

September 4, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 [CMS-1631-P]

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016*¹ (the "Proposed Rule").

BIO is the world's largest trade association representing 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 new treatments and ensuring patient access to them. Accordingly, we closely monitor changes to Medicare's reimbursement rates and payment policies for their potential impact on innovation and patient access to drugs and biologicals. With the goal of ensuring patient access to necessary vaccines, treatments, and therapies, BIO's comments with respect to the Proposed Rule:

- Urge CMS not to use CY 2016 as a transition year for valuing new, revised, and potentially misvalued codes and to ensure that, in reviewing potentially misvalued codes under the MPFS, adequate reimbursement is provided for all physician services based on the actual time, work, and cost that physicians incur;
- Support CMS's proposals to ensure adequate payment for care management, medication management, and advance care planning services;

¹ 80 Fed. Reg. 41,686 (July 15, 2015).

- Support CMS's proposal to waive the deductible for anesthesia services furnished on the same date as a planned screening colorectal cancer test in order to expand access to screening colonoscopies, an important preventive service;
- Urge CMS to reimburse each biosimilar based on its own average sale price (ASP), consistent with the methodology currently employed for all single-source products, to establish a unique Healthcare Common Procedure Coding System (HCPCS) code for each and every biosimilar product, and to apply the same payment policies to biosimilar products as currently are applied to all innovative drugs and biologicals for quarters for which there are no manufacturer data;
- Support CMS's phased-approach to adding additional measures for public reporting of performance and other data to Physician Compare, and urge the Agency to both ensure that such measures are selected based on feedback from a diverse group of stakeholders and to provide useful information, together with appropriate context, to consumers;
- Urge CMS not to extend aspects of one Medicare value-based payment program to other existing or proposed Medicare programs unless there is a robust evidence base that justifies doing so (e.g., the appropriateness of extending an aspect of one program to another should be based on the similarities of the patient populations, provider types, or diseases/conditions targeted by each program, and no aspect of any existing program should be incorporated into other new or future programs unless and until CMS has resolved any underlying limitations or flaws); and
- Urge CMS to take into account the following five core elements when developing and continuing the implementation of value-based reporting and payment programs: (1) quality measures should be disease-specific and meaningful to both patients and providers; (2) all risk-adjustment methodologies should be robust and should ensure that providers are not unduly penalized based on the underlying health of their patients; (3) patients should have access to the most appropriate therapies for them, including new-to-market therapies; (4) all performance periods should be meaningful in the context of the specific disease(s) and patient population(s) covered by the program; and (5) the Agency should engage in robust monitoring of patient and provider experiences to support continuous program refinement.

I. Potentially Misvalued Services Under the Physician Fee Schedule—BIO urges CMS not to use CY 2016 as a transition year for valuing new, revised, and potentially misvalued codes and to ensure that, in reviewing potentially misvalued codes under the PFS, adequate reimbursement is provided for all physician services based on the actual time, work, and cost that physicians incur.

In 2015, CMS finalized a high-expenditure screen for misvalued codes. For 2016, the Agency has again identified the top 20 codes for each specialty with more than \$10 million in Medicare spending.² Notably, these were the same codes that were identified, but not finalized, as potentially misvalued in the calendar year (CY) 2015 rulemaking cycle.³

² 80 Fed. Reg. at 41,706.

³ See 79 Fed. Reg. 40,318, 40,337-38 (July 11, 2014); 79 Fed. Reg. 67,548, 67,578 (Nov. 13, 2014).

