November 4, 2015

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

BY ELECTRONIC DELIVERY

RE: Nondiscrimination in Health Programs and Activities [RIN 0945-AA02]

Dear Secretary Burwell:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments in response to the Department of Health and Human Services' (HHS's) Proposed Rule entitled "Nondiscrimination in Health Programs and Activities" published on September 8, 2015 (the "Proposed Rule").[1] BIO represents biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

In the Proposed Rule, the Department focuses on improving protections for patients—who are enrolled in health programs that receive federal financial assistance—from discrimination on the basis of race, color, national origin, sex, age, or disability as required by the Affordable Care Act (ACA). BIO applauds HHS for its work to implement this requirement, including by issuing this Proposed Rule. We agree that it is critical to strengthen protections against discrimination in order to overcome barriers to care that patients may currently face.

Along these lines, BIO notes that nondiscrimination is a prominent theme throughout the ACA, addressed through multiple mechanisms; in addition to the nondiscrimination provisions addressed in the Proposed Rule, the ACA also established prohibitions against discrimination on the basis of "health status." These standards are three-fold: a group health plan and insurers offering group health or individual health insurance coverage are prohibited from establishing conditions of eligibility, or continued eligibility, on the basis of health status;[2] plans that are subject to the ACA's "Essential Health Benefits" requirements

[1] 80 Fed. Reg. 54,172 (September 8, 2015).
[2] ACA § 1201 (codified at section 2705 of the Public Health Service Act) (prohibiting "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage [from] establish[ing] rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual: (1) Health status. (2) Medical condition (including both physical and mental illnesses); (3) Claims experience; (4) Receipt of health care; (5) Medical history; (6) Genetic information; (7) Evidence of insurability (including conditions arising out of acts of domestic violence); (8) Disability; (9) Any other health status-related factor determined appropriate by the Secretary," and that "[n]othing in this section shall be construed as prohibiting the

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(hereinafter "EHB plans")[3] are prohibited from employing a benefit design that discriminates against individuals based on factors such as age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life;[4] and a group health plan or health insurance issuer offering group or individual health insurance coverage also is prohibited from discriminating against individuals based on their participation in a clinical trial.[5] Establishing comprehensive policies and oversight mechanisms to ensure that all of the ACA's nondiscrimination requirements are met across plan enrollment criteria and benefit design is a critical element of ensuring that access to health insurance actually results in timely access to medically necessary interventions for all insured patients.

BIO continues to express concerns that existing federal regulations and guidance are insufficient to ensure patients are protec202.434.7158 ted from discrimination on these grounds, and we believe that the failure to address this issue in the Proposed Rule represents a missed opportunity to consider mechanisms to improve plans' compliance with all statutory nondiscrimination requirements. BIO therefore strongly urges the Department to issue regulations implementing the ACA's prohibitions on discrimination based on health status in a timely manner. The Department also should take steps to build upon existing federal enforcement of these requirements, taking into consideration the recommendations outlined in this letter.

In the following sections of this letter, BIO identifies concerns regarding HHS's current oversight of plans' compliance with the prohibitions against discrimination based on health status. We also recommend mechanisms to strengthen the Department's oversight and enforcement activities in this area. Specifically:

- Section I identifies concerns with regard to HHS's oversight of plans' compliance with the prohibition on discrimination with respect to enrollment requirements.
- Section II identifies concerns related to incomplete oversight with regard to plans' compliance with the nondiscrimination requirements related to individual participation in clinical trials.
- Section III identifies high-level policy options that we ask HHS to adopt in setting standards across all EHB plans.
- Section IV identifies specific policy options that we ask HHS to implement via the Department's oversight of plans offered on the federally-facilitated Marketplaces (FFM).

We urge the Department to develop and implement all such policies via a public process that seeks regular and ongoing input from all stakeholders.

Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.")

