November 17, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, M.D. 22224

BY ELECTRONIC DELIVERY

RE: CMS Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization is pleased to submit feedback in response to the Centers for Medicare and Medicaid Services' (CMS's) Request for Information entitled "CMS Regarding Implementation of the Merit-Based Incentive Payment System (MIPS), Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models," (the "RFI") released October 1, 2015.[1]

BIO advocates on behalf of 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 represents an industry that is devoted to discovering, and ensuring patient access to, innovative treatments. Given its scope and breadth, MIPS can play a significant role in improving Medicare beneficiaries' access to the most appropriate care for them as well as contribute to an environment that incentivizes longer-term innovation. However, the impact of MIPS will depend on how CMS structures and implements the program, a process the Agency began through a request for feedback in the Calendar Year (CY) 2016 Physician Fee Schedule (PFS) Proposed Rule and is continuing through the RFI. While BIO appreciates CMS's interest in stakeholder feedback on the details of MIPS development, as an initial matter, CMS should identify how MIPS fits into the broader HHS effort to transition from paying for volume to paying for value.[2] Moreover, CMS should clearly state the goals and priorities of the program so that the Agency, as well as stakeholders, has a clear understanding of the purpose of program in the context of beneficiary care and has clear benchmarks against which to judge whether the program is fulfilling that purpose. For example, in our view, the primary goal of MIPS should be to aim to maintain, or improve, the quality and efficiency of individual patient care. Achieving this goal would contribute to HHS' broader objective of fulfilling the triple aim: improved individual patient outcomes, improved population health, and decreased overall health expenditures.

[1] 80 Fed. Reg. 59,102 (October 1, 2015).
[2] 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

As a general comment, BIO appreciates the Agency's engagement with stakeholders early in the development process. This is important to promote a productive, inclusive dialogue with regard to developing and implementing MIPS successfully to accomplish the goals Congress established in MACRA. BIO strongly urges CMS to continue to engage stakeholders throughout the MIPS development process, not only through formal comment periods, but through informal mechanisms as well, including but not limited to town hall forums, interactive webinars, and discussions with individual stakeholders.

In the remainder of this letter, BIO responds to the questions that CMS poses in the RFI. While our comments are specific to the nature and premise of the question posed, there are several prevailing themes throughout the letter that we strongly urge CMS to adopt throughout MIPS. Specifically, CMS should:

- Ensure that patients can access, and maintain access to, the most appropriate care for them, including with regard to prescription drugs;
- Ensure that MIPS incentivizes appropriate utilization and high-quality care, including with respect to patient access to new-to-market therapies;
- Preserve the patient/provider decision-making process;
- Only utilize accurate and reliable data on the quality of care an individual patient receives from a MIPS eligible professionals (EP);
- Ensure that quality and resource use measures, and reporting mechanisms, maintain pace with the progress in medicine and clinical practice;
- Ensure EPs are not unduly penalized for treating the sickest patients, or for circumstances beyond their control; and
- Provide opportunities for public comment throughout the MIPS development and refinement process—and, in particular, ahead of structural or substantive changes that impact the calculation of the MIPS composite score—and apply all changes to the program prospectively.

Each of these themes is expressed in greater detail in the sections below, which respond specifically to questions posed in the RFI in the order in which CMS poses them.

I. Virtual Groups: CMS should allow no more than 100 EPs to participate in a virtual group initially.

CMS asks stakeholders whether there should be restrictions on the number of virtual groups included in MIPS, providing the example of the potential to set a maximum (e.g., 100) and/or a minimum (e.g., 10) number of MIPS EPs.[3] BIO believes that there should be a maximum size for EP virtual groups to protect against unintended distortions in the calculation of the MIPS composite score that could arise by aggregating a very large number of practices into a virtual group. For example, very large virtual groups assessed together may distort the benchmark against which EPs that are similar (e.g., in terms of medical specialties or practice patterns), but do not participate in the virtual group, are judged (e.g., in terms of quality and resource use performance). In the absence of correlation data on the potential impact of the size and/or composition of a virtual group and performance on the MIPS composite score, BIO encourages CMS to implement the proposed 100-EPs limit initially. In the first two years after MIPS is implemented, the Agency can reassess this maximum, based on available evidence and data, as well as the need for a maximum going forward. BIO suggests that CMS conduct a similar assessment with regard to a minimum number of EPs once the MIPS has been implemented. As a related matter, we encourage

[3] 80 Fed. Reg. at 59,104.

CMS to require that each EP in a virtual group exceeds the MIPS low-volume threshold until the Agency can determine the potential implications of including EPs that would not otherwise be MIPS-eligible on the virtual group's composite score.

II. Quality Performance Category

A. PQRS Reporting Mechanisms: CMS should impose requirements on Qualified Clinical Data Registries (QCDRs) to ensure accurate and reliable data reporting.

CMS asks stakeholders whether the eight reporting mechanisms that providers currently use to fulfill PQRS requirements should be maintained under MIPS. In considering this question, BIO reiterates our support for the use of QCDRs—one of the eight reporting mechanisms—to report PQRS data, and in turn, fulfill MIPS requirements. However, we reiterate the need for CMS to impose specific requirements on QCDRs to ensure that the inclusion of these registries facilitates the accurate and reliable measurement and reporting of quality of patient care data, a recommendation BIO has made to CMS in the past. Specifically, BIO urges CMS to require qualified registries to:

1. Include only quality measures that have been developed and updated through a rigorous process—for example, a process similar to that utilized by the National Quality Forum (NQF)—that includes a structured opportunity for the incorporation of stakeholder feedback;
2. Review and regularly update data elements and quality measures;
3. Allow for flexibility in data collection methods, including opportunities to collect patient-reported outcomes;
4. Capture data longitudinally, not just at a single time interval;
5. Employ a transparent, peer-reviewed risk-adjustment methodology, as appropriate;
6. Supply meaningful feedback to providers to inform their clinical decision-making; and
7. Provide for adequate patient protections and consent procedures, if appropriate.

B. Reporting and Weighting Certain Types of Measures: CMS should not rely solely on one type of measure (e.g., outcomes- versus process-based), but instead consider what type of measure most appropriately reflects the quality of care an individual receives.

In considering CMS's questions around the types of measures that should be reported (e.g., process- versus outcomes-based), BIO supports CMS's efforts to "emphasize the reporting of certain types of measures, such as outcome measures . . ." across the various Medicare quality programs.[4] In fact, where possible, CMS should aim to employ quality measures that are outcomes-focused instead of those that are solely process-focused. This is because, while process-related outcomes are an important start to understand how a standard of care is implemented, outcomes-based measures more directly link the care provided with a specific health outcome. Since the ultimate aim of MIPS should be to maintain or improve the quality of individual patient care, it is preferable to measure actual changes in health outcomes rather than interpret the likelihood that changes in process directly result in changes in outcomes. This is particularly true in the case of complex and chronic diseases in which many different factors beyond the process of

[4] Id. at 41,816.

care can influence longer-term health outcomes. For these reasons, where outcomes measures are included, BIO believes they should be afforded additional weight.