In line with BIO's comments on CMS's assessment of potentially misvalued codes in previous rulemakings, we continue to urge CMS to refrain from finalizing any new revaluations of codes until CMS finalizes its new procedure for valuing new, revised, and potentially misvalued codes. Specifically, in 2015, CMS finalized a policy under which, beginning in 2017, such codes would have values proposed in each year's proposed rule, subject to public comment. BIO continues to strongly support this process. We believe that it represents a significant improvement over the current process, which does not give the public a meaningful opportunity to comment on proposed changes before they become effective. We do not, however, support CMS's plan to use the CY 2016 Proposed Rule as a "transition year." As proposed, for CY 2016, only those codes for which CMS has received Relative Value Scale Update Committee (RUC) recommendations prior to February 10, 2015 will be discussed in the proposed rule; for all other codes, CMS will post values in the Final Rule as interim with comment period.

In particular, we are concerned that many of the codes for which the Agency did not receive recommendations from the RUC by February 10 relate to drug administration and chemotherapy.⁴ We believe that CMS's proposal to post valuations for these codes in the CY 2016 final rule as interim with comment period does not provide adequate opportunity for stakeholder feedback and comment. Instead, such valuations should be established through the full notice-and-comment process with respect to CY 2017 in order to ensure that adequate reimbursement is provided for all physician services based on the actual time, work, and cost that physicians incur.

Moreover, as a general matter, we continue to urge CMS to ensure that each physician service is reimbursed at a rate that adequately reflects the totality of time and work required to furnish the service and to comply with any post-regulatory reporting requirements. In particular, we ask CMS to consider carefully the increased time and effort spent by physicians to comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements imposed by the Food and Drug Administration (FDA) on a growing number of drugs and biological products.

II. CY 2016 Refinement Panel Proposal—CMS should maintain the refinement panel process at least until the new policy for proposing new RVUs for new, revised, or potentially misvalued codes via notices of proposed rulemaking goes into effect for the CY 2017 proposed rule.

With respect to the CY 2015 interim final rates, CMS has proposed that stakeholders will continue to be able to request a refinement panel process to submit new information that was not considered when a code was valued under the RVU processes.⁵ Beginning in CY 2016, however, CMS proposes to eliminate the refinement panel process and instead allow for public input via the notice of proposed rulemaking (e.g., CMS will publish the proposed rates for all CY 2016 interim final codes in the CY 2017 PFS proposed rule for public comment).

⁴ These codes include: 96360, 96372, 96374, 96375, 96401, 96402, 96409, and 96411.

⁵ 80 Fed. Reg. at 41,708 (citing 79 Fed. Reg. at 67,609).

As noted above, BIO does not support CMS's plan to use the CY 2016 rulemaking cycle as a "transition year." We further disagree that the Agency should eliminate the refinement panel process with respect to the CY 2016 rulemaking cycle. While we agree that the opportunity for public comment inherent in the notice-of-proposed rulemaking process provides ample opportunity for stakeholder engagement—including the provision of relevant data for CMS's consideration—we believe that this process works best when stakeholders have the opportunity to inform code valuations on a *prospective* basis. Accordingly, we urge the Agency to maintain the refinement panel process at least until the new policy for proposing new RVUs for new, revised, or potentially misvalued codes via notices of proposed rulemaking goes into effect for the CY 2017 proposed rule.

III. Improving Payment Accuracy for Primary Care and Care Management Services—BIO supports CMS's commitment to supporting care management through its proposals to cover and adequately reimburse care management services provided to Medicare beneficiaries.

- A. BIO supports CMS's proposal to improve payment for the professional work involved in care management services, and urges the Agency to establish an add-on code to capture the resources required to provide comprehensive medication management (CMM) services.

Although both the transitional care management (TCM) and chronic care management (CCM) services describe certain aspects of the professional work involved in care management services, CMS notes in the Proposed Rule that stakeholders have suggested that neither of these new code sets, nor the inputs used in their valuation explicitly account for all of the services and resources associated with the more extensive cognitive work that primary care physicians and other practitioners perform in planning and thinking critically about the individual chronic care needs of particular subsets of Medicare beneficiaries, such as medication reconciliation and coordination across and among care providers.⁶ CMS is therefore interested in public comments on ways to recognize the different resources—particularly cognitive work—involved in delivering broad-based, ongoing treatment, beyond those already incorporated in the codes that describe the broader range of Evaluation and Management (E&M) services.

