Biotechnology Industry Organization

April 10, 2014

BY ELECTRONIC DELIVERY

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Proposed Rule (CMS-9949-P)

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) on March 21, 2014, entitled "Exchange and Insurance Market Standards for 2015 and Beyond" (the "Proposed Rule").[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 healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.[2]

As a result of the Patient Protection and Affordable Care Act (ACA), many uninsured individuals are able to purchase more affordable health insurance through the health insurance Exchanges (aka "Marketplaces"). To fulfill the goals of the ACA, the standards for the qualified health plans (QHPs) that are made available to these individuals through the Exchanges must ensure meaningful coverage for medically necessary care, including emerging innovative technologies. These standards must guard against the possibility that a health plan will design its covered benefits (or market those benefits) in a manner that discriminates against individuals with serious health conditions and the most complex treatment needs. We believe that this Proposed Rule moves in the right direction in this regard. Specifically:

[1] 79 Fed. Reg. 15,808 (March 21, 2014).
[2] See, e.g., Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services (Nov. 2012), available at: http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

- BIO strongly supports CMS's proposed improvements to the QHP exceptions process, and urges CMS to build on the protections afforded by this proposal by requiring QHPs to provide enrollees with transition fills, as proposed in the Draft 2015 Letter to Issuers.
- BIO supports CMS's proposal to revise its approach to indexing the ACA's cost-sharing requirements.
- BIO supports the requirement that QHPs both implement a quality improvement program and report to the Quality Reporting System (QRS), which we believe is not only consistent with the ACA, but will help CMS achieve the Agency's stated aims for the QRS.
- BIO strongly supports CMS's proposals to implement the QRS, and urges CMS to further ensure that: (1) measures employed by the QRS are valid and demonstrate meaningful differences in plan quality; (2) the performance ratings are easy to understand, while allowing consumers to review the underlying information, if desired; (3) performance ratings are plan-specific; and (4) performance ratings are accessible to enrollees as they are choosing from among QHPs, including during both the open enrollment and special enrollment periods.
- BIO supports CMS's efforts to make Enrollee Satisfaction Survey (ESS) data easily accessible to consumers, and urges CMS to incorporate all measures that rate ease of access to specialists and biopharmaceutical medications into the program.
- BIO supports CMS's Marketplace Survey proposal, and urges CMS to ensure that this survey assess implementation of the ACA's non-discrimination prohibition by the Exchanges.
- BIO supports CMS's proposal to require that QHPs issue standard notifications to enrollees on an annual basis, particularly notifications pertaining to modifications in coverage.

We were disappointed, however, that CMS did not address network adequacy as part of this Proposed Rule. We believe that this is a critical issue in terms of protecting QHP enrollees' access to needed care with affordable cost-sharing, as promised by the ACA, and therefore urge CMS to address this issue in future rulemaking.

I. BIO Strongly Supports CMS's Proposed Improvements to the QHP Exceptions Process, But Encourages CMS to Require QHPs to Provide Transition Fills

As CMS is aware, QHPs are required to have in place procedures that allow an enrollee to gain access to clinically appropriate drugs not covered by the plan.[3] Yet, as CMS notes in the Proposed Rule, enrollees—particularly those with "certain complex medical conditions"—continue to have challenges with access, including with respect to combination drugs not covered by their plan formularies.[4] Accordingly, we very strongly support CMS's proposal to amend the formulary exceptions standards to require that these processes can be expedited when necessary based on exigent circumstances (e.g., when an enrollee is suffering from a serious health condition or an enrollee is in a current course of treatment using a non-

[3] See 45 C.F.R. § 156.122(c).
[4] 79 Fed. Reg. at 15,845

formulary drug), and urge CMS to finalize this proposal.[5] We further urge CMS to finalize its proposal to require that QHP issuers render decisions regarding a formulary exceptions request within 24 hours following the issuers' receipt of the request, as suggested in both the 2014 and 2015 Letter to Issuers.[6] In implementing these proposals, CMS should ensure that the exceptions procedures are as transparent and non-burdensome as possible, so as not to discourage their use when expedient access to treatment is needed.