However, a sole reliance on outcomes measures is not necessarily appropriate. Accordingly, we urge CMS to continue to recognize the importance of having a combination of both process and outcomes measures for purposes of the MIPS, as the Agency has done in the context of PQRS.[5] As one example, we believe it is critically important for Medicare providers to continue to be evaluated for their performance on immunization measures to ensure that Medicare beneficiaries continue to receive these important services. Given these considerations, CMS should consider weighting outcomes-based measures higher only in instances in which these measures more accurately reflect the quality of care an individual patient receives.

C. Requiring Reporting Mechanisms to Stratify Data by Demographic Characteristics: CMS should require reporting mechanisms to stratify data not only by demographic characteristics, but also by other patient- and disease-specific characteristics (e.g., comorbidities, pathophysiology).

In response to CMS's question of whether the Agency should require reporting mechanisms that include the ability to stratify data by demographic characteristics, BIO strongly recommends that CMS implement such requirements, not only with respect to the ability to stratify data based on demographic characteristics, but to stratify data based on patient- and disease-specific characteristics as well (i.e., comorbidities, disease pathophysiology). MACRA section (r)(2)(D) identifies "the patient's clinical problems at the time items and services are furnished" and "clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history" as characteristics that should be included in CMS's development of care episode groups and patient condition groups. In each case, statute also allows the Secretary to consider other factors deemed appropriate. With this statutory foundation in mind, BIO asks CMS to consider requiring that reporting mechanisms are able to capture more detailed patient- and disease-specific characteristics in relation to quality measures—as well as resource use—reporting (the latter is discussed in more detail below). For example, in the case of an oncology patient, the stage and subtype of disease dictate treatment course and can be predictive of health outcomes and total costs of care. Thus, CMS should ensure that that reporting mechanisms capture these crucial data to avoid unduly penalizing MIPS EPs who treat a patient population that is inherently sicker. Furthermore, CMS should utilize the patient- and disease-specific characteristics that are reported through these mechanisms to risk-adjust patient populations—including adjusting for case mix—across disease states and sites of care.

BIO recognizes that existing reporting mechanisms may not be set up to identify disease characteristics, but we strongly urge CMS to take this opportunity to work with stakeholders to determine the most efficient way to collect and transmit this information, without being overly burdensome to providers. This is additionally important since medical

[5] We note, and strongly support that CMS has made a statement to this effect in the context of the Agency's Medicare Shared Savings Program (MSSP) proposals for CY 2016. See 80 Fed. Reg. at 41,885 ("We believe it is important to retain a combination of both process and outcomes measures, because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes."). We are concerned, however, that this statement goes on to suggest that the Agency may move away from process measures entirely. Id. ("We noted, however, that as other CMS quality programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we might also revise the quality performance standard in the Shared Savings Program to incorporate more outcomes-based measures and fewer process measures over time.").

science is increasingly looking to molecular, and even genetic, disease characteristics, and their interaction with patient characteristics, to determine what treatments may work best for certain patients. Ensuring that quality measurement and reporting mechanisms maintain pace with the progress in medical science is crucial to ensuring that the MIPS program is relevant in the context of modern, personalized medicine.

D. Applying MIPS Quality Performance Category to Specialists: CMS should consider differentially weighting the quality performance category for specialty providers based on the extent to which appropriate quality measures for a specialty are included.

In the RFI, CMS requests stakeholder feedback on how the Agency should apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet the defined criteria. As an initial matter, BIO appreciates CMS's focus on ensuring specialty providers are not disadvantaged in the MIPS performance calculations based solely on the type of care they provide. We also think it is important to distinguish between the type of care (e.g., in terms of intensity, reliance on specific types of covered benefits over others) that constitutes quality in specialty versus primary care. In response to the question posed by the RFI, BIO asks CMS to consider differentially weighting the quality performance category for specialty providers that qualify as EPs based on the extent to which appropriate quality measures for a specialty are included. To do so, CMS should use a Measure Applicability Verification Process developed in conjunction with input from provider specialty societies and other interested stakeholders. Through this process, CMS should initially consider establishing specific requirements for all participating specialty providers identified by a Medicare specialty code. However, since there are some provider subspecialties that do not yet have specialty codes, CMS also should consider mechanisms to refine the Measure Applicability Verification Process in future years to more accurately reflect the quality of individual patient care that these providers deliver. Alternatively, CMS could consider requiring specialty providers to report cross-cutting measures—such as pain-control—or other multi-disciplinary measures—such as care-coordination and patient-family engagement measures—to facilitate their assessment on relevant quality metrics under MIPS.

E. Requiring QCDRs and Health Information Technology (IT) Systems to Undergo Review and Qualification by CMS: CMS should establish a standard format and manner for all PQRS reporting mechanisms.

In the RFI, CMS asks stakeholders whether the Agency should require QCDRs and health IT systems to undergo review and qualification by CMS to ensure that CMS's form and manner are met, providing the example of the specific file format the Agency currently uses for qualified registry reporting. In considering this question, and the role of QCDRs relative to the broader PQRS reporting system, BIO encourages CMS to consider establishing a standard format and manner for all PQRS reporting in order to: (1) better ensure the consistency of the data being reported; and (2) more reliably compare data from different reporting mechanisms. To do so, CMS should use the specific file format for qualified registry reporting as a template, and work with stakeholders in advance of, and throughout, the implementation of MIPS to refine these requirements. As part of this process, CMS should identify a process for and requirements with respect to testing all of the reporting mechanisms to ensure the form and manner requirements are met. At a minimum, all reporting mechanisms should be tested at least once before the initial implementation of MIPS and re-tested at least annually, or potentially more often if major changes are made within a performance year.

F. CMS should continue to evaluate providers participating in Medicare on the basis of their performance on immunization measures, as relevant to their practice and patient population.

It is critically important for Medicare physicians to continue to be evaluated for their performance on immunization measures as such measures help ensure that they routinely discuss and offer recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system. Additionally, immunization measures are in line with Healthy People 2020 goals and provide a mechanism for evaluating and tracking progress. Therefore, we urge CMS to maintain within MIPS the immunization measures that are currently included in the Physician Quality Reporting System (PQRS) and the Hospital Value-Based Purchasing Program. BIO also encourages CMS to develop and integrate additional immunization measures recommended by the National Quality Forum (NQF) in MIPS.

The impact of immunization measures was clearly shown following the introduction of performance measures for influenza and pneumococcal vaccinations in the Veterans Health Administration (VHA) in 1995. Among eligible adults, influenza vaccination rates increased from 27 percent to 70 percent, and pneumococcal vaccination rates rose from 28 percent to 85 percent, with limited variability in performance between networks; pneumonia hospitalization rates decreased by 50 percent, and it is estimated that the VHA saved $117 for each vaccine administered.[6]

Such gains are still much needed in the broader adult population. Currently, the percentages of adults receiving influenza and pneumococcal immunizations, despite evidence of the reduction of influenza and pneumococcal-related morbidity and mortality and consequent cost-savings, remain suboptimal. For instance, in 2013, pneumococcal vaccination coverage among adults age 65 and older was only 59.7 percent, and among high-risk adults age 19-64 with conditions such as COPD, diabetes, and CVD, it was only 20 percent.[7] Approximately 175,000 people are hospitalized with pneumococcal pneumonia each year in the U.S. and in 2012, the total costs for Medicare beneficiaries during, and one year following, a pneumonia hospitalization were approximately $15,682 higher than those patients without pneumonia.[8]

In regard to influenza, during the 2014-15 season, the Centers for Disease Control and Prevention (CDC) reported nearly 18,000 cases of hospitalizations from influenza-like illness, 61 percent of which were among adults age 65 or older.[9] Between 1976 and 2007, the mortality rate from influenza ranged from 87 in 1986 to 48,614 in 2003-04, with the population of adults over age 65 being the most at risk.[10] Recognizing this burden, the Advisory Committee on Immunization Practices (ACIP) recommends routine influenza vaccination of all people over 6 months of age every year.