BIO supports CMS's commitment to supporting care management, which we agree is "one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth."⁷ We further support CMS's efforts to ensure that Medicare providers are adequately reimbursed for their care-coordination services, including the cognitive work inherent in the provision of both TCM and CCM services.

One area of care coordination we believe should be reflected in CMS's proposal relates to comprehensive medication management (CMM). CMM is a patient-centered, coordinated approach to drug therapy that relies on collaboration between providers—including clinical pharmacists, the patient's treating physician, and other healthcare providers and caregivers—who work together with the patient to ensure that medications

⁶ 80 Fed. Reg. at 41,709.

⁷ 80 Fed. Reg. at 41,708 (citing 77 Fed. Reg. at 68,978).

are appropriate for the patient, effective for the condition being treated, and able to be taken by the patient as intended.⁸ A growing body of evidence demonstrates the potential for CMM to maximize the benefits of appropriate medication use.⁹ We therefore believe that CMS should create an add-on code to describe the extended professional resources, including cognitive work, necessary to provide these important services.

B. BIO supports CMS's proposal to establish separate payment for collaborative care, as well as the related beneficiary protection proposals.

In the Proposed Rule, CMS articulates the Agency's belief that the care and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information-sharing, and planning between a primary care physician and a specialist.¹⁰ However, the Agency notes that Medicare does not currently make separate payment for these inter-professional consultative services.

BIO supports CMS's recognition of the importance of robust inter-professional consultation and agrees that providers should be adequately reimbursed for their services. In this regard, we further agree with CMS that certain guardrails are necessary with respect to this proposal in order to protect beneficiaries. Specifically, we support CMS's proposal to ensure that beneficiaries are fully aware of the involvement of the specialist in the beneficiary's care, as well as the benefits of the consultation, particularly before being billed for their share of the cost of such services. Alternatively, we also support the concept of testing a waiver of beneficiary co-insurance for these services, such as through a demonstration operated by the Center for Medicare and Medicaid Innovation (CMMI), such that cost does not present a barrier to patients receiving this important benefit. Finally, we support CMS's proposal to flesh this proposal out over the course of a number of rulemaking cycles "in order to facilitate broader input from stakeholders regarding details of implementing such codes."¹⁰

C. BIO supports CMS's efforts to reduce the administrative burden for CCM and TCM services, and urges the Agency to reevaluate the existing requirement to use certain health information technology resources for this purpose.

In light of comments from practitioners that the elements and requirements for TCM and CCM services "are too burdensome" and may "interfere with their ability to provide these care management services to their patients who could benefit from them," CMS is soliciting feedback on steps the Agency can take to further improve beneficiary access to TCM and CCM services.¹¹

⁸ For more information about CMM services, please refer to: Patient-Centered Primary Care Collaborative, *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Outcomes* (2012), available at: <http://www.accp.com/docs/positions/misc/cmm%20resource%20guide.pdf>.

⁹ D.M. Oliveira, et al., *Medication Therapy Management: 10 Years of Experience in a Large Integrated Health System*, 16 J. Mg'd Care Pharm. 185-95 (2010); B. Isetts, et al., *Clinical and Economic Outcomes of Medication Therapy Management Services: The Minnesota Experience*, 48 J. Am. Pharm. Ass'n 203-14 (2008).

¹⁰ 80 Fed. Reg. at 41,710.

¹¹ 80 Fed. Reg. at 41,711.