[3] These plans include: qualified health plans offered through the health benefit exchanges, as well as health insurance issuers that offer health insurance coverage in the individual or small group market. ACA §§ 1302; 1201 (codified as section 2707(a) of the Public Health Service Act).

[4] ACA § 1302 ("[i]n defining the essential health benefits . . . the Secretary shall— * * * (B) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life; (C) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; (D) ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life * * * "). See also 45 CFR § 156.125 (implementing ACA § 1302).

[5] ACA § 1201 (codified as section 2709(a)(1)(C) of the Public Health Service Act).

I. HHS Should Take an Active Oversight Role of Plans' Compliance with the ACA's Prohibition on Discrimination with Respect to Enrollment Requirements.

Ensuring that plans comply with the ACA's prohibition on discrimination in establishing enrollment criteria is a foundational element in achieving the law's primary goal: expanded access to health insurance. In fact, before the ACA was enacted, millions of Americans were denied healthcare coverage on the basis of their health status (e.g., based on the presence of a preexisting condition).[6] By some estimates, as many as 50 percent of Americans had a chronic disease that could be considered a preexisting condition at that time.[7] Treating chronic conditions accounts for the vast majority of the nation's healthcare costs, and excluding these individuals from health insurance plans often meant disruptions in care and/or an inability to receive care reliably. This, in turn, contributed to higher costs not only for the individual, but for the healthcare system in the form of otherwise-avoidable emergency department visits, hospitalizations, and surgical interventions.[8] The ACA's prohibition on discriminating against individuals based on their health status for the purposes of plan enrollment was meant to provide access to coverage, and in turn, access to care for these patients.

BIO understands that states have a primary role in ensuring compliance with this nondiscrimination requirement. Nonetheless, given its importance, we urge HHS to consider a more active role in establishing standards against which compliance with this requirement can be assessed. For example, HHS could work with states to identify aspects of enrollment eligibility criteria that would violate the nondiscrimination requirements versus those that largely support compliance. These model criteria could serve as an initial benchmark against which states can assess the compliance of group health plans and those offering group or individual health insurance coverage. Additionally, HHS could work with states to monitor complaints and appeals to identify patterns that suggest that discrimination in enrollment eligibility criteria based on health status may be occurring. HHS also should consider engaging patient advocacy organizations to understand the barriers to obtaining health insurance coverage that may still remain for patients with certain types of diseases/conditions, and work broadly with stakeholders to identify mechanisms to strengthen oversight of plans' compliance with this nondiscrimination requirement.

II. HHS Should Take an Active Oversight Role to Ensure Plans' Compliance with the ACA's Prohibition on Discrimination on the Basis of Participation in a Clinical Trial.

Clinical trials are a crucial element of drug discovery and medical advancement. Given their pivotal role as a research tool, patients should be encouraged to participate in clinical trials to further a common public health goal of continually improving the standard of medical care. The ACA's prohibition on discrimination on the grounds of clinical trial participation is a critical piece of ensuring that patients who are willing and able to contribute to clinical research are not discriminated against by their health insurance plans, either with regard to enrollment or benefit design. However, it is largely unclear whether plans subject to this prohibition are adhering to this requirement. To ensure compliance

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[6] Potter, W. 2015. *Why pre-existing conditions mattered … to millions*, available at: https://www.healthinsurance.org/blog/2015/08/19/why-pre-existing-conditions-mattered-to-millions/.
[7] ObamacareFacts. 2015. No More Pre-existing Conditions as of 2014, available at: http://obamacarefacts.com/pre-existing-conditions/.
[8] CDC. 2015. *Chronic Disease Prevention and Health Promotion*, available at: http://www.cdc.gov/chronicdisease/.

with this prohibition, HHS should work with states—that also are responsible for the oversight of such plans—to include a review of plans' policies regarding enrollee participation in clinical trials within the broader annual review and oversight process. HHS also can play an important role in establishing standards against which such plans' policies can be assessed for compliance with this nondiscrimination requirement, and share these standards with states. Finally, HHS is an important link in the oversight chain with regard to the Department's ability to help states identify trends in complaints and appeals that may signal noncompliance with this prohibition. Thus, BIO urges HHS to take a more active oversight role—including but not limited to these recommendations—and obtain stakeholder feedback on developing and implementing that role through notice-and-comment rulemaking.

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

The issue of enforcing the ACA's nondiscrimination requirements has been identified in previous Department communications, including, most recently, within the 2016 Notice of Benefits and Payment Parameters (NBPP) Final Rule and the 2016 Final Letter to Issuers on FFMs.[9] In both instances, HHS reiterates the Department's interpretation of the prohibition on discrimination within the EHB statutory provision,[10] specifically that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.[11] The Department also identifies the multiple entities responsible for ensuring plans' compliance, namely: HHS, the Office of Personnel Management (OPM) in the case of multi-state plans, and states. In fact, in the 2016 Letter to Issuers, HHS noted that enforcement of the nondiscrimination standard for EHB benefit design is "largely conducted by the states,"[12] even in the case of issuers operating on the FFMs. Though discussed in more detail in the next section, BIO acknowledges the important role of states in ensuring that nondiscrimination requirements are met by plans operating within and outside of the FFMs. However, since many issuers offer plans both within and outside of the FFMs, HHS's role in setting nondiscrimination standards for purposes of the FFM may be useful as a minimum benchmark for all issuers. Moreover, while we understand that each of these groups is a key player in preventing discrimination, the existing patchwork of enforcement undermines their respective ability to carry out this responsibility. This is evidenced by growing concerns with regard to EHB plans' provider networks and formulary design.[13]

Given these and other mounting concerns, BIO urges HHS to commit to providing more active federal oversight of plans' compliance with the prohibitions on discrimination, not only to ensure the ACA's standards are met, but to ensure the assessment of compliance with the nondiscrimination requirements is performed in a standardized,

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[9] 2016 Notice of Benefit and Payment Parameters Final Rule, 80 Fed. Reg. 10,750 (February 27, 2015); 2016 Final Letter to Issuers on FFMs: CMS. 2015 (February 20). *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.

[10] ACA § 1302(b)(4).

[11] 80 Fed. Reg. at 10,823.

[12] Final Letter to Issuers at 37.

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

consistent manner across plan types. This oversight should be comprehensive in its ability to identify noncompliance since discriminatory practices can result from different facets of a plan, including but not limited to, its benefit designs—including the cost-sharing requirements imposed on patients—the structure of its provider network, and/or its appeals and exceptions processes. Specifically, HHS should issue, and allow stakeholder comment on, regulations and/or guidance that:

- Identifies a timeline and process by which HHS will review plan offerings by issuers subject to EHB requirements to assess compliance with the health status nondiscrimination requirements;
- Identifies the criteria against which the Department and states, as applicable, will assess plans through this process, which will include criteria that identify:
    - Benefit designs that potentially limit, delay, or deny patient access to needed therapies on the basis of health status—including, at a minimum, the examples of discriminatory benefit design identified in the NBPP Final Rule;[14]
    - Provider network structures that are overly narrow and/or impose high cost-sharing on patients who must obtain services from out-of-network providers due to the narrowness of the network; and
    - Exceptions and/or appeals processes that result in an undue delay of medically appropriate care.
- Provides additional details—beyond those included in the NBPP Final Rule—with regard to the Department's process and criteria for reviewing plan justifications from those plans identified as potentially employing a discriminatory benefit design;[15] and
- Identifies a timeline and process for making public any enforcement actions taken against plans found to be in violation of the nondiscrimination requirements, to make patients aware of the plan compliance, and to encourage broader compliance across plans (i.e., via the sentinel effect).

These actions, taken in concert, would better ensure that all patients have equitable access to covered services and products, regardless of the state in which they live.

IV. HHS Should Expand Its Oversight Efforts to Ensure That Plans Offered on the FFMs Adhere to the ACA's Nondiscrimination Requirements.

HHS has direct oversight of issuers that offer plans on the FFMs through the annual Letter to Issuers guidance process, as well as its annual certification and recertification of issuer offerings. The Department does review plans' compliance with nondiscrimination requirements through these processes, but as noted above, largely delegates the responsibility of ensuring compliance to the states. In its own oversight, HHS relies on a two-track process: first, the Department requires plans to prospectively attest to compliance with the ACA's nondiscrimination requirement; and second, the Department conducts a retrospective analysis of data collected from these issuers, though it is unclear

[14] These included, but are not limited to instances in which: an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen; and where an issuer places most or all drugs that treat a specific condition on the highest cost tiers, effectively discriminating against, or discouraging enrollment by, individuals who have those chronic conditions. See 80 Fed. Reg. at 10,822. BIO also asks HHS to consider criteria that address violations such as those in which discriminatory benefit design negatively impacts patient access to therapies with biomarker targets.

[15] The NBPP Final Rule notes that, when a Department examination identifies an instance in which a plan reduces benefits for a particular group—based on factors other than clinically-indicated reasonable medical management practices—the Department will notify the issuer. The issuer then may be asked to submit justification with supporting documentation to HHS or the State explaining how the plan design is not discriminatory. 80 Fed. Reg. at 10,823.

how broad and/or comprehensive this retrospective analysis is and/or on what timeline it occurs (e.g., annually, bi-annually, ad hoc within a benefit year). The latter retrospective analysis consists of: assessing compliance through issuer monitoring and compliance reviews; analyzing patterns of appeals and complaints; performing an outlier analysis on plan cost sharing, comparing benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits; and analyzing the information contained in the Plans and Benefits Template with the objective of identifying discriminatory features or wording.[16]

As an initial matter, BIO acknowledges that these mechanisms are an important piece of identifying noncompliance, and we support their continued use. However, we are very concerned that HHS's existing efforts are not sufficient to identify instances of noncompliance among offerings on the FFMs *before* they threaten patient access to needed therapies. In the following subsections, we identify how HHS can bolster its existing oversight activities to, at a minimum, recognize and resolve instances of potential noncompliance quickly. While the Department can make many of these changes through the annual Letter to Issuers process, we strongly recommend that HHS issue regulations to codify additional oversight activities, not only to allow for broader stakeholder comment, but to ensure greater consistency and predictability across health plans nationwide.

We also encourage HHS to consider an expanded oversight role with regard to issuers on the FFM as an opportunity to improve the Department's capacity, in conjunction with OPM and states, to identify discriminatory benefit designs based on lessons learned from such oversight activities.

A. HHS should broaden its definition of "reduction in generosity" with respect to its review of issuers that offer plans on FFMs to be able to capture the range of potential practices that target patients based on health status.

In HHS's analysis of the information contained in the Plans and Benefits Template submitted by issuers offering plans on the FFMs, HHS aims to identify discriminatory features and wording that involve a "reduction in the generosity of a benefit for subsets of individuals for reasons not clearly based on common medical management practices."[17] In doing so, BIO continues to recommend that the Department judge a "reduction in generosity" by whether it introduces a delay in timely access to care for certain patient sub-groups, not just by whether it reduces the amount of coverage or introduces discriminatory changes in cost sharing for these groups.[18] Any plan policy that delays or denies certain patients' timely access to needed providers and/or treatments falls within the prohibition on discrimination on the basis of health status and thus should be considered by the Department as part of this analysis. We also ask that HHS provide more information with regard to how the Department will proceed when this analysis identifies an instance of potential noncompliance, including details regarding the processes and timeframes for notice, hearing, and appeal, as well as the final actions the Department may take when noncompliance is confirmed.