Our one concern with respect to this proposal is that we have obtained information—through our participation in the Center for Consumer Information and Insurance Oversight's (CCIIO's) Pharmacy Stakeholders Outreach Working Group—that existing cost-sharing limitations may not apply to drugs obtained through this exceptions process. We believe this would largely undermine the benefit of CMS's proposal, and therefore urge CMS to clarify that enrollees will still have out-of-pocket protections even if they obtain drugs through the exceptions process.

On a related note, we would like to express our concern and disappointment that CMS did not address its proposed transition fill policy in this Proposed Rule. In the past, CMS has issued both regulations and guidance that aim to protect beneficiaries from interruptions in care when switching between plans (e.g., in the Medicare Part D program), and BIO supports instituting similar protections for those switching into and between QHPs. For this reason, we supported CMS's proposal in the Draft 2015 Letter to Issuers "to propose through rulemaking that Marketplaces may require that issuers temporarily cover non-formulary drugs, including drugs that are on the issuer's formulary but require prior authorization or step therapy, as if they were on the issuer's formulary during the first 30 days of coverage, for coverage beginning on January 1 of each year, starting with the 2015 plan year."[7] Yet, this language was omitted from the Final 2015 Letter to Issuers,[8] and the topic of transition fills was not addressed in this Proposed Rule at all. We believe that transition fills are a critically important enrollee protection and therefore urge CMS to include this proposal in future rulemaking. Moreover, to specifically address the need for continued access after a transition period has lapsed, we urge CMS to ensure that patients who receive transition fills are made aware of the need to obtain an exception or begin an appeal with sufficient time to do so without risking an interruption in care.

II. BIO Supports CMS's Proposal to Revise Indexing of Cost-Sharing Requirements

As CMS is aware, the annual limitations on cost-sharing and deductibles in the small group market for years after 2014 are to be indexed by the premium adjustment percentage.[9] We strongly support CMS's proposal that any increase in the annual limits that does not result

[5] Id.
[6] 2014 Letter to Issuers on Federally-Facilitated and State Partnership Exchanges, Appendix C (April 5, 2013), available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_Lettter_to_Issuers_04052013.pdf ; 2015 Letter to Issuers on Federally-Facilitated and State Partnership Exchanges at 29 (March 14, 2014), available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf [hereinafter "Final 2015 Letter to Issuers"]
[7] See Draft 2015 Letter to Issuers on Federally-Facilitated Exchanges at 33 (Feb. 4, 2014), available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf [hereinafter "Draft 2015 Letter to Issuers"]
[8] See Final 2015 Letter to Issuers.
[9] 45 C.F.R. § 156.130(a).

in a multiple of $50 be rounded down to the lowest multiple of $50.[10] This is not only consistent with the convention employed by the Department of the Treasury and the Internal Revenue Service,[11] but it offers enrollees greater protection, as an increase in cost-sharing exposure of up to $49.99 may be consequential for many.

III. BIO Supports CMS's Proposal to Require QHPs to Report Quality Data and Implement a Quality Improvement Program

BIO strongly supports CMS's proposal to clarify that implementing a quality improvement strategy and reporting to the QRS are conditions of participation in an Exchange.[12] We note that this first requirement is consistent with section 1311(c)(1)(E) of the Affordable Care Act (ACA), which expressly requires QHPs to "implement a quality improvement strategy" as a condition of certification, and believe that this second requirement is a critical means for ensuring that the QRS meets CMS's stated aims for the program, discussed in greater detail in the subsequent section of this letter.

