>44</sup> 80 Fed. Reg. at 75,549.

<sup>45</sup> Id.

setting the federal default standard since it is an existing, discrete geographical classification utilized by all 50 states, and can act as a proxy for population density (e.g., the physical size of a county is often based on population density). BIO also agrees with the proposal that county-specific time and distance parameters include specifications for specific provider and facility types, as the sufficiency of a provider network must be assessed based on number and type of provider (e.g., a network that only includes primary care providers could not be deemed as appropriately providing all covered benefits). Finally, BIO supports HHS's proposal to update the specifications for specific provider and facility types annually, as a more frequent interval may be overly burdensome for plans that need to construct networks around these standards and a less frequent interval may not capture meaningful changes in patients' healthcare needs with respect to access to a diverse range of providers.

In developing time and distance standards for specific facility and provider types, BIO asks HHS to consider the following issues. First, in addition to focusing on the provider types that patients most frequently visit, BIO urges HHS also to identify such standards for all specialist types with a specialty code assigned by the Centers for Medicare and Medicaid Services (CMS). At a minimum, HHS should identify standards for providers who treat the sickest, most vulnerable patients including those in need of complex and chronic care to ensure that these patients have access to providers with the requisite training and expertise. In particular, this should include: primary care providers (including obstetrician/gynecologists), dermatologists, emergency medicine, gastroenterologists, hematologists, hepatologists, nephrologists, neurologists, oncologists, ophthalmologists, orthopedists, otolaryngologists, pain medicine specialists, pathologists, psychiatrists, pulmonologists, rare disease specialists, rheumatologists, and surgery.

Second, HHS also should consider the potential to identify time and distance standards for providers who act as immunizers. This is a concern because a patient who seeks to be immunized at a public health clinic or pharmacy that has been excluded from a plan's provider network may be denied first dollar coverage (or coverage at all) for that service. In turn, the patient may decide not to receive the vaccine due to cost and an immunization opportunity would be lost. Alternatively, a more affluent patient could elect to pay the bill, but none of these costs would count toward the patient's deductible, and the patient would understandably be upset and confused as to why he/she did not receive the benefits he/she were promised.<sup>46</sup>

Third, HHS should consider the potential to identify standards for subspecialists. With regard to subspecialists, while we believe that QHPs' inclusion of oncologists should be specifically assessed—given the importance of timely and convenient access to this type of specialist for those with cancer—not all cancers are the same, and access to subspecialists, where they are available in a given geographic area, can be crucial to ensuring patients obtain expert and individualized care. Thus, in identifying time and distance standards for specific providers to serve as the federal default, we ask HHS also

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<sup>46</sup> 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>.

to consider including the subspecialties of the five most prevalent cancers by incidence—breast, prostate, lung, colorectal, and melanoma.

**B. Provider Transitions Proposal: HHS should strengthen the proposals to provide continuity of care for patients whose providers leave the plan network in the middle of a benefit year.**

BIO supports the proposed requirement in section 156.230(e) such that, when a provider's contract is terminated, a QHP offered through a FFE must provide notice to enrollees at least 30 days prior to the effective date of the change.<sup>47</sup> Additionally, HHS proposes that, if a provider is terminated without cause, a patient in active treatment must be allowed to continue treatment for the shorter of 90 days or the conclusion of the treatment. BIO strongly supports the finalization of this provision. This patient protection is important to ensure patients undergoing care do not experience interruptions in that care, which can negatively impact their short- or longer-term health outcomes. In fact, BIO urges HHS to further strengthen this important protection by both: clarifying that it extends to patients with chronic conditions that are being managed, and thus do not necessarily fit the definition of active treatment; and, allowing patients to continue to receive covered services from such a provider, as if the provider were still in-network, through the end of the plan year, rather than just for the subsequent ninety days. This extension would encompass all out-of-pocket-cost requirements, such that patients would not incur higher costs than if the provider had remained in-network, and all out-of-pocket costs would continue to count toward the patient's annual out-of-pocket maximum.

Strengthening the provider-transition provision in these important ways would help ensure continuity of care for these enrollees, thereby preventing disruptions in access to a provider who has been assisting a patient to manage a chronic condition, which could have a negative impact on patient adherence to treatment regimens and health outcomes—consequences that HHS intends to avoid through the inclusion of this provision in the first place. Additionally, these individuals often consider provider networks when choosing a health insurance plan, so extending this requirement through the end of the benefit year would facilitate patient access to the network they anticipated when enrolling in a particular plan at the beginning of the year.

**C. Out-of-Network Cost Sharing: HHS should finalize the proposals related to patient cost sharing for out-of-network provider services furnished in an in-network setting and establish protections for patients who must seek care from out-of-network providers where a plan's network does not include providers with the requisite expertise and training.**

BIO strongly supports, and urges HHS to finalize, the proposal to count the cost sharing paid by a patient for an EHB provided by an out-of-network provider in an in-network setting toward the enrollee's annual limitation. We also support the proposal to notify a patient if there is the potential for him/her to receive non-emergency care from

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<sup>47</sup> Id. at 75,585 (Proposed 45 C.F.R. § 156.230(e)).

an out-of-network provider in an in-network setting, including information with respect to potential additional charges associated with such care.<sup>48</sup> These two proposed provisions are important given the often substantial differences in patient cost-sharing between covered services rendered by in-network versus out-of-network providers. When implemented, these requirements will serve as key protections that provide patients with the best information available as they make decisions about where to receive non-emergency services.

Though not included in the Proposed Rule, BIO also asks HHS to consider adopting—through future notice-and-comment rulemaking—an additional, critical feature of the National Association of Insurance Commissioners (NAIC) Model Act, that the development of which the Department noted it was closely watching.<sup>49</sup> Specifically, BIO urges HHS to consider introducing a patient protection to address circumstances in which a patient must see an out-of-network provider because their plan’s network does not include a provider with the sufficient training or expertise to provide needed care in a timely manner. Specifically, HHS should consider requiring plans to have in place a process such that patients can request, and obtain access to, services furnished by out-of-network providers at in-network cost-sharing rates and that all out-of-pocket costs count toward the annual out-of-pocket maximum. These requirements would apply in situations in which a QHP operating on a FFE does not have a network provider of the required specialty or subspecialty with the professional training and expertise to treat the patient, or cannot provide reasonable access to a network provider with the professional training and expertise necessary without unreasonable delay. HHS also should consider applying these requirements in situations in which patients prefer to see an out-of-network mental health professional (e.g., based on the existence of a prior relationship with a given provider). BIO believes that patient preference for a provider in the instance of mental health treatment is particularly important to take into account, given the unique set of factors that can contribute to choosing a mental healthcare provider outside of simple expertise (e.g., the patient is comfortable talking about sensitive issues, trust has been established over time, the patient has grown accustomed to the treatment setting of a particular mental health provider).

We believe this comprehensive definition of when a patient may need to seek care from out-of-network providers is crucial to ensure covered patients are able to ask for and receive access to covered benefits. Moreover, ensuring patients facing these circumstances are not subject to higher cost-sharing requirements is important because cost-sharing has an inversely proportional relationship to adherence to care and patients’ willingness/ability to seek appropriate care.<sup>50</sup> Thus, higher cost sharing for out-of-network provider services can have a negative impact on patients’ short- and longer-term health outcomes. While these patient protections should be established for all patients enrolled in QHPs operating on the FFE, we note that such provisions are especially important for

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<sup>48</sup> 80 Fed. Reg. at 75,585 (Proposed 45 C.F.R. § 156.230(f)).

<sup>49</sup> NAIC. 2015. Health Benefit Plan Network Access and Adequacy Model Act. MDL-74, available at: <http://www.naic.org/store/free/MDL-74.pdf>.

<sup>50</sup> See, e.g., 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.

patients with rare diseases, for whom there may be only a few specialists in the country capable of offering appropriate care.