As articulated in our comments in response to the CY 2015 MPFS proposed rule, BIO continues to believe that the CCM service—including the development and revision of a plan of care, continuity of care with a designated member of the healthcare team, communication with other healthcare professionals who are treating the patient, management of care transitions, and medication management—is critical for ensuring that beneficiaries with two or more significant chronic conditions can obtain the best possible outcomes. However, while we support encouraging the use of electronic health records, we are concerned about CMS’s inclusion of a scope-of-service requirement for electronic health records and care planning capabilities as part of this service. Specifically, we believe that requiring electronic health records and care planning capabilities as a condition of Medicare coverage for CCM services will inadvertently penalize Medicare beneficiaries who require these services, but whose healthcare provider lacks these resources. Accordingly, we urge CMS to revise this proposal such that these capabilities are identified as desirable, but not mandatory, components of the CCM service.

IV. Valuation of Specific Codes: Advance Care Planning Services

For CY 2015, the Current Procedural Terminology (CPT®)¹² Editorial Panel created two new codes describing advance care planning services: CPT code 99497 and an add-on CPT code 99498. In the CY 2015 MPFS Final Rule, CMS assigned a PFS interim final status indicator of “I” (“Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services.”) to both codes, stating that the Agency would consider paying for the codes after the opportunity for notice-and-comment rulemaking.¹³ In the Proposed Rule, CMS is now proposing to assign these CPT codes the MPFS status indicator “A” (“Active code. These codes are separately payable under the PFS. There will be RVUs for codes with this status.”) CMS seeks comments on this proposal, including whether payment is needed and what type of incentive this proposal may create.

BIO supports CMS’s proposal to add coverage and RVUs for these services. Patients and their physicians should be encouraged to have conversations about the full range of treatment and care options. Further, CMS should ensure that its hospice and concurrent care project—the Medicare Care Choice Models—run through CMMI truly allow patients to explore all options, and consider implementing this program nationally. Forcing patients to choose between treatment and palliative care, as is the case under the current Medicare hospice benefit, is an unfair distinction for patients to make, even in full consultation with their physicians.

V. Medicare Telehealth Services—CMS should consider extending coverage for medication therapy management services under the MPFS, as well as adding these services to the list of telehealth services covered by Medicare.

In the Proposed Rule, CMS declined the application to add certain medication therapy management (MTM) services provided by pharmacists (CPT codes 99605, 99606, 99607) to the list of Medicare telehealth services for CY 2016 on the grounds that these codes are

¹² CPT® is a registered trademark of the American Medical Association (AMA).

¹³ 80 Fed. Reg. at 41,773 (citing 79 Fed. Reg. at 67,670-71)).

noncovered services for which no payment may be made under the MPFS.¹⁴ BIO recommends that CMS consider extending coverage for these MTM services under the MPFS, as well as adding these services to the list of Medicare telehealth services.

As we have articulated in previous comments to the Agency, BIO supports Medicare coverage and reimbursement for MTM services, as these programs typically have provided patients with access to better care management, particularly for patients suffering from complex, chronic diseases. Indeed, Congress recognized the importance of these services by adding a requirement to the Part D statute that each Part D sponsor incorporate an MTM program into their plans' benefit structure.¹⁵ While Part B drugs are generally physician-administered, and thus not dispensed by pharmacists, there are important exceptions to this rule, including drugs for which MTM services would be particularly beneficial to support patient adherence (e.g., oral cancer drugs, oral anti-emetics).¹⁶ We therefore believe that these important services should similarly be available under Medicare Part B, particularly given that the Part B program covers those drugs that often treat the sickest, and thus most vulnerable, patients. We also believe that these services lend themselves well to being provided via telehealth and therefore urge the Agency to add them to the list of telehealth services to ensure that patients in rural and medically underserved areas are able to obtain access to them.

VI. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements—BIO urges CMS to clarify that the physician who supervises an “incident to” service does not need to be the same physician upon whose professional service the “incident to” service is based.

CMS proposes to revise 42 C.F.R. § 410.26 to clarify that “incident to” services must be performed under the direct supervision of the physician who bills for the services.¹⁷ As described in the Proposed Rule, CMS does not regard this as a change in policy; CMS had previously stated this policy and is now taking this opportunity to include the policy explicitly in regulation. For example, CMS notes that the Medicare Physician Fee Schedule final rule for 2002 had stated that “when a claim is submitted to Medicare under the billing number of a physician or other practitioner for an “incident to” service, the physician or other practitioner is stating that he or she performed the service or directly supervised the auxiliary personnel performing the service.”¹⁸

In making this clarification, however, CMS proposes to delete the following sentence from 42 C.F.R. § 410.26(b)(5): “The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.” This proposed deletion has caused confusion about whether a physician supervising an incident to service must be the same

¹⁴ 80 Fed. Reg. at 41,784.

¹⁵ See Social Security Act (SSA) § 1860D-4(c)(1)(C).

¹⁶ See SSA §§ 1861(s)(1)(Q); 1861(s)(1)(T).

¹⁷ 80 Fed. Reg. at 41784.

¹⁸ 80 Fed. Reg. at 41785 (citing 66 Fed. Reg. at 55267).

physician who performed the initial physician service to which the incident to services are related.

CMS does not indicate that the proposed deletion is intended to signify a change in its long-standing policy allowing incident to services to be supervised by physicians other than the physician who initiated the patient's course of treatment. Instead, in explaining its proposal, CMS focuses on the need to provide clear guidance regarding the billing of the incident to service.

To avoid confusion, however, BIO urges CMS to clarify that the Agency is not changing the policy that the physician who supervises an incident to service does not need to be the same physician upon whose professional service the incident to service is based. This clarification is important because a requirement that the physician who initiates a course of treatment must always be the physician who directly supervises the provision of incident to services would require substantial changes in practice patterns and place unjustified burdens on physicians. This would be particularly true for physicians caring for beneficiaries with treatment regimens requiring a large number of incident to services, such as oncologists whose patients are undergoing chemotherapy. Therefore, CMS must make clear that such a requirement has not newly been imposed.

To clarify that the initial physician service can be provided by a different physician than the physician who supervises the incident to service, BIO urges CMS to retain the sentence in 42 C.F.R. § 410.26(b)(5) that the Agency has proposed to delete. This sentence could be retained in a new subparagraph (b)(6) to avoid confusion with the guidance regarding billing for the service by the supervising physician. At an absolute minimum, CMS should make clear in the CY 2016 OPPI Final Rule preamble that the physician who initiates the course of treatment does not have to be the same physician who supervises incident to services. Nonetheless, we agree with CMS's current approach of moving important standards into regulatory text so that stakeholders can locate them readily and do not have to search for guidance on key points in old preambles, and hope CMS will take that approach in implementing this clarification.

VII. Technical Correction: Waiver of Deductible for Anesthesia Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test—BIO supports CMS's proposal to waive the deductible for these services in order to expand access to screening colonoscopies, an important preventive service.

In the Proposed Rule, CMS proposes to make a technical correction to expressly recognize anesthesia services as exempt from the deductible requirement when furnished on the same date as a planned colorectal cancer screening test.¹⁹ While CMS had modified the regulatory definition of colorectal cancer screening test with regard to colonoscopies to include anesthesia services in the CY 2015 MPFS Final Rule, CMS did not make the conforming changes to express the inapplicability of the deductible.

¹⁹ 80 Fed. Reg. at 41,786.

In line with our comments regarding the related proposal in the CY 2015 Proposed Rule, BIO supports this proposal, which we believe will further expand access to screening colonoscopies by ensuring that beneficiaries will not be charged a deductible for medically appropriate anesthesia services that are furnished in conjunction with screening colonoscopies. We urge CMS to clarify that this change should not be construed to impact established local coverage decisions on monitored anesthesia services, however.

VIII. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)—BIO supports CMS’s proposal to provide separate payment for CCM services provided by RHCs and FQHCs, and to adopt beneficiary notification requirements generally applicable to CCM services for this purpose.

BIO generally supports CMS’s efforts to “explore[] ways in which care coordination can improve health outcomes and care expenditures.”²⁰ In particular, we support CMS’s proposal to provide an additional payment for the costs of CCM services that are not already captured in the RHC all-inclusive rate or the FQHC prospective payment system, beginning on January 1, 2016.²¹ We agree that this proposal addresses the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not currently captured by the current RHC and FQHC payment methodologies by allowing both RHCs and FQHCs, as well as practitioners working at these locations, to receive supplemental reimbursement for providing CCM services. As noted in section (III)(C) above, BIO strongly supports Medicare coverage and reimbursement for CCM services, which we believe are critical for ensuring that beneficiaries with two or more significant chronic conditions can achieve the best health outcomes. Given that RHCs and FQHCs often serve rural and low-income patients, we are very supportive of CMS’s proposal to make separate payments to RHCs and FQHCs for these services, in line with those already available to providers paid under the PFS.

We agree with other stakeholders, however, that the requirements for electronic exchange of information and interoperability with other providers may be difficult for some entities, and that some patients—particularly those served by RHCs and FQHCs—may not have the resources to receive secure messages via the Internet. We therefore continue to urge CMS to eliminate the electronic health record requirements of the CCM service and instead identify the electronic recording and provision of beneficiary health information as a desirable—rather than mandatory—aspect of CCM services, as articulated in section (III)(C) of this letter and in prior BIO comments.

BIO further supports CMS’s proposal to adopt requirements consistent with the beneficiary notification and consent requirements under the PFS with respect to CCM services provided by RHCs and FQHCs.²² BIO supports these requirements because, as CMS notes, not all patients who are eligible for separately payable CCM services may not necessarily want these services to be provided. In addition to this proposal, we urge CMS to consider options for waiving the applicable coinsurance and deductible requirements with

²⁰ 80 Fed. Reg. at 41,793.

²¹ 80 Fed. Reg. at 41,794.

²² 80 Fed. Reg. at 41,795.

respect to CCM services (e.g., through CMMI's waiver authority) such that cost does not present a barrier to patients receiving this important benefit.

IX. Payment for Biosimilar Biological Products Under Section 1847A—BIO urges CMS to reimburse each biosimilar based on its own average sale price (ASP), consistent with the methodology currently employed for all single-source products, to establish a unique HCPCS code for each and every biosimilar product, and to apply the same payment policies to biosimilar products as currently are applied to all innovative drugs and biologicals for quarters in which there are no manufacturer data.

CMS proposes to amend its regulations "to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code."²³ In the preamble, the Agency notes that "[i]n general, this means that products that rely on a common reference product's biologics license application will be grouped into the same payment calculation." CMS describes its approach as "similar to the ASP calculation for multiple source drugs."

BIO does not support CMS's proposed approach, which has the potential to push patients to one non-interchangeable biosimilar over another based on price, contrary to the statute and its underlying policy rationale that drove Congress to establish the biosimilar reimbursement framework in the first place. Moreover, as described in more detail in the sections below, the Agency's proposal can make it difficult for prescribers, patients, and Medicare contractors to distinguish between biosimilars utilizing the same reference product. This is problematic, as the Food and Drug Administration (FDA) has identified the need to ensure such a need in its proposal to apply distinct nonproprietary names to biosimilars. Specifically, FDA states that "[t]here is a need to clearly identify biological products for the purpose of pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable."²⁴ Instead, we urge the Agency to reimburse each biosimilar based on its own ASP—consistent with the text of the Social Security Act (SSA) § 1847A(b)(8)—which is the methodology currently employed for all single-source products, a category that is statutorily defined to include all biologics, including biosimilars.²⁵ Moreover, in line with our prior comments to the Agency, BIO urges CMS to establish a unique Healthcare Common Procedure Coding System (HCPCS) code for each and every biosimilar product.