IV. BIO Strongly Supports CMS's Proposals to Implement a Quality Reporting System But Recommends that CMS Make Minor Modifications

The ACA requires the Secretary to develop a system that rates QHPs based on their relative quality and price.[13] CMS has implemented this requirement by establishing the Quality Rating System (QRS), which is based on two fundamental tenets: (1) providing comparable and useful information regarding the quality of QHPs offered through the Exchanges to inform consumer and employer choice; and (2) facilitating regulatory oversight of QHPs with regard to the quality standards set forth in the ACA.[14] BIO strongly supports both of these aims and believes that CMS has made inroads into achieving them. Nonetheless, we believe there are several aspects of the current QRS proposal that could be further improved.

As a general matter, for the QRS to meet CMS's stated aims, we believe that: (1) the measures employed must be valid and demonstrate meaningful differences in plan quality; (2) the performance ratings should be easy to understand, while allowing consumers to seek additional information; (3) performance ratings should be plan-specific; and (4) performance data should be accessible to consumers while they are choosing from among QHPs, including during both the open enrollment and special enrollment periods. We urge CMS to take into account these considerations, described in greater detail in the following sections, as the Agency moves towards phasing-in the QRS program.

A. Measures Employed by the QRS Should be Valid and Demonstrate Meaningful Differences in Plan Quality

BIO commends CMS for its efforts to ensure that the measures employed in the QRS are valid and demonstrate meaningful differences in plan quality. As to the validity of quality measures, we particularly support that measures selection and measure set evaluation

[10] 79 Fed. Reg. at 15,846.
[11] See id.
[12] 45 C.F.R. § 156.200(b)(5) [proposed].
[13] ACA §§ 1311(c)(3) & (c)(4).
[14] 78 Fed. Reg. 69,418, 69,419 (Nov. 19, 2013).

criteria were developed by CMS using the National Quality Forum (NQF) Measure Evaluation Criteria and that the majority of measures (76 percent) are NQF-endorsed.[15] Endorsement by a consensus-based entity like NQF ensures that the measures are valid and reliable when used in the field. We also support CMS's proposed requirement that data submitted by issuers on the quality measures be validated by an independent third party, which we agree will "ensure that only valid and appropriate data are used to calculate the quality rating information for QRS public reporting."[16] We also agree that quality ratings "calculated by CMS on a standard scoring methodology," may allow for "reliable, uniform, and comparable QHP ratings across Exchanges,"[17] which we anticipate will be valuable for consumers.

In terms of ensuring that the quality measures themselves demonstrate meaningful differences in plan quality, we concur with CMS that the QRS should "provide QHP ratings that are based on health care quality, health outcomes, consumer experience, accessibility of care and affordability of care," because, as CMS highlights in the Proposed Rule, this information "is essential to inform consumer choices and to perform certain required functions of an Exchange."[18] And we believe that the Agency has taken a number of concrete steps to ensure that such measures are included in the QRS program. For instance, we support CMS's proposal that, at least for the initial years, measures included in the QRS will be aligned with measures that health plans report in the commercial markets and public programs.[19] We believe that this will make the transition easier for participating plans, and will also allow CMS to determine whether measures that have been successful in other programs translate well to the Exchanges. We also support many of the specific measures selected. For example, we believe that measures that assess outcomes (e.g., LDL-C control, A1c control) and patient experience (e.g., the Consumer Assessment of Health Providers and Systems [CAHPS®] measures for Customer Service and Getting Needed Care, Getting Care Quickly) provide critical information for potential enrollees aiming to select high-quality plans during the open and special enrollment periods.[20] We also support the inclusion of medication management and care coordination measures, which are critical since many current measures cannot adequately guide the use of medications, and because there is a lack of robust measures across diseases states.

That said, we believe that certain modifications are necessary to the QRS measures set. Most notably, BIO strongly urges CMS to require QHPs to report on the medication adherence measures used in the Medicare Advantage Star Rating program.[21] We believe that these measures have the potential to improve enrollee health outcomes and reduce inefficiencies in health care delivery. BIO strongly supports policies that increase patient adherence to therapies, and believes that improved adherence can have a significant positive impact on patient care and reduce costs over the long term. In addition, to ensure that the applicable measures continue to be valid, consistent with CMS's intent "that the development and evolution of the QRS should be public and transparent and should allow for flexibility to incorporate changes in measures and methodologies as medical treatments

[15] See 78 Fed. Reg. at 69,420-21.
[16] 79 Fed. Reg. at 15,849.
[17] Id. at 15,844.
[18] Id.
[19] Id.
[20] See 78 Fed. Reg. at 69,422 (outlining the proposed measure set for the QRS).
[21] CMS, Fact Sheet – 2014 Star Ratings, available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

and technology evolve and the Exchanges mature,"[22] we urge CMS to articulate a procedure under which the Agency will evaluate the applicable measures on an ongoing basis. We believe that this procedure should include criteria for the retirement of measures, as well as a regular process for assessing whether there is a need to modify the applicable measures based on the unique nature of the Exchange population, as well as the state of science and medical practice. BIO also asks that CMS further describe how the Agency will solicit and incorporate stakeholder feedback during its measures evaluation process, as this input will be critical to ensuring the measures keep pace with the evolving standards of medical care.

B. The Performance Ratings Should be Easy to Understand, But Allow Consumers to Review the Underlying Information, if Desired

BIO strongly supports CMS's proposal to "implement a quality rating to a QHP using a five star scale," which "would be displayed in a similar style and format to that of the Medicare Advantage and Prescription Drug Plan ratings,"[23] as well as CMS's proposal "for the display of quality ratings . . . to be capable of drilling down to the results for individual quality measures."[24] We agree that presenting a plan's quality data as a single score will likely be understandable by most consumers, while the ability to drill down at the individual quality measure-level will allow those individuals who are interested to obtain greater detail on the underlying data. To these ends, we urge CMS to incorporate a methodology for how individual quality measure-level data will be made available as part of its final "Quality Rating System Scoring Specifications," as this topic was not addressed in the draft specifications.[25] Moreover, while BIO also generally supports CMS's proposal to allow State Exchanges to display additional QHP quality-related information,[26] we urge CMS to require that such data be clearly identified as additional and separate from the standardized QHP quality ratings implemented under this Proposed Rule. CMS should also require states to provide consumers with the relevant context for these additional data, including how they were collected and any potential sources of bias. Similarly, in terms of CMS's proposal to allow states to adopt their own quality rating programs, we believe that any state-level quality rating programs should supplement, but not supplant, the QRS and ESS systems to be implemented by CMS.

C. Performance Ratings Should be Specific to the Plan In Question

While we are generally very supportive of CMS's QRS proposal, BIO is concerned that the proposal fails to ensure that performance ratings will be specific to the plan in question, which may significantly limit the ability of enrollees to make informed decisions about any particular plan, relative to other plan options. Indeed, as proposed, QHPs would only be required to report performance at the plan-type level (e.g., health maintenance organization [HMO] versus Preferred-Provider Organization [PPO]), rather than product metal level (e.g., bronze versus silver). We do not believe that this requirement is consistent with the ACA,

[22] 78 Fed. Reg. at 69,422.
[23] 79 Fed. Reg. at 15,845.
[24] Id.
[25] See CMS, Draft Quality Rating System Scoring Specifications (March 28, 2014), available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QRS-Scoring-Specification.pdf.
[26] Id.

which obligates the Secretary "develop a rating system that would rate qualified health plans offered through an Exchange in each benefits level . . . "[27]

Moreover, BIO disagrees with CMS's stated rationale for this policy. Specifically, in support of this proposal, CMS articulates its belief that "a QHP's enrollment size at the product metal level will be too small to ensure reliable QRS results across the measure domains in the beginning years of the Exchange."[28] Yet, we believe this issue will be addressed, at least in part, by CMS's proposal to allow plans to submit quality data on a plan offered both inside and outside the Exchange (as long as they are considered the same plan),[29] which will increase the available sample size, as CMS itself notes.[30] Moreover, we do not believe there is any reason to treat the QRS reporting differently from the ESS reporting, for which CMS proposes to require QHP issuers to report data at the metal-tier level.[31]

D. Performance Ratings Should be Accessible to Enrollees During the Open Enrollment and any Special Enrollment Periods

Finally, we strongly support the steps CMS has taken to ensure that the quality ratings are accessible to enrollees at the time they are deciding from among QHPs. For instance, CMS proposes that each Exchange must prominently display quality rating information assigned for each QHP under the QRS on its website.[32] Moreover, these data are to be displayed on an annual basis, before open enrollment. We commend CMS for these measures, and urge the Agency to similarly ensure access to performance ratings year round for those individuals selecting from among QHPs during a special enrollment period, and to verify that QHP issuers are meaningfully complying with these requirements.

V. BIO Supports CMS's Efforts to Make ESS Data Easily Accessible to Consumers and Urges CMS to Require Access to All ESS Data

The ACA also requires the Secretary to establish an enrollee satisfaction survey system (ESS) that assesses the level of enrollee satisfaction with QHPs.[33] To these ends, CMS established the ESS, which is based on the CAHPS® Health Plan 5.0 Medicaid survey. BIO generally supports the use of the CAHPS® tool for this purpose, which has a long history of measuring the patient healthcare experience. We also support CMS's proposal to direct a QHP issuer to contract with an enrollee satisfaction survey vendor approved by the Department of Health and Human Services (HHS), and to require the submission of validated data, both of which will help ensure the validity of the resulting survey data.

In addition, as BIO believes that the level of enrollee satisfaction with the plan is a critical metric of plan quality, we applaud CMS for its proposal to "incorporate enrollee experience data from the results of the ESS into the quality rating for each QHP."[34] We agree that

[27] ACA § 1311(c)(3) (emphasis added).
[28] 79 Fed. Reg. at 15,850.
[29] Id. at 15,850.
[30] See id. at 15,851 ("Similar to our proposed approach with the QRS, we are considering in the initial years to allow a QHP issuer to include enrollees of QHPs offered through and outside of the Exchange, to ensure a reliable ESS sample size . . . ") (emphasis added).
[31] Id. at 15,851.
[32] Id. at 15,844.
[33] ACA § 1311(c)(4).
[34] 79 Fed. Reg. at 15,845.

CMS's proposal to incorporate experience data as part of the quality rating information will simplify the information presented to consumers to ease their comprehension of the material. That said, while we strongly support CMS's proposal to include measures regarding appointments with specialists[35] and whether individuals delayed or did not fill prescriptions due to cost,[36] we urge CMS to ensure that all CAHPS® measures related to access to specialty care[37] and prescription medicine[38] are assessed via the ESS program and also incorporated into the QRS metric, as we believe these particular measures are a critical indicator of plan quality for individuals with chronic, rare, and complex conditions. We also believe that these measures can help assess the extent to which QHP networks may not be adequate when it comes to certain specialty-care providers.[39] Furthermore, to ensure that consumers can access data on all patient experience measures for all QHPs, we urge CMS to modify its proposal such that the Exchanges are required to both: (1) enable enrollees to obtain information on all ESS results, including those scores that are not used as part of the QRS; and (2) collect ESS data on all QHPs, rather than solely for those QHPs with greater than 500 participants.

VI. BIO Supports CMS's Marketplace Survey Proposal and Asks CMS to Ensure that This Survey Assess Exchange Implementation of the ACA's Non-Discrimination Prohibition

BIO strongly supports CMS's proposal to establish a Marketplace Survey to assess consumer experience with each Exchange.[40] We, like CMS, "believe it is important to assess experience of consumers interacting with an Exchange," including individuals who did not actually enroll in a plan through the Exchange.[41] Indeed, we note that it is particularly important that CMS evaluate the experience of individuals who did not ultimately enroll, as these data may highlight instances in which Exchanges are certifying QHPs that employ discriminatory benefit designs, contrary to the requirements of the ACA.[42] We believe that insight into how the ACA's non-discrimination provision is being implemented is especially critical given the substantial leeway CMS has granted the Exchanges and issuers with respect to this requirement. To these ends, we urge CMS to incorporate into the Marketplace Survey questions regarding whether a particular QHP afforded access to all of the benefits and in-network providers necessary to treat an individual's medical condition(s), at a reasonable cost, regardless of whether the individual ultimately enrolled in the plan.

