Biotechnology Industry Organization

June 10, 2014

Jacob J. Lew
Secretary, Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

Thomas E. Perez
Secretary, Department of Labor
Frances Perkins Building, 200 Constitution Ave., NW,
Washington, DC 20210

Sylvia Mathews Burwell
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding Provider Nondiscrimination

Dear Secretaries Lew, Perez, and Burwell:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the "Request for Information Regarding Provider Nondiscrimination" (the "RFI") issued by the Departments of Treasury, Labor, and Health and Human Services ("the Departments") on March 12, 2014.[1]

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Thanks to the Affordable Care Act (ACA), many uninsured individuals are able to purchase more affordable health insurance through the group and individual markets, including through state-based and federally-facilitated health insurance Marketplaces. However, increased access to insurance coverage does not necessarily translate to increased access to appropriate, high-quality care. To fulfill the goals of the ACA, the Departments must ensure that plans offered in the group and individual market, including those offered through the Marketplaces, design their provider networks in a manner that does not limit enrollee access to the most appropriate healthcare providers, based on both the provider's specialty and geographic location.

As the RFI notes, the ACA specifically prohibits health plans from discriminating against "any health care provider who is acting within the scope of that provider's license or certification under applicable state law."[2] However, a July 2013 report from the Senate

[1] 79 Fed. Reg. 14,052 (March 12, 2014).
[2] Public Health Service Act (PHS Act) § 2706(a), as added by ACA § 1201.

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Committee on Appropriations—prepared partially in response to the Departments' April 2013 guidance on implementing this nondiscrimination requirement—goes further to state that the basis for the ACA's provider nondiscrimination requirement was the tenet that "patients have the right to access covered health services from the full range of providers licensed and certified in their State."[3] Based on this description, BIO has significant concerns, discussed in detail below, that adherence to this underlying principle is not being met by the Departments' current implementation of the ACA's nondiscrimination requirement. Specifically, we believe that insufficient tracking of provider networks has made it difficult to gauge compliance with the ACA's nondiscrimination requirements. Nonetheless, we are concerned that initial information indicates patients are being denied access to the most appropriate providers for their care. We are further concerned that the Departments have inaccurately interpreted the criteria under which variations in provider reimbursement may be permissible under the statutory nondiscrimination provision.

I. Insufficient tracking of provider networks offered in the group and individual markets has made it difficult to gauge compliance with the ACA's provider nondiscrimination requirements.

BIO appreciates the Departments' attention, through activities such as issuing this RFI, to the importance of enforcing the ACA's provider nondiscrimination requirement. However, it is our understanding that the Departments' implementation of this provision currently relies solely on information gained passively through, for example, "complaint data, issuer self-reporting of problems, [and] information related to customer service and satisfaction . . . ."[4] BIO is concerned that this strategy cannot produce the data required to make an accurate and timely assessment of compliance with the ACA's provider nondiscrimination requirements.

By contrast, an approach that utilized reporting requirements for issuers, along with an active review of the information reported, would be more likely to keep noncompliant offerings from being introduced on the market, while enabling more rapid identification of noncompliance and the ability to track broader trends across markets and within specific Marketplaces. We note that this latter strategy is currently employed to assess compliance with the ACA's requirement regarding essential community providers, as described in the 2015 Final Letter to Issuers on Federally-facilitated Marketplaces,[5] and there is no reason that a similar strategy could not be adopted for determining patients' overall access to providers. We encourage the Departments to collaborate to identify a strategy along these lines that balances minimizing the reporting burden to issuers and the review burden to the government with the need to preserve and protect patient access to all types of needed providers.

For instance, BIO supported the Centers for Medicare & Medicaid Services' (CMS's) proposal in the Draft 2015 Letter to Issuers to consider "appropriate formats for collection of [data on the specific providers included in a plan's networks] which would enable creation of a search engine function for consumers to search for particular providers and provider types."[6]

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[3] S. Rep. No. 113-71, at 126 (2013).
[4] CCIIO, CMS. 2014. Final Letter to Issuers in the Federally-facilitated Marketplaces, p.36. Baltimore, MD: CMS, Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.
[5] Id. at 18-20.
[6] Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS). 2014. Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces, p.20. Baltimore, MD: CMS, Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf.

Compiling and sharing this information for all offerings in the group and individual markets would not only allow the Departments to proactively track each plan's provider inclusiveness, but would allow patients to make better-informed decisions when choosing the coverage most appropriate for them and their families. This proposal was reiterated in the Final Letter to Issuers but not finalized. Thus, we urge CMS to more completely develop the proposal for inclusion in the 2016 Letter to Issuers, and for the Departments in general to determine how best to support the collection, analysis, and dissemination of this information to ensure compliance with the ACA's provider nondiscrimination requirements.