**IX. Third Party Payment of Qualified Health Plan Premiums (§156.1250):  
HHS Should Modify its Policy to Provide that QHPs May Not Discriminate  
Among Patient Assistance Programs and Instead Must Accept all Such  
Payments, Regardless of the Source of Funding.**

In the Proposed Rule, HHS is proposing to modify an Interim Final Rule with Comment (IFC) that was issued in early 2014,<sup>51</sup> which requires QHP issuers to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; other Federal and State government programs that provide premium and cost-sharing support for individuals; and Indian tribes, tribal organizations, and urban Indian organizations.<sup>52</sup> While BIO continues to support HHS's efforts to ensure that the patients served by these vital programs continue to benefit from them—including those patients who enroll in QHPs sold through the Exchanges—we remain very concerned that HHS has failed to provide a valid rationale as to why these assistance programs are so critical that they are treated as mandatory, while others are actively discouraged by the Department. Moreover, we believe that this policy is harmful to patients and inconsistent with the aims and intent of the ACA. We therefore support the Department's proposal to ensure patient access to premium and cost-sharing assistance provided by private, not-for-profit charitable foundations and we strongly urge HHS to further modify its policy to provide that QHPs may not discriminate among patient assistance programs and instead must accept all such payments, regardless of the source of funding. We also urge HHS not to finalize its proposed reporting requirements, which would impose an undue burden on patient assistance programs.

**A. The IFC is Harmful to Patients and Inconsistent with the Aim and Intent of the ACA.**

Over the past several decades, new therapies have made it possible to prevent, slow the progress of, and even cure many diseases, which has, in turn, reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.<sup>53</sup> However, these medications are effective only if patients take them as prescribed.

Numerous studies have found high patient out-of-pocket costs to be a major cause of non-adherence (i.e., patients not taking medications in the amount or for the duration as prescribed), and the related problem of prescription abandonment (i.e., patients failing

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<sup>51</sup> 79 Fed. Reg. 15,240 (Mar. 19, 2014).

<sup>52</sup> 45 C.F.R. § 156.1256.

<sup>53</sup> See McWilliams, J. M., A. M. Zaslavsky, and H. A. Huskamp. 2011. Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults With Limited Prior Drug Coverage. *JAMA* 306(4):402-409; See also Viswanathan, M., C. E. Golin, C.D. Jones, M. Ashok, S. J. Blalock, R.C. Wines, E.J. Coker-Schwimmer, D. L. Rosen, P. Sista, and K. N. Lohr. 2012. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. *Annals of Internal Medicines* 157(11):785-795.

to fill even the first prescription).<sup>54</sup> As noted in prior BIO comments,<sup>55</sup> for decades, insured patients—both in the employer-sponsored and individual markets—struggling to afford health insurance coverage, including the applicable cost-sharing obligations, have turned to patient assistance programs to help bridge this financial gap and obtain access to needed medications. These programs serve a particularly critical role for patients who take medications placed on the highest tiers of a plan’s benefit structure—a benefit design that has become increasingly prevalent among plans sold on the Exchanges.

As a result of the ACA, many uninsured individuals are able to purchase more affordable health insurance through the Exchanges. Yet, for many of these individuals, the cost of insurance coverage—including the applicable premium and cost-sharing obligations—is still out of reach. Indeed, although the ACA established caps on annual cost-sharing exposure and provided significant premium and cost-sharing subsidies, a review of more than 600 exchange plans revealed that QHP enrollees face high cost-sharing amounts, which will contribute to reaching the out-of-pocket maximum faster, in some cases in the span of a single month.<sup>56</sup> Moreover, despite EHB and QHP-specific requirements, drug coverage in QHPs appears to be less generous than in employer-sponsored commercial plans. To illustrate, this same analysis found that 91 percent of QHPs had specialty drug tiers—compared to only 23 percent of employer-based plans—with coinsurance rates as high as 50 percent of the cost of specialty drugs.

Furthermore, in spite of statutory and regulatory non-discrimination requirements, these high cost-sharing requirements for specialty-tier drugs disproportionately affect people with chronic diseases and disabilities. Consequently, QHP enrollees, particularly those with certain conditions, may be required to make tremendous financial sacrifices in order to access their vital medications, highlighting the acute need for patient assistance programs that serve this population.

In this context, HHS has nonetheless adopted a policy that discourages QHPs from accepting premium and cost-sharing support from healthcare providers and commercial entities.<sup>57</sup> We believe that this policy aimed at denying QHP enrollees access to patient assistance programs (whether company-based programs or not-for-profit-based programs) is wholly inconsistent with the ACA’s goals of expanding access to affordable care. We further believe that this policy undermines the ACA’s prohibition against denying coverage to individuals with pre-existing conditions by effectively barring them from accepting aid from the patient assistance programs that they rely on, and is wholly inconsistent with the ACA’s non-discrimination provisions, which require that the Secretary

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<sup>54</sup> Eaddy, M, et. al., 2012. How Patient Cost-Sharing Trends Affect Adherence and Outcomes (Literature Review). *Pharmacy & Therapeutics* 37(1): 45-55.