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[6] A. Jha, S. Wright, J. Perlin, *Performance measures, vaccinations, and pneumonia rates among high-risk patients in Veterans Administration Health Care,* 97 Am. J. Public Health 2167-2172 (2007).
[7] Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rpt.* 2013;63(04):66-72.
[8] National Foundation for Infectious Diseases. Pneumococcal Disease Call to Action. April 2012.
[9] Centers for Disease Control and Prevention. Influenza Activity – United States, 2014-15 Season and Composition of the 2015-16 Influenza Vaccine. *MMWR Morb Mortal Wkly Rpt.* 2015;64(21);583-590.
[10] Centers for Disease Control and Prevention. Estimates of Deaths Associated with Seasonal Influenza --- United States, 1976-2007. *MMWR Morb Mortal Wkly Rpt.* 2010;59(33);1057-1062.

Quality measures currently in place for influenza and pneumococcal disease help improve immunization rates by ensuring healthcare providers offer these recommended vaccines to their patients, reducing the number of missed vaccination opportunities. Pneumococcal vaccination also reduces the need for antibiotic treatments thereby slowing the spread of antimicrobial resistance (AMR).

Currently, the PQRS includes the following immunization measures in various groups:

- NQF#0041/PQRS#110, Preventive Care & Screening: Influenza Immunization
- NQF#0043/PQRS#111, Pneumonia Vaccination Status for Older Adults
- NQF#0399/PQRS#182, Hepatitis A Vaccination in Patients with Hepatitis C Virus
- NQF#1407, Immunization for Adolescents
- NQF#0038/PQRS#240, Childhood Immunization Status

BIO urges CMS to ensure that these measures persistent in the MIPS quality component of provider assessment.

Beyond these current immunization measures, BIO encourages CMS to consider including additional adult immunization measures to address gaps identified by the NQF in their report, "Priority Setting for Healthcare Performance Management: Addressing Performance Measure Gaps for Adult Immunizations." Among the Medicare population, the NQF committee identified zoster vaccination for both ages 60-64 years and ages 65+ years as a priority for measurement, as well as a number of composite measure priorities, such as measures to help manage chronic diseases like diabetes and end-stage renal disease (ESRD), which are prevalent in the Medicare population. BIO is supportive of CMS' intent to align quality reporting systems and the alignment of additional immunization measures with the National Quality Strategy (NQS), CMS Strategic Plan, and other CMS quality reporting and value-based purchasing programs.

Vaccination of healthcare workers is one of the most effective preventive measures against the spread of influenza, especially among sick individuals, such as cancer patients, who are already at an increased risk of developing infectious disease. Increasing vaccination rates among healthcare personnel is an important step in protecting patients from developing nosocomial influenza. CMS should consider including a measure of healthcare personnel vaccination rates, such as was proposed for the FY 2018 PCHQR program, to help avoid preventable adverse patient outcomes, while also improving work productivity among HCPs.

CMS plays a critical role in leading on quality measures. In fact, the Agency for Healthcare Research and Quality's (AHRQ's) 2014 National Healthcare Quality and Disparities Report observed that CMS's publicly-reported quality measures were more likely to promote high performance levels than other sources' measures. The report also comments that pneumococcal vaccination of hospital patients over age 65 is a particular area of success among CMS quality measures.[11] Hence, CMS should transition these immunization measures that have seen success in the past to the new MIPS program, as the inclusion of immunization and preventive services measures would help reduce vaccine-preventable diseases, facilitate better management of individuals with chronic conditions, and therefore improve the health of both Medicare beneficiaries and the broader U.S. population.

[11] Agency for Healthcare Research and Quality. National Healthcare Quality and Disparities Report. 2014.

III. Resource Use Performance Category

A. Aligning MIPS Measures with Measures Utilized in Other Parts of Medicare: CMS should use significant caution when aligning resource use measures across MIPS and other Medicare programs since not all measures are appropriately applied to all providers and/or in all care settings.

BIO cautions CMS against including resource use measures used in other Medicare payment systems in the MIPS without a robust assessment, incorporating stakeholder feedback, of the appropriateness of such measures for MIPS EPs. MACRA allows the Secretary to "use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the performance categories" under MIPS.[12] However, the Secretary may not use measures for hospital outpatient departments except with regard to the items and services furnished by emergency physicians, radiologists, and anesthesiologists. While BIO supports efficiency in the metrics assessment process across Medicare, and we are sensitive to the need to ensure the reporting burden on providers is not unduly high, we are concerned that not all measures are appropriate metrics of resource use in all care settings. For example, resource use measures tailored to care commonly provided in an inpatient setting may not capture the resources required to deliver such care in an outpatient setting (e.g., the setting in which care is delivered may act as a proxy for the severity of a patient's disease/condition). Thus, we urge CMS to request stakeholder feedback on the applicability of specific metrics used in other settings, like the hospital inpatient setting, to MIPS EPs before finalizing any such quality measures for a performance period.

B. Medicare Part D and MIPS: CMS should address concerns with regard to preserving patients' access to care when considering the feasibility and applicability of including Part D costs in the MIPS resource use category at this time.

BIO has consistently advocated for alternative payment models that protect the patient/provider decision-making process and afford patients timely access to the therapies that are most appropriate for them. Thus, we recognize that how CMS structures the resource use metrics for drugs and biologicals, no matter how Medicare covers them, could significantly impact patient access. This is especially the case if the Agency introduces a financial incentive to providers, in the form of a better MIPS composite score, that distracts from what should be the primary criterion of patient/provider decision-making: what is the most clinically appropriate for an individual patient. Thus, in establishing a methodology for calculating EPs' resource use, BIO urges CMS to work with stakeholders to ensure that providers are not unduly penalized for their treatment decisions based on how those therapies are covered under Medicare.

The Agency should consider the following circumstance: for patients with a given disease or condition, there may be competitive classes in which at least one Part B-covered and one Part D-covered therapy are indicated to treat their disease/condition. Depending on an individual patient's characteristics and disease pathophysiology, a provider may prescribe one therapy over the other, a decision that reflects the provider's clinical expertise and experience as well as the patient's priorities and preferences. However, in this circumstance, the provider who prescribes the Part B therapy will be penalized under a MIPS composite score that only takes into account Part B costs. While we believe that most providers will

[12] MACRA § 101(q)(2)(C)(ii).

put their patients' needs first, a system that does not proactively prevent this type of distortion will reward those few who act arbitrarily and inappropriately as well as those EPs who treat patients who are most appropriately prescribed the Part D, rather than the Part B, therapy based on their specific clinical circumstances. It also could affect where and how patients access necessary care and potentially increase their out-of-pocket costs, which, in turn, could affect their medication adherence and thus their health outcomes in both the short- and longer-term.

To address concerns about providers' incentives to prescribe Part B versus Part D therapies for a specific clinical indication, we recommend that the Agency pursue an innovative approach that would utilize the MIPS benchmarking methodology to ensure that EPs are compared only to other EPs with similar prescribing patterns for a similar patient population (*see* next section, III(C)). BIO looks forward to the opportunity to work with CMS to consider and work to implement this, or another similar, solution to ensure patient access to the most appropriate therapy for them, no matter how it is covered under Medicare. Furthermore, in considering MACRA's instruction that the Secretary determine the feasibility and applicability of incorporating Part D costs under MIPS, BIO strongly urges CMS to share any evolving analyses and methodologies with the public and solicit feedback from a diverse range of stakeholders.[13] Similar to recommendations made throughout this letters, BIO strongly urges CMS to engage stakeholders early and often in the process of developing a valid resource use metric that ensures EPs are not disincentivized to, or penalized for, prescribing the most appropriate therapy for an individual patient.

C. Peer Groups and/or Benchmarks in the Resource Use Performance Category: CMS should utilize, but improve upon, the Value-based Payment Modifier's (VM's) specialty adjustment methodology.

In the RFI, CMS requests stakeholder feedback on the peer groups or benchmarks that should be used when assessing performance under the MIPS resource use performance category. In considering this question, BIO strongly agrees that CMS only should compare resource use among similar providers based on the provider type and the underlying health of his/her patient population. BIO recommends CMS initially consider using the specialty adjustment methodology currently employed in the context of the VM program. Specifically, in this adjustment method, the standardized score for the VM cost measures is adjusted based on the average costs of care for the specialties represented in a given physician group. While BIO supported this methodology as an important refinement in the early stages of the VM program, we encourage CMS to improve upon it in the MIPS context, by including other facets of clinical care, including site of care, and additional patient and disease characteristics (discussed in more detail in BIO's response in Section V(A)).

BIO recommends that CMS make one specific improvement on the VM methodology with respect to prescription drug utilization. As described in more detail in section III(b) above, BIO is concerned that providers who prescribe Part B therapies may be unduly penalized in circumstances in which there are both Part B-covered and Part D-covered therapies available to treat a patient's disease/condition. In this case, EPs whose patients are appropriately treated with the therapy covered under Part B may be unduly penalized in the MIPS composite score when compared to EPs whose patient populations are most appropriately treated by the Part D therapy. This is because, if the resource use metric is structured similarly to the VM's total per-capita cost metric, it will include the drug

[13] MACRA § 101(q)(1)(D)(ii).

utilization of the former EP's patients since it is covered under Part B, but exclude the drug utilization of the latter's patients, since it is covered under Part D.

One potential mechanism to resolve this distortion is to utilize a robust risk-adjustment methodology within the MIPS so that patients who are more likely to require the Part B therapy can be identified, and the providers who treat these patients can be benchmarked only to providers who treat similar patients. However, existing risk-adjustment methods are not yet sufficiently sophisticated to accomplish this, and this mechanism may not be possible for all patients and/or disease/conditions. Thus, BIO recommends that CMS include, as a component of the benchmark, a comparison of the ratio of EPs' Part B prescriptions for diseases/conditions for which both a Part B and Part D therapy are clinically indicated. Under this proposed methodology, EPs would be benchmarked not only based on their specialty and the similarity of their patient populations, but also in terms of the similarity of their Part B prescription drug ratios. Specifically, the Agency could calculate the percent of a provider's patients with a specific disease—for which both a Part B and a Part D therapy (or therapies) may be clinically indicated—that were prescribed the Part B therapy. In turn, providers would be benchmarked only to other providers with similar such ratios of patients who are prescribed the Part B therapy/therapies for a specific disease/condition. Thus, all other variables held constant, EPs for whom the majority of their patient population utilizes the Part B therapy would be benchmarked to similar EPs, but not inappropriately compared to EPs for whom the majority of their patient population utilizes the Part D substitute.

Whatever methodology is used, CMS should assess its effectiveness based on: whether it incentivizes high-quality care; prevents against underuse of appropriate care, including with respect to the utilization of drugs and biologicals; and protects patient and provider decision-making. CMS also should actively identify other opportunities to account for the inherent differences between the performance of different clinical specialties on quality and cost measures within other aspects of the MIPS resource use calculation.

D. CMS should structure the MIPS cost composite such that it encourages broader and consistent vaccination practices.

In measuring provider performance, BIO encourages CMS to exclude vaccine administration costs from measures of total per capita costs and Medicare spending per beneficiary. The inclusion of such costs in these calculations is seen by some providers as financial strain, and therefore a disincentive from providing these services. Administering a vaccine involves more than just removing a vaccine from the refrigerator and delivering it to the patient. Providers must contract with health plans, order and manage their vaccine supply, ensure proper storage of vaccines, assess a patients' vaccination status and make a strong recommendation for vaccination, check for contraindications, provide the patient with information regarding the vaccine to be received, update patient records and Immunization Information Systems (IIS), and assess a patients' insurance status and bill for the service, all of which takes time and resources. Immunizations improve the public health and drive down other healthcare spending, and CMS should ensure that any policies or reporting mechanisms introduced do not institute barriers to patients receiving these critical preventive services.

IV. Clinical Practice Improvement Activities Performance Category: CMS should use the Standards for Adult Immunization Practice as a guide for developing measures for clinical practice improvement related to vaccination.

The Standards for Adult Immunization Practice, developed and then updated by the National Vaccine Advisory Committee (NVAC) in 2013, offers a framework for providers to ensure their adult patients are fully immunized.[14] CMS should use the Standards for Adult Immunization Practice as a guide for developing measures for clinical practice improvement as related to vaccination. The Standards encourage the assessment of a patient's immunization status at every clinical encounter, strong provider recommendations for needed immunizations, the administration of needed vaccines or referral to an immunization provider, and documentation of vaccines received or refused by patients. Patient education, a providers' offer of needed vaccines, and documentation of acceptance or refusal should take place at every visit, and should be documented at every visit.

In measuring these activities, providers should be incentivized to input relevant data into existing IIS. Communication, both among providers and between providers and patients, is a major barrier to adult immunization. Increased use of IIS systems – and their interoperability with EHRs – is vital to providing patients with the opportunity to get the vaccines they need, therefore impacting the uptake of vaccines across the lifespan.

V. Other Measures

A. Aligning Measures (e.g., process, outcomes, populations) between Other Payment Systems and the MIPS Quality and Resource Use Performance Categories: CMS should incorporate measures of high quality care and appropriate resource use from other Medicare programs, as well as develop such measures where they do not currently exist, to ensure that patients are able to access, and maintain access to, the most appropriate care.