II. Initial evidence suggests that patients are not able to access the full range of appropriate providers.

As the previous section illustrates, the Departments' current policies for tracking plans' compliance with provider nondiscrimination requirements leave much to be desired. Nonetheless, emerging anecdotal evidence illustrates that patients may not have access to the providers they need. For instance, the Associated Press (AP) recently surveyed 23 institutions that are part of the National Comprehensive Cancer Network.[7] They found that only four of 19 nationally-recognized comprehensive cancer center respondents in the AP sample reported that patients had in-network access to their services through all offerings in their state's Marketplace.

This example demonstrates that the express Congressional intent stated in the July 2013 Senate Committee on Appropriations' Report is not being met universally, as patients may not be able to "access covered health services from the full range of providers licensed and certified in their State."[8] Hindering access to this broad array of providers disproportionately impacts some of the sickest and most vulnerable patients, limiting their access to the highest-quality care, and thereby impeding the potential for the best possible health outcomes. These concerns around access to providers are further exacerbated for patients in rural areas and those with rare diseases. Currently, it remains unclear whether patients in rural areas are able to access appropriate providers close to them, or whether patients with rare diseases can access specialists of which there may be very few throughout the country. It also is unclear whether excluding comprehensive cancer centers from covered provider networks—as reported by the AP—may have on patients' ability to participate in clinical trials ongoing at these institutions in particular.

Across-the-board, excluding certain types of providers from plan networks not only can negatively impact health outcomes but may serve to increase overall healthcare costs. This is because patients who are not able to access the highest degree of individualized care for their specific characteristics may end up requiring additional hospitalizations, surgical interventions, and/or physical office visits. We also note that limiting access to high-quality, integrated care undermines the ACA's focus on improving coordinated care—evidenced by the ACA provisions that established the Medicare Shared Savings Program's Accountable Care Organizations and CMS's Center for Medicare and Medicaid Innovation.

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[7] Seattle Cancer Care Alliance is excluded by five out of eight insurers in Washington's insurance exchange; MD Anderson Cancer Center reported it is in less than half of the plans in the Houston area; Memorial Sloan-Kettering is included by two of nine insurers in New York City. *See* Alonso-Zaldivar, R. 2014 (18 March). Concerns about cancer centers under health law. *Associated Press*, Available at: http://bigstory.ap.org/article/concerns-about-cancer-centers-under-health-law.

[8] S. Rep. No. 113-71, at 126 (2013).

While BIO is aware that there are ongoing efforts by other stakeholder groups, including at the state level, to address the issue of access to providers, we feel it is appropriate for the Departments to address these issues, including through guidance implementing the ACA's nondiscrimination requirement, to ensure that a single standard exists regardless of where an individual resides.[9]

III. The Departments should clarify that provider reimbursement rates can only vary based on quality or performance measures.

As the RFI notes, the ACA's provider nondiscrimination requirements do not prohibit the establishment of varying provider reimbursement rates based on quality or performance measures.[10] Yet BIO shares the concern stated by the Senate Committee on Appropriations' July 2013 Report[11] that the Departments' July 2013 guidance incorrectly states that provider reimbursement rates "may be subject to . . . market standards and considerations."[12] Specifically, BIO urges the Departments to immediately amend their existing guidance to omit this language and to clarify that "market standards and considerations" falls outside of the accepted criteria on which plans may vary provider reimbursement rates.

Furthermore, with respect to the plans' ability to vary reimbursement rates based on quality and performance, the Departments should urge plans to exclusively utilize quality measures that are endorsed by the National Quality Forum (NQF) or another consensus-based organization that uses similarly sophisticated processes for developing and endorsing measures. Any quality or performance measures utilized should avoid penalizing providers with sicker underlying patient populations or those who employ treatment regiments whose benefits may only be observable over a longer period of time. Finally, plans should be urged to take into consideration appropriate timeframes over which to measure quality and performance and whether the identified measures are meaningful to patients.

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[9] For example, efforts are ongoing to change state law for network adequacy, *See* National Association of Insurance Commissioners and The Center for Insurance Policy and Research. 2014. *Committees and Activities: Network Adequacy Model Review (B) Subgroup Regulatory Framework*. Available at: http://www.naic.org/committees_b_rftf_namr_sg.htm.

[10] PHS Act § 2706(a).

[11] S. Rep. No. 113-71, at 126 (2013).

[12] *See* FAQs about Affordable Care Act Implementation Part XV, Available at: http://www.dol.gov/ebsa/faqs/faq-aca15.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.

IV. Conclusion

BIO appreciates the opportunity to provide feedback to the Departments on the important issue of provider nondiscrimination. We look forward to continuing to work with the Departments to ensure that plans provide patients with access to the range of healthcare providers necessary to provide meaningful, individualized care. Please feel free to contact me at (202) 962-9220 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy