November 20, 2015

Alternative Payment Model Framework and Progress Tracking Work Group
Health Care Payment Learning & Action Network
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

RE: Alternative Payment Models Framework Draft White Paper

Dear Alternative Payment Model Framework and Progress Tracking Work Group:

The Biotechnology Industry Organization (BIO) is pleased to submit feedback in response to the U.S. Department of Health and Human Services' (HHS's) Health Care Payment and Learning Action Network's (HCP LAN) "Alternative Payment Models Framework Draft White Paper" (the "Draft White Paper"), released on October 22, 2015.[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.

BIO views the HCP LAN as an important opportunity to participate in the Department's effort to meet the payment reform goals identified by the Secretary earlier this year: specifically, that by the end of 2016, 30 percent of traditional Medicare payments are tied to quality or value through alternative payment models (APMs) (50 percent by 2018) and 85 percent of all traditional Medicare payments are tied to quality or value (90 percent by 2018).[2] In order to meet these ambitious goals, HHS will need to work closely with stakeholders to ensure that efforts to transition from reimbursing for volume to value do not result in unintended consequences that restrict individual patient access to the most appropriate, timely care. The HCP LAN is one such opportunity for ongoing stakeholder input, and BIO supports HHS's efforts to strengthen this collaborative discussion through the formation of work groups and the launch of public forums. In particular, we applaud the Work Group's interest in receiving public feedback in advance of finalizing the Draft White Paper. We strongly encourage the HCP LAN, and the Department more generally, to continue and expand this outreach to ensure broad participation.

In considering the Draft White Paper, as an initial matter, BIO encourages the Work Group to incorporate a conceptual framework that establishes how their work fits into the

[1] Alternative Payment Model Framework and Progress Tracking (APM FPT) Work Group. 2015 (Version Date: 10/22/15). Alternative Payment Model (APM) Framework Draft White Paper, available at: https://publish.mitre.org/hcplan/wp-content/uploads/sites/4/2015/10/2015-10-23-APM-Framework-White-Paper-FPO.pdf.

[2] Department of Health and Human Services (HHS). 2015 (January 26). Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value, available at: http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html.

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

broader reform environment, including the Centers for Medicare and Medicaid Innovation's (CMMI's) demonstration programs, HHS's payment reform goals, and the implementation of the Medicare and CHIP Reauthorization Act of 2014 (MACRA). For example, while at least one CMMI demonstration is included in the Appendix as a case study (i.e., the Bundled Payment for Care Improvement Initiative), the extent to which CMMI will rely on the findings of the Work Group, and whether and how CMMI will employ the APM categorization Framework is unclear. Similarly, it is unclear what, if any, interaction the Work Group's findings will have with MACRA implementation: for example, will, and how will, the Work Group's APM Framework interact with the determination of whether an APM entity qualifies as Eligible APM or a Physician-Focused Payment Model under MACRA. In this time of major transition in the Medicare reimbursement system, likely to last years, stakeholders who depend on this system—including patients—benefit from more information on the parameters of the transition itself, not just its end goals. Although the scope of the Work Group is limited, it brings together a diverse group of stakeholders and is an initial forum for greater stakeholder participation, and thus is a natural venue to posit a suggested conceptual framework.

In the reminder of the letter, BIO focuses our feedback on specific elements of the Draft White Paper. Overall, we are pleased with the progress the Work Group has made on this preliminary step of categorizing APMs. However, we request additional clarity and, in some instances, detail on how the categorization scheme will work, including with regard to:

- The three pillars of patient care,
- Key principles of the APM Framework, and
- The APM Framework.

In the final section of BIO's comments, we also propose measures that we believe are of upmost importance in assessing the impact of an APM on patient access to medically appropriate care. Though the Draft White Paper states that measures development with be within the scope of the Work Group's future work, BIO nonetheless takes the opportunity to provide initial thoughts, and looks forward to working with the Work Group further as this second phase begins.

I. Three Pillars of Patient-Centered Care

BIO applauds the overall structure of the Draft White Paper—beginning with the three pillars, continuing with the principles, and concluding with the case studies—as it is an effective way of reflecting the Work Group's conceptual roadmap to drafting the Framework. In fact, providing this context allows stakeholders to offer feedback that targets the Work Group's thinking, perspectives, and ultimate goals. In general, BIO is supportive of the three pillars as defined in the Draft White Paper, but we ask the Work Group to consider including additional clarity in each to capture the complexity of the concepts that are introduced.

First, with regard to the "quality" pillar, BIO urges the Work Group to finalize the text that focuses on the importance of individualized patient care. This is critical to ensure that the transition to APMs does not reduce health care to a one-size-fits-all approach in an era in which medical and scientific advancement is focused on increasingly personalized approaches to prevent, diagnose, treat, and even cure disease. In fact, BIO asks the Work Group to strengthen the text in this description to acknowledge that robust quality measures are the only bulwark against a sole focus on cost within an APM, which can perversely incentivize under-utilization of appropriate care or "stinting." We also urge the

Work Group to clarify and outline a process for establishing quality metrics as part of APM and that this process takes into account the importance of ensuring that there are metrics to assess access to care, in addition to quality and performance. In particular, in considering the importance of quality and access metrics, the Working Group should acknowledge that patient access to new-to-market therapies (and new indications of existing therapies, and new compendia entries that address existing therapies) is a critical component of ensuring that individual patients receive the most tailored, appropriate care for them. As seen with the recently released Medicaid final rule and Request for Information, access issues are important to consider as we're seeing many payment and delivery reforms and APMs adopted within the Medicaid program.[3] Additionally, in discussing the "harmonized set of process and outcomes measures" that an APM utilizes, the Work Group should note that these measures must be continuously updated with the input of providers and patients to ensure they reflect the evolving standard of care.[4]

Second, with regard to the "cost effectiveness" pillar, BIO appreciates that the Work Group states that "care that is less expensive than expected, but that results in poor clinical outcomes, is not considered cost effective."[5] This recognition is paramount to ensure that the transition to APMs does not result in a sole focus on cost such that individual patient health outcomes are put at risk. In addition to this text, BIO urges the Work Group to include a discussion that recognizes that a focus on short-term costs is inappropriate as it shortchanges the assessment of care that may be delivered in a short period of time but impact a patient's care over a matter of weeks, months, or even years. If an APM's quality and cost assessments do not take into consideration the longer-term benefits and cost offsets of treatment options, patient health outcomes could suffer—especially in the case of patients who suffer from chronic conditions, which often manifest over the course of several years or even decades—and overall health expenditures could rise (e.g., due to the overall number of hospitalizations, surgical interventions, and provider office visits). For example, if an APM does not comprehensively account for benefits and cost offsets of a treatment option, participating providers could be penalized for utilizing a high-cost curative therapy for a chronic disease patient, since the role of the short-term cost will be inappropriately emphasized over the long-term benefits and cost savings. Thus, to ensure that APMs represent a sustainable transition to better individual patient care, improved population outcomes, and lower overall expenditures, BIO urges the Work Group to recognize the importance of considering cost effectiveness over the long term in the discussion of this pillar in the final White Paper.

Third, with regard to the "patient engagement" pillar, BIO asks that the Work Group define the difference between the terms "patient" and "consumer" used in this section and throughout the Draft White Paper. In fact, the discussion in these introductory sections suggests the broader need for a glossary of terms to ensure that stakeholders, including HHS, have a clear understanding of the context for the Framework. As a single example, the term "patient-centered" is not defined in the document, but it is used as a foundational element of categorization in the Framework (i.e., the Work Group states that "providers are held accountable for meeting quality and, increasingly, patient-centered goals" in the description of Category 4 APMs).[6] Further, the report does not specifically outline how consumer input should be obtained or what patient satisfaction measures should be

---

[3] CMS Final Rule on Methods for Assuring Access to Covered Medicaid Services, *see* 80 Fed. Reg. 67,576 (November 2, 2015); CMS Request for Information on Data Metrics and Alternative Processes for Access to Care in the Medicaid Program, *see* 80 Fed. Reg. 67,377 (November 2, 2015).
[4] Draft White Paper at. 2.
[5] Ibid.
[6] Id. at 14.

considered within the APMs. To this point, we urge the Work Group to include patient satisfaction and other metrics to address the patient experience.

In addition to refining the description of the three pillars, BIO also urges the Work Group to acknowledge that not all APMs and APM categories will be appropriate for all providers and/or patient populations. While this reality can be inferred from the Work Group's discussions of the Framework categories in later sections of the Draft White Paper, BIO believes it is important to tackle this issue overtly and as context for the Framework categories. This point also emphasizes the need to ensure that the transition to APMs does not result in one-size-fits-all health care, but instead increasingly focuses on establishing structural incentives to improve the efficiency and effectiveness of individualized patient care.

To this end, it is essential to ensure that not only are APMs appropriate for the target patient group, but that quality and access measures used to evaluate an APM are appropriate for the target population. As with programs for a chronically ill population, quality and access measures should be developed with a model's target population and their unique needs in mind. Measures should incorporate well-established and tested metrics proven to be effective—ideally across payors. This includes ensuring that access and quality metrics for models specifically targeting a chronically ill population are built into this framework for AMP Categories 2 (B-D) through 4. Additionally, quality of care metrics must address continuum of care issues for Categories 3 and 4. Alignment of quality metrics across the continuum of care and across payors will help ensure that the implementation of APMs as well as incentives for providers and health systems to adopt these models are streamlined.

Finally, the Draft White Paper should reinforce that initiatives need to address quality measures for delivery reforms as well as for value-based payments (VBP). As there is greater movement towards including VBPs into larger payment and delivery reforms—as we have seen with CMS/CMMI's Medicaid (e.g. State Innovation Model grants) and Medicare (e.g. Home Health VBP Model) initiatives—it is important to ensure that quality measures asses the delivery reform in addition to the VBP. This is essential to analysis and evaluation of payment and delivery reforms and VBPs models as it can be used to assess the scalability of models and expansion to new populations and payors.

II. Key Principles of the APM Framework

BIO generally supports the Work Group's proposed seven key principles, which underlie the Framework categorization. In particular, we believe that Principle 4 is pivotal to ensure a continued focus on quality and value in developing and implementing APMs. While we do not recommend specific changes to the text of the Principles, BIO does urge the Work Group to strengthen the supporting text of several of the Principles, in part, to align with the comments provided in the previous section. Specifically, we ask the Work Group to make the following changes:

- **Principle 1:** The Work Group should reiterate the importance of assessing whether an APM's cost and quality measures take into account the full range of benefits and cost offsets over time. Especially as the APM becomes more sophisticated and transitions among and between the identified categories, the quality and cost metrics utilized must reflect a holistic view of patient care. In the case of patients with chronic diseases, in particular, this necessitates a focus on the short- and longer-term benefits and costs of a therapeutic regimen across the spectrum of patient care (i.e., not just confined to one

type of insurance benefit, but assessed across the patient's overall health outcomes and treatment costs).

- **Principle 2:** BIO agrees generally with the goals espoused in Principle 2, which align with our discussion in the previous section of these comments. However, we ask the Work Group to recognize the reality that not all APM models and/or Framework categories will be appropriate for all providers and/or patient populations in the supporting text of this principle. This acknowledgement is important to ensure that the focus of APM development and implementation remains on improving individual patient care, and does not resort to employing a one-size-fits-all solution to the complex issues surrounding the provision of efficient, effective health care. We urge the Work Group to emphasize the importance of considering the target patient population when developing an APM and selecting quality and access metrics, as not all models or metrics will be appropriate for all patients, especially more complex patients with multiple comorbidities or with chronic illness.
- **Principle 5:** In the supporting text for this principle, BIO asks the Work Group to include a discussion of the importance of allowing providers to acclimate to the structure of an APM before increasing their risk-sharing requirements. BIO strongly believes that, to avoid the creation of perverse incentives to stint on care, providers should be allowed a "pilot" phase of participation before a significant percentage of their payment is at risk. Such a phase would allow providers to become comfortable with the reporting requirements of an APM, to understand exactly how their clinical behavior impacts how they are assessed on quality and cost measures, and to establish any infrastructure within the practice that is necessary to be successful within the APM environment. This pilot phase may be structured differently in each APM, but is necessary both when a provider/provider practice initially enrolls in an APM and/or when the provider/provider practice transitions among and between APMs in the four categories.

III. The APM Framework

BIO is generally supportive of the Framework categories and appreciates the delineation that the Work Group has made between different types of models with each of the four broad categories. However, in finalizing the Draft White Paper, we ask the Work Group to clarify several issues in this section. First, the discussion in Category 2B, *Pay for Reporting and Rewards for Performance*, raises an important question that should be addressed throughout the Framework section of the Draft White Paper. Specifically, the Work Group notes that "[b]ecause pay-for-reporting does not link payment to quality performance, the Work Group maintains that participation in Category 2B payment models should be time-limited."[7] However, the Work Group does not address what factors dictate the length of time a provider should be required to participate in this type of APM before "graduating" to a Category 3 or 4 APM. In fact, the Work Group should address this issue more broadly by including a discussion, either at the start of the Framework section of the Draft White Paper or earlier, that identifies the facets of determining when a provider should transition between categories. For example, it is unclear how much experience a provider should have before transitioning and how that experience should be measured (e.g., based on the strength of a provider's annual assessment, the number of years in which a provider has participated, or some combination of these two metrics). In fact, it is critical for providers and policymakers to understand what drives a successful transition to greater risk-sharing so that, for each APM type and category, best practices can begin to be collected and disseminated.

[7] Id. at 12.

Second, Category 4 APMs are described as "involve[ing] population-based payments, structured in a manner that encourages providers to deliver person-centered and coordinated care within a global budget."[8] While BIO agrees with the patient-centered approach of this definition, BIO urges the Work Group to address the following concern: population-based payments have historically relied on establishing quality and cost benchmarks through the use of retrospective data that averages across an entire patient population. This methodology is contrary to the goal of delivering person-centered care since providers may be financially penalized for attributed patients who require care that deviates significantly from the average (e.g., due to the patient's underlying health status). BIO believes that resolving this fundamental tension is critical to ensuring that Category 4 APMs do not reduce care to one-size-fits-all.

Third, BIO asks the Work Group to clarify, before the release of the final White Paper, with what information it intends to populate the "conclusions" section of the White Paper. If the Work Group's conclusions will consist of a recitation and general grouping of the findings of the case studies ultimately included in the Appendix, for example, BIO first asks the Work Group to clarify whether the intention is to include all existing APMs. If not, the Work Group should identify what inclusion criteria will be utilized to determine which APMs are represented as case studies (e.g., participation by public and/or private payor, participation by certain types of providers, number of impacted patients, total revenue of participating providers). Furthermore, if the Work Group does intend to include findings from the identified case studies in the final Appendix, BIO recommends that the Work Group consider utilizing the following metrics:

- Type of APM by structure (e.g., ACO, patient-centered medical home);
- Type of APM by Framework category and subcategory;
- Extent of participation by different stakeholder groups (e.g., public/private payors, specialty providers) in different APM categories;
- Examples of progression between and among APM categories, including observed rate of progression for all examples (where available); and
- Quality and cost metrics that were measured by each APM and averaged annual scores across all participants of an APM.

Each of these metrics would provide relevant information to the Work Group as it begins to consider and develop the methodological approach for measuring progress within the Framework (discussed in more detail in the next section).

Fourth, BIO asks the Work Group to clarify if, and how, the Framework will be updated as new information about APM development and implementation becomes available. This should include the Work Group's process and timelines for considering updates to the Framework as well as opportunities for stakeholder input.

IV. Potential Considerations for the Methodological Approach to Assessing Progress within an APM

In footnote 1, the Work Group notes that "[i]n a subsequent White Paper, the Work Group will put forth a methodological approach for measuring progress within the Framework."[9] BIO nonetheless looks forward to the opportunity to engage with the Work Group on this next phase of their work. However, it is unclear whether this refers to the

[8] Id. at 14.
[9] Id. at 4.

successfulness of individual APMs included in the Framework or the progression of providers through APMs in increasingly advanced Framework categories. If the Work Group intends to structure a work stream based on the latter interpretation of this footnote, BIO urges the Work Group to consider the discussion around transitioning between Framework categories included in this letter in Section III. If, instead, the Work Group's future work stream focuses on the former interpretation, we recommend that the Work Group take into consideration the following criteria for assessing an APM as the draft methodological approach is developed for stakeholder comment:

- The robustness of included quality and access measures, specifically, whether the quality and access measures are: meaningful to patients and providers; relevant metrics of care for the disease and patient population included in the model; and able to capture the full extent of benefits and side-effects of treatment options available to the population included in the model. We also recommend that the Work Group obtain patient input in establishing as assessment mechanism of APMs' quality and access measures.
- The comprehensiveness of the risk-adjustment methodology an APM utilizes to account for the underlying differences in an individual provider's, or provider practice's, patient population.
- The mechanisms an APM utilizes to ensure patient access to the most appropriate therapy for them, including to new-to-market therapies (note: the exact mechanism will depend on the structure of payment/reimbursement utilized by the APM).
- The appropriateness of the performance period that an APM establishes in the context of the patient population that is treated by participating providers (e.g., the type of participating provider (primary versus specialty), the type of care needed (acute versus chronic)).
- The ability of an APM's monitoring mechanisms to collect data on provider and patient experiences, and the ability of the APM to refine its operations based on these data.

V. Conclusion

BIO appreciates the opportunity to engage with the Work Group as it pursues a categorization scheme for APMs and looks forward to serving as a resource as this work progresses. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement & Health Policy