With regard to the types of measures that the MIPS quality and resource use performance categories should include, BIO strongly urges CMS to incorporate measures that are specific enough to capture information on the patient and disease characteristics of the reported populations. Considerations of high quality care and appropriate resource use rely on identifying, analyzing, and comparing these characteristics (*see* BIO comment in response to III(c) above). For example, the stage of cancer with which a patient is diagnosed not only determines what appropriate courses of treatment are available, but what commitment of resources reflects the provision of, at least, the standard of care. Given the growing understanding of the heterogeneity of disease pathophysiology, especially in the context of chronic conditions that disproportionately impact the Medicare population, being able to identify and compare quality and resource use on a reliable basis will be increasingly dependent on having disease and patient characteristic information available. The incorporation of metrics that include this information also reflects the trend toward increasingly personalized medicines that target patients based on biomarkers and genetic composition. These measures may be imported from other payment systems, to the extent that they have been shown to be applicable to the patients MIPS EPs will treat, but also may need to be developed and refined in advance of, and throughout, MIPS implementation.

[14] National Vaccine Advisory Committee. Update on the National Vaccine Advisory Committee Standards for Adult Immunization Practice. 2013.

As CMS develops and implements the MIPS, as well as other integrated aspects of MACRA, the Agency should include quality measures that assess patient access to the most appropriate therapies under these programs. Such an assessment must be multi-faceted, including whether patients have timely access to the most appropriate therapy at the beginning of their treatment—including new-to-market therapies—and whether patients are able to remain on a therapy that works for them throughout the course of their treatment (i.e., in consultation with their provider). Not only does access to the most appropriate therapy have the greatest potential to help patients achieve their desired health outcomes, but adherence to therapy can result in decreased overall health expenditures (e.g., as a result of decreased hospitalizations, physician office visits, and surgical interventions). In considering how to assess whether patients are able to remain on an appropriate therapy throughout the course of their treatment (to the extent that they, and their provider, determine it to be necessary), BIO urges CMS to consider the negative impact of the practice of non-medical switching (NMS) and mechanisms to mitigate this impact through the MIPS implementation.

NMS is the emerging term used to describe the substitution of a therapy on which a patient is already stable with another treatment option in the same therapeutic class on the basis of a non-clinical rationale, usually that of cost. Currently, NMS appears to be most common in chronic conditions such as rheumatoid arthritis, Crohn's Disease, ulcerative colitis, psoriasis, and lupus. Preliminary research has found that NMS can negatively impact patient health outcomes by, for example, increasing negative side-effects and the number of episodes/flare-ups a patient experiences after the NMS has occurred.[15] This can lead to increased consumption of healthcare resources, such as increased physician office visits and hospitalizations. NMS is prohibited in certain sectors of Medicare (i.e., for the six Part D protected classes), but this patient protection is not available to all beneficiaries. Given the importance of this issue, we urge CMS to consider how assessments of NMS can be included for MIPS EPs through the implementation of quality and performance measures that directly assess patients' continued access to appropriate therapies. BIO looks forward to working with the Agency to identify, develop, and implement such metrics.

B. Including Global and Population-Based Measures under MIPS**:** CMS should only utilize global and population-based measures where they accurately reflect the care received by an individual patient.

BIO cautions CMS against the use of global measures to assess provider performance in the MIPS in the absence of robust evidence that such measures are able to capture the quality and effectiveness of care individual beneficiaries receive. MACRA allows the Secretary to use global measures (e.g., global outcome measures) and population-based measures for purposes of assessing provider performance on quality measures. BIO supports what we assume to be the underlying goal of this provision: to create efficiencies in collecting and analyzing data on quality and effectiveness of care and to limit the reporting burden on MIPS EPs. However, we note that the ability of a global and/or population-based measure to accurately reflect the care an individual is receiving from a MIPS EPs will vary significantly depending on the type of care, the expected homogeneity of the impact of that care on a patient population, and the condition/disease the care is meant

[15] See Rubin, D.T., M. Skup, S. J. Johnson, J. Chao, and A. Gibofsky. 2015 [Abstract Presentation]. Tu1305 Analysis of Outcomes After Non-Medical Switching of Anti-Tumor Necrosis Factor Agents. *Digestive Disease Week ® Gastroenterology Conference*, Washington, D.C.; also see Global Health Living Foundation. 2015. *Patient Perspectives on Medication Switching for Non-‐-‐Medical Reasons*, available at: http://www.50statenetwork.org/wp-content/uploads/2015/04/GHLF-Switching-Stable-Patients-Survey_Summary.pdf.

to prevent, diagnose, and/or treat. While these types of measures may be more appropriate for certain aspects of primary care (e.g., the provision of vaccines), using global measures to assess the performance of specialty providers may obscure important information about the care individual patients, or subpopulations of patients, receive. Thus, we caution CMS against the use of global measures unless there is evidence to suggest such measures can appropriately capture the quality and effectiveness of care individual Medicare beneficiaries receive.

VI. Development of Performance Standards

A. Incorporating Historical Performance Standards under MIPS: CMS should not be overly reliant on historical performance standards since they are unable to account for the dynamic pace of medical advancement, particularly in the case of new-to-market therapies.

In the RFI, CMS asks stakeholders to identify specific historical performance standards that should be incorporated under MIPS, whether the Agency should use providers' historical quality and cost performance as a benchmark or threshold for future performance, whether performance standards should be stratified and by what criteria, and to consider relevant similarities between the VM and MIPS that can be instructive in this context. These questions get to the heart of the development of performance standards that incentivize high quality care and efficient resource use. In fact, to ensure the structure of MIPS is able to meet these goals, BIO urges CMS to establish performance standards based on existing evidence of what constitutes high quality, effective care for individual beneficiaries, and not to be overly reliant on historical performance metrics or measures of improvement.

Under MIPS, the Secretary must establish performance standards with respect to specified measures and standards for a performance period. In doing so, MACRA directs the Secretary to consider: (1) historical performance standards; (2) improvement; and (3) the opportunity for continued improvement. While we understand that statute directs the Secretary to consider these three factors in establishing performance standards, BIO urges the Agency to do so in the context of the following concerns. First, historical performance standards may not be relevant to the population served by MIPS EPs and do not take into account the impact of technologies that have come to market in the meantime that may significantly impact the practice of medicine. Moreover, performance standards that are based on historical costs may disincentivize the uptake of new-to-market innovations. This is because an assessment of providers' attributable expenditures in this situation will penalize those who are prescribing/utilizing these newer innovations, which are not reflected in the historical cost benchmark. To the extent that attributable expenditures will be included as a factor in assessing MIPS EPs' performance, BIO urges CMS to establish a mechanism to "carve-out," or otherwise account for, the costs of new-to-market innovative technologies, as has been done in the Medicare inpatient setting (i.e., through the use of new technology add-on payments) and the Medicare outpatient setting (i.e., through the use of pass-through payments).

B. Impact of the Definition of the Baseline Period for Measuring Improvement on Quality Performance: CMS should exercise caution is establishing baseline periods for measuring improvement to avoid penalizing providers who are already delivering high-quality care and those who treat the sickest patients.