<sup>55</sup> BIO. 2014. *Comments Submitted in Response to Third Party Payment of Qualified Health Plan Premiums Final Rule with Comment Period* (May 20, 2014), available at: <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0035-0157>.

<sup>56</sup> Avalere Health, Analysis: Exchange Formulary Structure More Similar To Part D Than Employer Coverage (Dec. 2013), available at: <http://avalere.com/expertise/managed-care/insights/analysis-exchange-formulary-structure-more-similar-to-part-d-than-employer>. See also Avalere Health, *Consumers Likely Face High Out-of-Pocket Costs for Specialty Drugs in Exchange Plans* (Feb. 20, 2014), available at: <http://avalerehealth.net/expertise/managed-care/insights/consumers-likely-face-high-out-of-pocket-costs-for-specialty-drugs-in-excha>.

<sup>57</sup> See 79 Fed. Reg. at 15,241 (citing Center for Consumer Information & Insurance Oversight (CCIIO), *Third Party Premiums for Qualified Health Plans in the Marketplaces* (Nov. 4, 2013)).

“not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in a way that discriminates against individuals because of their age, disability, or expected length of life.”<sup>58</sup>

BIO is further concerned that HHS has adopted this policy based primarily on the unsubstantiated and cursorily described proposition that such payments could negatively affect the insurance risk pool and create an “unlevel field” in the Exchanges.<sup>59</sup> Under the Administrative Procedure Act (APA), an agency’s policy is “permissible” only to the extent that it is “rational and consistent with the statute.”<sup>60</sup> For these purposes, an agency may not consider factors Congress never authorized it to consider,<sup>61</sup> nor may an agency “avoid the Congressional intent clearly expressed in the [statutory] text simply by asserting that its preferred approach would be better policy.”<sup>62</sup> Yet, this seems to be precisely the approach taken by HHS in adopting the policy established by the IFC.

Specifically, we are unaware of a provision in the ACA that requires the Secretary to establish policies—particularly discriminatory policies—aimed at manipulating the insurance risk pool. Furthermore, even if the ACA does somehow authorize HHS to consider the impact of third-party payments on the insurance risk pool,<sup>63</sup> the APA further obligates the Department to adequately explain why this factor, when balanced against other relevant considerations and potentially conflicting statutory provisions, supports the policy in question.<sup>64</sup> This standard simply has not been met by the IFC nor the Proposed Rule. For instance, we are extremely concerned that HHS appears to be interested in balancing the risk pool by keeping people out of coverage. This would seem to directly contradict a core purpose of the ACA: to expand coverage in a non-discriminatory manner, including to those individuals with pre-existing conditions. Furthermore, HHS has yet to reconcile this policy with express requirements in the ACA that the Secretary establish standards for the certification of QHPs requiring such plans to “not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.”<sup>65</sup>

Indeed, the Department seems to recognize that it has not fully analyzed nor explained its policy. The preamble to the Proposed Rule notes that, “in making [the] determination [whether to extend the policy to cover private, not-for-profit foundations], [HHS] intend[s] to carefully review data provided by entities currently making third party premium payments and data related to the overall risk pool to better understand the impact

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<sup>58</sup> ACA § 1302(b)(4)(B).

<sup>59</sup> See 79 Fed. Reg. at 15,241 (citing CCIIO, Third Party Premiums for Qualified Health Plans in the Marketplaces (Nov. 4, 2013)).

<sup>60</sup> *NLRB v. Food & Commercial Workers*, 484 U.S. 112, 123 (1987). See also *Sullivan v. Everhart*, 494 U.S. 83 (1990).

<sup>61</sup> See, e.g., *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (“Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider . . .”).

<sup>62</sup> See *Engine Manuf. Ass’n v. EPA*, 88 F.3d 1075 (D.C. Cir. 1996).