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[16] 2016 Final Letter to Issuers at 37.
[17] Final Letter to Issuers at 38.
[18] For previous instances in which BIO made this recommendation, see BIO. 2015 (January 12). *BIO Response to the DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces*, available at: https://www.bio.org/sites/default/files/BIO%20Final%20Comments_CY%202016%20Draft%20Letter%20to%20Issuers%20on%20FFM_12%20January%202014.pdf; also see BIO. 2014 (February 25). *BIO Response to the Draft 2015 Letter to Issuers on Federally-facilitated Marketplaces*, available at: https://www.bio.org/sites/default/files/BIO%20Final%20Comments_draft%202015%20Letter%20to%20Issuers%20on%20FFM_25%20Feb%202014_0.pdf.

B. HHS should assess whether its current outlier analysis is able to identify potentially discriminatory practices with respect to the use of utilization management techniques and the specialty tier.

BIO appreciates that HHS continues to conduct an outlier analysis—in assessing FFM plans' compliance with the ACA's health status nondiscrimination requirements—that applies broadly to EHB plans. However, in addition to assessing plans' cost sharing requirements (e.g., copayments and coinsurance) as part of this analysis, we urge the Department also to include an assessment of each plan's use of specialty tiers and other utilization management techniques. This is important because certain prescription drug utilization management techniques, including specialty tiers, can discriminate against individuals with complex or chronic health conditions, who may need highly-targeted drug therapies or a regimen of multiple concurrent therapies. Thus, utilization management techniques could disproportionately affect these individuals, delaying or effectively denying their timely access to care, and thereby discouraging them from enrolling or re-enrolling in such a plan. Similarly, specialty-tier policies that place all therapies for a given condition on the highest cost-sharing tier may discourage plan participation by the patients who rely on those therapies to manage their disease. Moreover, a clear link has been established between higher cost sharing and decreased patient adherence to therapy.[19] Thus, among those patients who remain enrolled in these plans, discriminatory specialty-tier policies can negatively impact patient health outcomes and may even increase overall costs by leading to increased hospitalizations, physicians' office visits, and surgical interventions.

C. HHS should clarify its existing out-of-pocket-costs-based analysis' CY 2015 methodology and findings, and expand the therapeutic areas targeted by the analysis to include multiple sclerosis, hemophilia, rare diseases, and cancer in future years.

In the 2016 Final Letter to Issuers, as an extension of the outlier analysis described in the previous section, HHS committed to employing an analysis to identify plan outliers based upon estimated out-of-pocket costs associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines.[20] HHS went on to identify five specific conditions for which this analysis would be performed: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia. However, no additional details about the methodology for this analysis were provided in the Final Letter to Issuers.

BIO continues to support the conduct of this additional analysis, as we did in comments in response to the Draft Letter to Issuers, as we believe it represents important progress in HHS's oversight of plans' compliance with the ACA's nondiscrimination requirements. In general, this outlier analyses should help HHS ensure that the structure of plans' benefits are not incentivizing the choice of a therapy based on factors other than what is the most clinically appropriate for an individual patient. These assessments also can offer insights into each plan's coverage of innovative or newly-approved therapies aligned with clinical guidelines and best practices (e.g., use of therapies in first-line or only in second- or third-line cancer cases).

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[19] Eaddy, M, et. al., "How Patient Cost-Sharing Trends Affect Adherence and Outcomes", Literature Review, P&T, 37(1): 45-55, (2012). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/.
[20] Final Letter to Issuers at 38.

That said, to help stakeholders understand the sensitivity of the analysis and its contribution to the Department's oversight framework, we ask HHS to provide additional details about the methodology that will be used for this analysis—to be implemented in 2016—as soon as possible (e.g., which guidelines will be referenced, how estimated out-of-pocket costs will be calculated). We also encourage the Department to allow stakeholder input on this methodology both prior to implementation and on an ongoing basis as HHS refines this new analysis tool. BIO also urges HHS to adapt the outlier analysis to assess whether patients have meaningful access to the therapies they need, whether covered through inclusion on a plan's drug formulary or through a plan's comprehensive medical benefit.

Additionally, HHS should consider including four additional conditions in future iterations of the analysis: multiple sclerosis, hemophilia, rare diseases, and cancer. Patients with these conditions rely on access to therapies as a vital part of their treatment regimen, and as noted previously, high out-of-pocket costs can adversely impact access to therapies and patient adherence to medication regimens.[21] Additionally, evidence is emerging that patients with these conditions already may have trouble accessing needed therapies:

- **Multiple Sclerosis:** A 2014 Avalere analysis found that 50 percent of the 123 silver plans offered through the Exchanges require coinsurance of at least 30 percent for all multiple sclerosis therapies.[22]
- **Hemophilia:** Concerns around the potential difficulties that hemophilia patients face in gaining access to needed therapies—due to the out-of-pocket costs associated with the formulary tiers on which these therapies are often placed—have been documented as well.[23]
- **Rare Disease:**[24] Similarly, recent analysis has shown that certain rare disease therapies are most likely to be placed on plans' highest formulary tiers, subjecting patients to coinsurance of up to 50 percent.[25]
- **Cancer:** Additional Avalere analysis found similar practices for therapies treating certain types of cancer covered under plans' pharmacy benefits. Moreover, concerns have been raised with regard to the adequacy of plans' inclusion of innovative drugs and biologicals used to treat cancer as part of a comprehensive medical benefit: a 2014 American Cancer Society analysis raised concerns about potential gaps in formulary coverage of anti-cancer therapies that are administered intravenously (since these are often included as part of plan's medical benefit, but federal oversight of plans' compliance with prescription drug requirements generally focuses on the structure of plans' pharmacy benefit).[26]

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[21] Eaddy, M. et. al. 2012.
[22] Avalere. 2014. *An Analysis of Exchange Plan Benefits for Certain Medicines*. Washington, DC: Avalere, http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines.
[23] For example, *see* Hemophilia Federation of America. 2013. Issue Brief: Specialty Tiers, available at: http://www.hemophiliafed.org/uploads/Specialty-Tiers_Issue-Brief_HFA_2013_FINAL.pdf.
[24] Though there is no formal definition of a "rare disease," it is generally considered to affect fewer than 200,000 people in the U.S., *see* FDA. 2015. *Developing Products for Rare Diseases & Conditions*, available at: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm.
[25] Robinson, S. W., K. Brantley, C. Liow, and J. R. Teagarden. 2014. An Early Examination of Access to Select Orphan Drugs Treating Rare Diseases in Health Insurance Exchange Plans. *Journal of Managed Care and Specialty Pharmacy* 0(10):997-1004.
[26] American Cancer Society-Cancer Action Network. 2014 (March). Cancer Drug Coverage in Health Insurance Marketplace Plans, available at: http://www.acscan.org/content/wp-content/uploads/2014/03/Marketplace_formularies_whitepaper.pdf.

Thus, to better understand whether plans operating in the FFMs are providing adequate access to the therapies these vulnerable patients need, we strongly urge HHS to include multiple sclerosis, hemophilia, rare diseases, and cancer to the outlier analysis in future years.

In addition to supporting the inclusion of additional conditions in the outlier analysis, we encourage the Department to provide more detail on what criteria and timelines will be used to update this list of specific conditions in the future and ensure that stakeholders have an opportunity to comment on any such amendments before they are finalized. We also encourage HHS to consider compiling and publicly releasing a general summary of the findings of these analyses. This would be helpful for stakeholders interested in evaluating the utility of such an analysis in ensuring plan's compliance with nondiscrimination standards for future years and the potential to expand this analysis more broadly to all plans subject to the ACA's nondiscrimination requirements.

V. 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 compliance across all of the ACA's nondiscrimination requirements. 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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