---

[35] Got appointment with specialist as soon as needed. Qualified Health Plan Enrollee Survey for 30 Day FRN (Sept. 24, 2013), available at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QHP-Enrollee-Survey-English.pdf.

[36] Delay or not fill prescription because of cost. Id.

[37] Namely, the following additional measures: (1) Easy to get referral to a specialist; (2) How often it was easy to get appointment with specialists; (3) reasons it was not easy to get appointments with specialists. See Reporting Measures for the CAHPS® Health Plan Survey 5.0, Document No. 2150 (May 1, 2012), available at: https://cahps.ahrq.gov/surveys-guidance/hp/about/2150_Overview_HP_Surveys.pdf.

[38] Specifically, the measure assessing whether it was easy to get prescription medicine from the health plan. See id.

[39] See, e.g., NBC News, Health Law Concerns for Cancer Centers (March 18, 2014), available at: http://abcnews.go.com/Health/wireStory/concerns-cancer-centers-health-law-22960368.

[40] 79 Fed. Reg. at 15,852.

[41] Id.

[42] See ACA § 1302(b)(4)(B) (prohibiting plans that offer the Essential Health Benefits, to include QHPs, from "mak[ing] coverage decisions, determin[ing] reimbursement rates, establish[ing] incentive programs, or design[ing] benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.").

On a related note, we would like to reiterate our concern that CMS's current standard for prescription drug coverage[43] is not adequate, particularly to ensure access to medical benefit drugs, further underscoring the need for robust non-discrimination review—at least until a better pharmacy benefit standard is adopted. Specifically, because the U.S. Pharmacopeia (USP) Medicare Model Guidelines (MMG) was created for use with drugs provided through the Part D benefit, it does not reflect the full range of drugs that may be needed by patients enrolling in QHPs. This construct can impede access to therapeutic interventions for those patients suffering from life-threatening and debilitating rare diseases and complex chronic conditions. Thus, multiple stakeholders, including BIO, have recognized the need to consider a potential replacement for the USP benchmark to be implemented after 2015. We have learned through our participation in CCIIO's Pharmacy Stakeholders Outreach Working Group that CMS is indeed considering a different standard for 2016 and beyond, and we therefore encourage CMS to begin collecting data from QHPs to assess medical benefit adequacy for the purpose of both identifying discriminatory benefit design, and as part of identifying a better benchmark for guaranteeing robust medical benefit drug coverage among QHPs beginning in 2016.

VII. BIO Supports CMS's Proposal to Require Standard Notifications

BIO strongly supports CMS's proposal to require QHP issuers to distribute standardized notifications when they discontinue or renew coverage.[44] We agree with CMS that this requirement is necessary "[t]o reduce confusion and ensure consumers receive clear, accurate, and consistent information about their coverage options."[45] Indeed, we believe it is particularly critical that issuers of plans slated for renewal identify where the coverage is subject to modifications, as CMS proposes. Absent this requirement, we believe that enrollees may renew their enrollment in a given QHP without understanding that the plan coverage is actually subject to change. Accordingly, we strongly urge CMS to finalize this proposal.