As discussed in the section above, under the MIPS, the Secretary must establish performance standards with respect to specified measures and standards for a performance period. In doing so, MACRA directs the Secretary to consider: (1) historical performance standards; (2) improvement; and (3) the opportunity for continued improvement. Considering both the second and third factors together, we remain concerned that a focus on improvement may disadvantage providers who are already performing well, potentially regardless of where the baseline is established. In fact, CMS has recognized the potential for this issue in the Medicare Advantage Star Rating program, and addressed it through assigning consistently high-performing plans an additional score (captured in the form of an "i" factor). BIO also strongly urges the Secretary to take into account the variability in performance and improvement based on: a provider's specialty or subspecialty and the characteristics of a provider's patient population when considering improvements in quality performance. For example, on an absolute scale of quality, MIPS EPs who treat sicker or more complex to treat patients may not appear to improve year to year. However, if EPs are instead judged against a baseline period that is adjusted for their specialty type and the underlying characteristics of their patient population, CMS can identify significant, relative improvements in the quality of care these EPs deliver. Thus, BIO urges CMS to ensure that performance metrics are tailored to account for these factors to avoid unduly penalizing providers for aspects of care outside of their influence.

VII. MIPS Composite Performance Score and Performance Threshold

A. Assessing Performance on the Four MIPS Performance Categories: Assuming the use of robust quality metrics that are specialty-specific and outcomes-focused, CMS should weight quality of care above the other performance categories**.**

In the RFI, CMS seeks stakeholder input into how the Agency should assess performance on each of the four performance categories (i.e., quality, resource use, clinical practice improvement activities, and meaningful use of certified EHR technology) and combine the assessments to determine a composite performance score. In considering these questions, BIO encourages CMS to perform an analysis that utilizes template data from VM program participants to identify the impact of varying the weights assigned to each of the four performance categories on the boundaries between composite scores that would result in negative or positive payment for EPs of varying composition. This multivariate analysis would provide better guidance with regard to the results of different weighting structures, allowing CMS to determine which of the measures to emphasize. However the Agency structures the composite score, BIO strongly urges CMS to reconsider how the composite score is calculated after the first MIPS implementation year. This reassessment is important since the Agency, and stakeholders, will have a much more in-depth knowledge of the program's incentives and its initial impact on provider behavior and patient access once it has been implemented. Any such reassessment should be conducted through a notice-and-comment process to obtain input from the broader possible range of stakeholders participating in and affected by MIPS. In considering this option, CMS also should explore the potential advantages of allowing MIPS EPs a pilot year before MIPS goes into full effect, in which all of the elements of the program are operational—including reporting requirements and the provision of metrics reports to the provider—but the financial reward/penalty a provider may accrue is not assessed. Structuring a provider's first

participating year in such a manner can improve their familiarity with the program requirements and the impact of their clinical behavior on their performance under MIPS to better facilitate success once their Medicare reimbursement is at risk.

In considering a specific weighting structure, BIO recommends that CMS use the flexibility provided by statute to maximize the weight assigned to quality measures in the first two years of MIPS. Specifically, in the first year of MIPS implementation, CMS can assign quality measures a weight between 50-59 percent of the MIPS composite score (with resource use weighted between 1-10 percent, such that the two weights total to 60 percent). In year two, CMS can assign quality measures a weight between 45-59 percent of the composite score (with resource use weighted between 1-15 percent, such that the two weights total to 60 percent).[16] CMS also can reduce the meaningful use weight by up to 10 percent and reallocate this percentage to the other categories, if the Agency determines that at least 75 percent of EPs are compliant with EHR meaningful use requirements.

BIO believes that Congress directed CMS to increase the percentage of the MIPS composite score based on quality measures in the first two years exactly because stakeholders have had little experience with physician-level resource use measures. For example, stakeholders have repeatedly raised concerns about the reliability of the resource use measures currently used in the value-based modifier program, and substantial challenges exist in developing appropriate methods to risk adjust physician-level resource use measures.[17] Therefore, CMS should use the discretion given to it by MACRA to maximize the quality weight and minimize the resource use weight, within the statutory parameters (i.e., set the quality and resource use weights at 59 percent and 1 percent respectively), for the first two years of MIPS, recognizing that valid and appropriately risk-adjusted resource use measures will take time to develop.

B. Implementing the VM Weighting Structure under MIPS: CMS should take into account the implications of the VM methodology for assessing specialists when considering its applicability under MIPS.

In the RFI, CMS requests stakeholder input on utilizing a methodology similar to what is currently used for the VM with respect to equally weighting quality and resource use measures across National Quality Strategy domains. The one consideration BIO asks CMS to take into account when considering the VM methodology is that not all provider types will report the available quality and resource use metrics to an equal extent of, especially in the first several years of the program as these metrics are refined for specialists. Thus, we recommend CMS further analyze the impact of the structure of the VM on how specialty providers are scored, whether modifications to the equal weighting across National Quality Strategy domains may positively impact how certain specialty provider types are scored, and from these analyses determine the applicability of this methodology under MIPS.

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[16] See SSA §§ 1848(q)(5)(E)(i)(I)(bb) and (II)(bb), which provide respectively: (bb) FIRST 2 YEARS.—For the first and second years for which the MIPS applies to payments, the percentage applicable [for quality] shall be increased in a manner such that the total percentage points of the increase under this item for the respective year equals the total number of percentage points by which the percentage applied [for resource use] for the respective year is less than 30 percent [§ 1848(q)(5)(E)(i)(I)(bb).]; (bb) FIRST 2 YEARS.—For the first year for which the MIPS applies to payments, not more than 10 percent of such score shall be based on [resource use]. For the second year for which the MIPS applies to payments, not more than 15 percent of such score shall be based on [resource use]. [§ 1848(q)(5)(E)(i)(II)(bb).]

[17] See, e.g., National Quality Forum, January 31, 2014 Technical Report, Endorsing Cost and Resource Use Measures (declining to endorse the Total Per Capita Cost For FFS Beneficiaries measure used in the VBM due to concerns about the measure's construction and the ability of the attribution approach to capture costs appropriately and assign them to appropriate providers).

C. Determining Minimum Case Size Threshold: CMS should develop and test different thresholds for each physician specialty that are reliable, statistically significant and replicable.

BIO encourages CMS to utilize a minimum patient threshold to ensure that the composite score is not overly skewed by the presence of outlier data. While a certain extent of outlier data is expected within any sample size, its influence on the composite score will increase—and potentially serve to distort a provider's true quality of care and relative resource use—as the number of cases considered decreases. However, as an initial minimum, BIO is concerned that a 20 non-random minimum case threshold is not a reliable resource cost benchmark for a practice, does not lead to replicable results, and is unlikely to result in statistically significant differences between a small practice and a specialty practice benchmark. For example, CMS's risk score credibility guidelines for Medicare Advantage (MA) and Part D bid pricing tools (BPTs) suggest a minimum of 300 beneficiaries for plans to demonstrate the calculated risk scores are credible. This aligns with the standard statistical practice for calculating appropriate samples sizes for continuous, non-normally distributed variables. Specifically, the greater the standard deviation within a sample, the greater the required minimum sample size.[18]

Rather than impose a pre-specified sample size minimum, BIO asks CMS to calculate appropriate sample size minimums using accepted statistical practices, as described above, as well as the Agency's own data on the standard deviations and differences by specialty, information which should be publicly released. We note that physicians' societies do not have enough information to provide these minimum figures to CMS themselves. Moreover, similar to the risk score evaluation reports that CMS is required to release to the public per ACA mandate, CMS should test and publish the results of an evaluation of applying the Hierarchical Chronic Condition (HCC) risk adjustment model to varying levels of patient aggregation for different types of specialists in order to best determine the appropriate thresholds to use. We do not believe it is appropriate to pre-determine a minimum patient threshold prior to assessing the reliability, accuracy, and stability of the model for a specialty type. Therefore, BIO asks CMS to model different thresholds for different types of practitioners, as the expected distribution of spending patterns may vary by specialty given the difference in practice organizations (e.g., some specialties have typically small practices, while some are organized more commonly into large practices).