<sup>63</sup> We recognize that the Secretary does have broad authority with respect to the Exchanges, in particular the FFE. See CCIIO, Third Party Premiums for Qualified Health Plans in the Marketplaces (Nov. 4, 2013) (citing ACA § 1321(a)).

<sup>64</sup> *State Farm*, 463 U.S. at 42-43.

<sup>65</sup> ACA § 1311(c)(1)(A).



of these payments.”<sup>66</sup> While we support the Department’s decision to evaluate data in support of its policymaking, we believe that the Department’s policymaking process should work in the opposite direction. Specifically, patients enrolled in Exchange plans should retain access to patient assistance programs unless and until HHS can articulate a clear, statutorily supported rationale for limiting such access. Meanwhile, we also urge the Department to examine other ways to address imbalances in the risk pool that are clearly and directly contemplated in the statute itself, including robust risk-adjustment and ensuring that the federal non-discrimination standards are properly overseen and enforced.

**B. HHS Should Modify its Policy to Provide that QHPs May Not Discriminate Among Patient Assistance Programs and Instead Must Accept all Such Payments, Regardless of the Source of Funding.**

In the Proposed Notice, HHS is considering whether the Department should expand the list of entities from whom issuers are required to accept payment under section 156.1250 to include not-for-profit charitable organizations. BIO generally supports this proposal, but urges the Department to go further and modify its policy to clarify that QHPs may not discriminate against patient assistance programs and instead must accept all such payments, regardless of the source of funding.

As noted in prior BIO comments, the IFC failed to expressly confirm that premium and cost-sharing payments on behalf of QHP enrollees by private, not-for-profit charitable foundations are permissible, notwithstanding that the Department had stated as much in prior guidance.<sup>67</sup> Compounding this oversight, the IFC states that the Department’s “new standard does not prevent QHPs . . . from having contractual prohibitions on accepting payments of premium and cost sharing from third party payers other than those specified in this interim final regulation.” Thus, while the Department has issued guidance indicating it intends to allow third-party payments from private not-for-profit foundations, this language from the IFC would appear to permit, and even encourage, QHPs to reject these payments, to the detriment of their enrollees. Indeed, the 2014 rule has created uncertainty and confusion among the patient support community that some independent charities that provide premium and cost-sharing might, as a result of not being specifically named in the IFR, be barred from those activities by QHPs.<sup>68</sup> Even more troublingly, the policy has had a real, negative impact on patients, as QHPs have, in fact, actually rejected patient assistance payments other than from the governmental sources enumerated in the IFC. We therefore support efforts to clarify that such payments are, indeed permitted, as proposed here, and urge the Department to move forward with this proposal as soon as possible, recognizing that any barriers to obtaining this assistance in the interim could

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<sup>66</sup> 80 Fed. Reg. at 75,558 (emphasis added).

<sup>67</sup> Specifically, on February 7, 2014, CMS issued an FAQ articulating that third-party premium/cost-sharing assistance is permissible when made by private, not-for-profit foundations on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees’ health status. CCIIO, Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces at 2 (Feb. 7, 2014). See also Letter from Gary Cohen, Director, CCIIO to Peter Saltonstall, President & CEO, National Organization for Rare Disorders (NORD) (Mar. 5, 2014).

<sup>68</sup> See Patient Services Inc. (PSI). 2014. *Comments Submitted in Response to Third Party Payment of Qualified Health Plan Premiums Final Rule with Comment Period* (May 20, 2014), available at: <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0035-0016>.

prevent individuals with significant health needs from obtaining access to insurance coverage or covered treatments.

That said, we are concerned that HHS has proposed to extend its policy only to private, not-for-profit charitable foundations, as opposed to all patient assistance programs. As noted earlier, we do not believe that the Department has sufficiently articulated its legal and policy bases for adopting this policy generally, which has had real, negative implications for patients, including those who rely on patient assistance programs operated by manufacturers and other commercial entities.<sup>69</sup> Moreover, these programs operate throughout the commercial insurance market under well-understood guidelines and may be subject to enforcement by the oversight arms of HHS and others in the event that they run afoul of these standards.<sup>70</sup> We therefore urge HHS to modify its policy such that patients enrolled in Exchange plans retain access to patient assistance programs unless and until HHS can articulate a clear, statutorily supported rationale for limiting such access. Specifically, we ask the Department to direct QHPs not to discriminate against patient assistance programs and instead must accept all such payments, regardless of the source of funding. We also ask HHS to reconsider the guardrails proposed to accompany the expansion.