VIII. BIO Encourages CMS to Further Address Network Adequacy Concerns

BIO is disappointed that this Proposed Rule does not address network adequacy requirements in the Exchanges. As we have repeatedly emphasized in our comments to the guidance and regulations implementing the ACA's Essential Health Benefit (EHB) provisions:[46] to ensure that access to affordable health insurance through the Exchanges actually provides meaningful access to care, it is critical that plans contract with a broad network of healthcare providers that includes a wide range of both healthcare professionals

[43] 45 C.F.R. 156.122(a) ("A health plan does not provide essential health benefits unless it: . . . covers at least the greater of: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan . . . ").
[44] 79 Fed. Reg. at 15,817.
[45] Id.
[46] See Biotechnology Industry Organization (BIO). 2014. Comments to the Centers for Medicare and Medicaid Services (CMS) Regarding the Draft 2015 Letter to Issuers on Federally-facilitated Marketplaces. Washington, DC: BIO, Available at: http://www.bio.org/advocacy/letters/bio-submits-comments-centers-medicare-and-medicaid-services-cms-regarding-draft-201; BIO. 2013. Comments to the Affordable Exchanges Guidance: Letter to Issuers on Federally-facilitated and State Partnership Exchanges. Available at: http://www.bio.org/sites/default/files/BIO%20Final%20Comments_Affordable%20Exchanges%20Guidance_15%20Mar%202013_0.pdf; BIO, 2012. Comments on the Essential Health Benefits Proposed Rule. Available at: http://www.bio.org/advocacy/letters/ehb-bio%E2%80%99s-comments-essential-health-benefits-proposed-rule.

and healthcare settings that are conveniently located throughout the plans' service areas. BIO believes that a comprehensive network of providers must include not only a variety of specialists, which will be crucial to preserve access for enrollees with complex or rare conditions who may need multiple types of specialized care, but also a broad range of immunization providers and other providers of preventive services.

While we understand that CMS took some steps to improve network adequacy in the Exchanges through the Final 2015 Letter to Issuers,[47] we believe that CMS should go further in protecting enrollee access to their medical providers. For instance:

- To ensure that QHPs have sufficiently broad provider networks, BIO urges CMS to provide more detailed guidance regarding the number and types of providers that must be included in a plan's network in order to satisfy the federal network adequacy requirements for QHPs. We also urge CMS to finalize its proposal to require QHP issuers to provide a list of their network providers as part of the certification process, as outlined in the Proposed 2015 Letter to Issuers.[48]
- To fulfill the ACA's intent to increase access to immunizations for all covered individuals,[49] BIO continues to recommend that CMS clarify that a network of providers for immunization services must include those health care providers and locations allowed by state law to provide such services. To these ends, we urge CMS to include complementary immunization providers—namely pharmacies, public health department clinics, school-based clinics, and other community sites—to the list of "Essential Community Providers" that must be included in QHP provider networks.
- To ensure access to in-network care for individuals with rare or complex diseases, BIO urges CMS to take the Office of Personnel Management's (OPM's) lead and require QHPs to "have in place, a process to provide timely exceptions to ensure that consumers who need care from out-of-network providers (because of rare or complex medical conditions or a lack of in-network providers in a geographic area) can receive it with reasonable cost-sharing, applying enrollee costs to the in-network out-of-pocket maximum, and protection from balance billing."[50]

BIO believes that more specific standards will help ensure that all QHPs have sufficiently broad networks for both specialists and providers of immunizations and other preventive services. That, in turn, will protect QHP enrollees' access to needed care with affordable cost-sharing, as promised by the ACA.

IX. Conclusion

BIO appreciates the opportunity to comment on this Proposed Rule, entitled "Exchange and Insurance Market Standards for 2015 and Beyond." We look forward to continuing to work with CMS and interested partners to ensure that consumers have meaningful quality-related

[47] See Final 2015 Letter to Issuers at 17-26.
[48] Proposed 2015 Letter to Issuers at 19.
[49] Specifically, section 1001 of the ACA, codified as section 2713 of the Public Health Service Act, requires health plans to cover all vaccines recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) for all ages without cost-sharing when administered by an in-network provider.
[50] See Office of Personnel Management, Multi-State Program Issuer Letter No. 2014-002 (Feb. 4, 2014), available at: http://www.opm.gov/media/4517978/2014-002_dms_.pdf.

information regarding available QHPs and that such plans provide meaningful coverage and access to providers, including for the most vulnerable patients with serious, complex medical conditions and significant health care needs. Please feel free to contact Laurel Todd 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