VIII. Public Reporting: CMS should release, in aggregate, information related to disease characteristics in addition to patient demographic information to contextualize MIPS composite scores.

In the RFI, CMS asks stakeholders to comment on whether the Agency should include individual EP and group practice-level quality measure data stratified by patient demographics, including race, ethnicity, and gender, in public reporting. BIO supports this proposal. Additionally, and in the same vein of comments BIO offers throughout this letter, we encourage CMS to consider releasing the disease characteristics-related information in aggregate, in addition to other patient characteristics that are released, to contextualize MIPS composite scoring further (*see* BIO comments in response III(c)).

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[18] The formula for calculating sample size for continuous variables is $n = 1 + 2C(s/d)^2$, where C is a constant function of alpha and beta, see National Research Council (US) Committee on Guidelines for the Use of Animals in Neuroscience and Behavioral Research. Washington (DC): National Academies Press (US); 2003. Available at: http://www.ncbi.nlm.nih.gov/books/NBK43321/.

IX. Feedback Reports

A. MIPS EP Feedback Reports: CMS should apply lessons learned from the VM's Quality and Resource Use Reports (QRURs) when developing and refining the structure and composition of MIPS feedback reports.

In considering what type of information, and in what format, CMS should provide information within the feedback report, BIO urges CMS to analyze provider response to the VM's Quality and Resource Use Reports (QRURs). BIO previously has expressed concerns with these reports based on feedback from our members' and our discussions with providers. Specifically, we have been concerned that the performance information included in QRURs and Supplemental QRURs could have serious unintended consequences for providers, as well as patient access to care—concerns that are highly relevant to CMS's implementation of the MIPS. This is because data in QRURs may be confusing, irrelevant, and not timely enough for providers to understand and derive actionable steps to adjust and improve their performance. To illustrate, the 2012 QRUR Experience Report indicates that, among groups of 25 providers or more (amounting to 6,779 groups), 42 percent (2,903) received no QRUR, generally due to insufficient data.[19] Thus, in designing the MIPS feedback reports, we strongly caution CMS to identify and implement lessons learned from providers' experience with the VM QRURs. One way to do so would be to conduct a survey of Medicare providers with respect to their receipt, comprehensive, and use of QRURs and apply these data and subsequent analysis to the development and refinement of feedback reports under MIPS. In doing so, BIO also asks CMS to request provider feedback on whether an appeals process should be established to allow providers to challenge the accuracy of the information provided on these data reports before the reports are finalized, and if so, how such a process should be structured.

B. Stratifying MIP EP Feedback Reports by Patient Demographic Characteristics: CMS should include patient demographic information as well as information related to disease characteristics, as possible and appropriate, in the MIPS EP feedback reports.

BIO supports the inclusion of patient demographic information—including race, ethnicity, and gender—in the MIPS feedback reports to EPs. Not only will this information help CMS track and address trends and gaps with regard to health equity, but it will be helpful to individual practices in identifying mechanisms to improve their own patient care. Based on these potential benefits, BIO encourages CMS also to include information, to the extent that it is available, on the disease characteristics of EPs' patient populations (*also see* BIO's response to question III(c)). We are sensitive to the need to ensure that providers are not overwhelmed by the information in these reports, thus we note that this disease characteristic information may not be appropriate for all EPs. For example, the relative homogeneity of primary care providers' patient populations—with regard to disease characteristics—may render this information unconstructive. Thus, we urge CMS to determine how patient information is stratified based on an EP's provider type.

[19] CMS. Experience Report for the Performance Year 2012 Quality and Resource Use Reports. January 8, 2014. Available here: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2012-QRUR_Experience_Report.pdf

C. Inclusion of Information in the Feedback Reports about Items and Services Furnished to an EP's patients: CMS should include information about items and services furnished to an EP's patients to facilitate the EP's care coordination activities.

CMS's question in the RFI regarding the inclusion of items and services furnished to the EP's patients by other providers on the EP feedback report is a recognition that there are aspects of patient care that are not within an individual EP's control. Moreover, these aspects—depending on the patient and his/her disease—can have a significant impact on the patient's health outcomes and/or the intensity of healthcare resources he/she may require, which in turn, can impact an EP's MIPS composite score. Thus, we are supportive of providing EPs with more information about their patients' other interactions with the healthcare system to enable the EP to provide more holistic patient care based on this information. This information also may be useful as the composite score structure evolves to take into account patient health outcomes and resource use that are outside of an individual EP's control.

BIO believes that the information that would be most useful to EPs includes whether patients: are receiving a certain quantity (measured by spending and/or frequency of interactions) of care from another provider, especially a specialty provider; are receiving care from a provider/providers for a condition that is considered comorbid to the condition(s) for which they are receiving care from the EP; and/or have been hospitalized. CMS should work with EPs to identify how this information is most usefully presented (e.g., in aggregate or grouped by specific patient and/or disease characteristics). To the extent feasible, we believe it will be important to provide this additional information as often as feedback reports are distributed in order to maintain a consistent source of information to EPs since their patient populations are dynamic.

X. Information Regarding APMs

A. QPs and Partial Qualifying APM Participants (Partial QPs): CMS should utilize different standards for determining whether an EP is a QP or partial QP to avoid excluding a provider on the sole basis of the type of patients he/she treats.

Under section 1833(z)(2)(D) of the Social Security Act, the Secretary can use percentages of patient counts in lieu of percentages of payments to determine whether an EP is a QP or partial QP. In the RFI, CMS requests stakeholder feedback with respect to whether this option be used in all or only some circumstances. While BIO is not offering specific recommendations with regard to the circumstances in which percentages of patient counts should be used in lieu of percentages of payments, we note the need for CMS to consider these standards based on the EP type in question. This is important because the use of either metric will have a different impact on which providers are considered a QP or partial QP and can preferentially exclude certain provider specialties based on the nature of their practices and/or patient populations: for example, use of percentages of payments may exclude a primary care provider who treats a large number of patients, relatively speaking, but whose patients do not require higher-cost services. Thus, different standards should be considered for different provider types—or the requirement that a provider must meet a multi-pronged threshold utilizing both of these metrics—is necessary since the accuracy of defining whether an EP should be considered a QP or a partial QP will vary depending on the metric and the type of patients a provider treats.

B. Nominal Financial Risk: CMS should take into account the costs that entities expend to participate in an EAPM in the calculation of "nominal amount."

EPs participating in an identified EAPM are eligible for an incentive payment that is a specified percent (which differs depending on the year) of the EP's payments during the performance period. Under section 1833(z)(3)(D) of the Social Security Act, there are two criteria that an entity must meet to be considered an Eligible APM (EAPM) entity. The first criterion of an EAPM—that an EAPM must participate in an APM that requires participants to use certified EHR technology and provides for payment for covered professional services based on quality measures comparable to the MIPS quality measures—is discussed in more detail in the next section. The second criterion is that the EAPM must either bear financial risk for monetary losses under the APM that are in excess of a nominal amount or is a medical home expanded under an 1115 wavier. In the RFI, CMS asks stakeholders how "nominal amount" should be defined for purposes of qualifying an EAPM.

In considering MACRA's goal to foster broad, genuine practice transformation, BIO agrees that an EAPM must take on more than nominal risk such that participating EPs would be eligible for the additional incentive payments. However, if the nominal amount is set too high, this may exclude from consideration entities that are smaller in size but nonetheless have the potential to engage in practice transformation that can significantly benefit patient care and help reduce overall healthcare expenditures. Thus, we ask CMS to survey providers to identify the true costs of practice transformation before establishing a definition for "nominal amount" For example, a 2013 survey by the National Association of ACOs found the average start-up costs for an ACO were approximately two million dollars, and described the associated risks as follows:

> Estimates in the published literature of ACO start-up costs have ranged widely, with $1.8 million estimated by CMS in the draft regulations being the most often quoted. [The American Hospital Association] estimated in 2011 that they would range from $11.6 to $26.5 million. The average actual start-up costs of the [survey] respondents in the first 12 months of operations were $2.0 million with a range from $300,000 to $6,700,000. Since savings are slow to flow as a result of data and complex reconciliation process, ACOs will have almost a second full year of operations until their cash flow can be replenished with shared savings from CMS (if any). This means that the average ACO will risk $3.5 million plus any feasibility and pre-application costs. We estimate that in total, ACOs on average will need $4 million of startup capital until there is a chance for any recoupment from savings.[20]

BIO believes that instances in which an APM invests in practice transformation to such a great extent (e.g., the investment can only be recovered over a significant period of time, or perhaps not at all) fall within the common conception of "financial risk," and promote the goals Congress sought to advance through MACRA's EAPM provisions. Thus, BIO encourages the Agency to consider the different types of financial arrangements and investments into which an entity may enter that could qualify as having met the "nominal amount" definition. Entities' investment in EHR infrastructure, additional staff (for the purposes of offering more comprehensive patient services), and staff training to be able to participate in an EAPM should be taken into consideration in determining whether they have met the "nominal amount" standard.

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[20] National Association of ACOs, National ACO Survey, conducted November 2013, Final report January 1, 2014, at 1 (emphasis added).

C. Regarding EAPM Entity Requirements

i. In addition to assessing the comparability of potential EAPM's quality measures with those of MIPS, CMS should ensure that all an EAPM's quality measures are sufficiently robust to capture the quality of care an individual patient receives.

In addition to the nominal financial risk criterion discussed in the immediately preceding section, an EAPM must participate in an APM that requires participants to use certified EHR technology and provides for payment for covered professional services based on quality measures comparable to the MIPS quality measures established under section 1848(q)(2)(B)(i). In considering the quality metrics employed by a potential EAPM entity, BIO urges CMS to utilize the same metrics previously identified to assess quality measures: specifically, that they 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.

In response to CMS's request for stakeholder input into how comparability of quality measures should be determined, BIO asks the Agency to first consider what patient population is likely to be treated by the potential EAPM entity. This is important to ensure that the potential EAPM's quality measures are compared to MIPS quality metrics for similar patient populations and provider types. This will help to ensure an "apples-to-apples" comparison that will be important to meet the comparability standard identified in statute. In addition to this principal criterion, BIO also asks the Agency to take into account the following aspects of comparability: (1) whether similar percentages of a potential EAPM's quality metrics are outcomes versus process-based compared to MIPS quality measures; (2) whether the measures utilized by a potential EAPM and MIPS are similar in structure such that they rely on similar methodology and similar types of data inputs (e.g., claims, patient-reported) to calculate a provider's score; and (3) whether the two measures sets depend on similarly reliable data. Moreover, based on feedback received in response to the RFI, CMS should propose, and allow stakeholder comment on, specific metrics of comparability, a timeline for assessment, and mechanisms for potential EAPMs to submit justifications for non-comparable quality measures to allow for flexibility in quality measures development and implementation that keeps pace with the standard of care.

ii. CMS should establish rigorous criteria, beyond what is included in statute, for EAPMs.

In addition to the statutory criteria, discussed above, for qualifying an EAPM, BIO urges CMS to establish rigorous criteria for EAPMs through future notice-and-comment rulemaking to ensure that an APM has proven successful in its ability to achieve the Agency's goals before it can eligible for the additional financial incentives of an EAPM. In fact, utilizing robust criteria to ensure that an APM has the infrastructure in place to transition to an EAPM will benefit the entity itself, serving as a check to ensure that data collection, reporting, and analysis capabilities are in place, as well as mechanisms to reliably engage participants, before it evolves to an EAPM. Specifically, BIO recommends that CMS evaluate a potential EAPM based on the following criteria, in addition to the statutory criteria established in MACRA:

- The robustness of included quality measures, specifically, whether the quality 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.
- The comprehensiveness of the risk-adjustment methodology an APM utilizes to account for the underlying differences in an individual provider's, or a 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.

BIO would like to be a resource to the Agency in refining and adding further detail to these assessment criteria in the future.

XI. Information Regarding Physician-Focused Payment Models: CMS should require the Technical Advisory Committee to utilize the criteria identified in the RFI as well as additional criteria.

In the RFI, CMS identifies a list of criteria for use by the Technical Advisory Committee to assess physician-focused payment models under MACRA. BIO strongly supports this list of criteria. We also submit the following additional criteria for the Agency's consideration and incorporation:

1. The variables of patient access assessed in determining how the model would affect access to care for Medicare and Medicaid beneficiaries (with specific focus on access to appropriate providers and preventive and therapeutic interventions);
2. Mechanisms for tracking patient and provider experiences (including effects on patient access) as the model is implemented, and for addressing any access problems identified;
3. With regard to payment mechanisms used in the model, details with regard to how the model intends to account for new-to-market therapies and ensure patients timely access to medical innovation; and
4. A detailed risk-adjustment methodology.

BIO also recommends that these models should be assessed by the same rigorous criteria against which we have recommended potential EAPMs be judged, identified in the previous section.

Additionally, PFPMs can provide an opportunity for physician specialists without previous APM experience to participate in APMs or EAPMs, especially those who treat patients with complex, chronic diseases, including rare diseases. These types of specialists, and subspecialists in some cases, may require additional support and guidance that can be incorporated into PFPMs. For example, the Technical Advisory Committee can identify and recommend the implementation of models that include elements targeted to support specific provider specialties. To do this, the Technical Advisory Committee should leverage existing expertise and experience among stakeholders in the provider community to determine

barriers to practice transformation that certain provider types may face and the aspects of existing APMs that prove most challenging for certain specialty providers to implement (e.g., concerns with regard to accurate risk-adjustment, difficulties in applying commonly used attribution methodologies for certain patient populations that may constitute a majority, or plurality, percentage of a certain type of provider's patient population). In this manner, CMS should consider PFPMs as an incubator for innovative APM design.

XII. Conclusion

BIO reiterates our appreciation for the opportunity to provide this feedback on the RFI. We look forward to additional opportunities to work with HHS to develop, implement, and refine MIPS. 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 & Health Policy