We also are concerned, that the two guardrails proposed by HHS to accompany any extension of the IFC to payments to private, not-for-profit foundations are unclear and potentially nonsensical. Specifically, HHS “would intend to include guardrails intended to minimize risk pool impacts, such as limiting assistance to individuals not eligible for other [minimum essential coverage] MEC and requiring assistance until the end of the calendar year.”<sup>71</sup> We therefore urge HHS to either eliminate these proposals, or revise them in line with the following comments.

First, we disagree that premium and cost-sharing support from private, not-for-profit foundations should only be available to individuals not eligible under other MEC. As an initial matter, we are concerned that HHS has not articulated a rationale for this proposed policy, which makes it more difficult to meaningfully comment. We also are very concerned that the proposed policy would effectively direct patients who rely on patient assistance programs to enroll in non-QHP plans, which we believe is inappropriate. Individuals may choose to enroll in a QHP for any number of reasons, including that other forms of available coverage do not provide access to the benefits or to the providers they need. These individuals should not be forced to enroll in a less appropriate coverage option solely in order to retain access to the patient assistance programs that they rely on.

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<sup>69</sup> As articulated in prior BIO comments, in light of the negative tone of the FAQ discouraging QHPs from accepting premium and cost-sharing support, and the threat of undefined “action,” a minority of manufacturers have since discontinued their patient assistance programs with respect to QHP enrollees, cutting off a critical lifeline for patients who had relied on these programs to access lifesaving therapies. Furthermore, within less than a month of the IFC’s publication, at least three QHPs have barred payments from not-for-profit patient assistance programs on behalf of their enrollees.

<sup>70</sup> For example, Congress specifically applied the False Claims Act to the Exchanges, and HHS has explicitly recognized that the Department of Health and Human Services Office of Inspector General (HHS-OIG) has jurisdiction to audit, investigate, and evaluate HHS-administered programs under Title I of the ACA. In addition, depending on the conduct in question, there may be additional federal and state criminal or civil authorities that apply. See Letter from HHS Secretary Kathleen Sebelius to The Honorable Jim McDermott, U.S. House of Representatives (Oct. 30, 2013).

<sup>71</sup> 80 Fed. Reg. at 75,558.

Second, it is not clear what is meant by “requiring assistance until the end of the year.” If this is meant to require the assistance to be provided on a continuous basis, we support this proposal, but urge the Department to clarify that such assistance only need be ongoing to the extent that the patient still qualifies for assistance and is in need of support for their care. If, on the other hand, it is meant to require foundations to delay their provision of support until the end of the year in question, we are very concerned that this proposal could undermine one of the core functions of patient assistance programs: to lessen the financial impact of a patient’s course of treatment at any given point in time. Forcing patients to shoulder this burden, potentially incurring substantial debt, over the course of the year, only to receive a lump sum of assistance at the end of the year would be unworkable and unfair.

**C. HHS’s Proposed Reporting Requirements Would Impose an Undue Burden on Patient Assistance Programs.**

HHS also has proposed to require entities that make third-party payment of premiums under the IFC to notify HHS, in a format and timeline to be specified in guidance.<sup>72</sup> The notification would include, as proposed: (1) the entity’s intent to make payments of premiums; and (2) the number of customers for whom it intends to make payments. Particularly given that these data points fluctuate regularly, often on a daily basis, BIO urges the Department to re-consider this proposal, which we believe would impose an undue burden on patient assistance programs and would serve no articulated public policy interest. We also disagree with HHS’s estimate that it would take entities only about four hours to comply with this requirement,<sup>73</sup> particularly to the extent that HHS intends for these data to be segregated by market (e.g., Exchange vs. non-Exchange) and/or regularly updated. We therefore urge the Department not to finalize this proposal.

**X. Conclusion**

BIO reiterates our appreciation for the opportunity to provide this feedback in relation to the Proposed Rule. We look forward to additional opportunities to work with HHS to strengthen patient protections in the Exchanges. 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.

Respectfully submitted,

/s/

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<sup>72</sup> Id.

<sup>73</sup> Id. at 75,567.