A. BIO disagrees that CMS's proposal to establish a blended ASP for biosimilars that share a reference product is authorized by the text of section 1847A of the SSA.

As a threshold matter, we disagree that CMS's proposal to establish a blended ASP for all biosimilars that share a reference product is authorized by the text of section

²³ 80 Fed. Reg. at 41,801.

²⁴ 80 Fed. Reg. 52,224 (August 28, 2015)..

²⁵ See SSA § 1847A(c)(6)(D) (defining a "single source drug or biological" to mean "a biological"); Public Health Service Act § 351(i)(2) (defining the term "biosimilar" solely "in reference to a biological product.").

1847A(b)(8) of the Social Security Act (SSA)—the provision that establishes the reimbursement methodology for biosimilar products.

As CMS notes in the Proposed Rule, section 1847A(b)(8)(A) cross-references the methodology for calculating volume-weighted-average ASPs under section 1847A(b)(6).²⁶ While we agree with CMS that section 1847A(b)(6) is the ASP methodology used for multiple source drugs,²⁷ we note section 1847A(b)(6) is titled “use of volume-weighted average sales prices in calculation of average sales price” and that its average volume-weighting methodology also is used to create a weighted average ASP for each single-source product across all of that product’s NDC-11s. Specifically, although section 1847A(b)(6)(A) refers to “drug products within the same multiple source drug billing and payment code,” section 1847A(b)(4)—which establishes payment rates for single source drugs²⁸—also cross-references section 1847A(b)(6) using language similar to that in 1847A(b)(8)(A).²⁹ As with single-source drugs reimbursed under 1847A(b)(4), manufacturers will report ASP values to CMS for biosimilar products reimbursed under 1847A(b)(8) at the NDC-11 level, and CMS therefore needs an average volume-weighting methodology to use in any case where an ASP-based payment rate for these products includes multiple NDC-11s. The cross-reference to 1847A(b)(6) in 1847(b)(8) should thus be read as establishing a methodology for creating a weighted-average ASP across all NDC-11s of each individual biosimilar product. This reading is reinforced by the statutory language expressly applying the methodology in (b)(6) to “all National Drug Codes assigned to such product” in both (b)(4) (for single source drugs) and (b)(8) (for biosimilars).

The use of an unblended reimbursement for each biosimilar product—including each biosimilar that shares a reference product—is further supported by the language of section 1847A(b)(8) itself, which applies the ASP payment methodology to “[a] biosimilar biologic *product* for all National Drug Codes assigned to such *product*” (emphasis added). The repeated use of the word “product”—in the singular—indicates that the calculated payment rate for each biosimilar must be unique to that particular molecular entity.³⁰

²⁶ 80 Fed. Reg. at 41,801 (“ . . . we plan to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. In general, this means that products that rely on a common reference product’s biologics license application will be grouped into the same payment calculation. This approach, which is similar to the ASP calculation for multiple source drugs, is authorized by section 1847A(b)(8)(A) of the Act, which states that the payment determination for a biosimilar biological product is determined using the methodology in paragraph 1847A(b)(6) applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph.”) (emphasis added).

²⁷ See SSA § 1847A(b)(1)(A) (“ . . . the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance . . . 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008”) (emphasis added).

²⁸ See SSA § 1847A(b)(1)(B) (“ . . . the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance . . . in the case of a single source drug or biological . . . 106 percent of the amount determined under paragraph (4).”).

²⁹ SSA § 1847A(b)(1)(4) (“The amount specified in this paragraph for a single source drug or biological is the lesser of the following . . . the average sales price as determined . . . using the methodology applied under paragraph (6) for single source drugs and biologics furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.”) (emphasis added).

³⁰ SSA § 1847A(c)(6)(D) (defining a “single source drug or biological” to mean “a biological”). See also SSA § 1847A(c)(6)(C) (defining a “multiple source drug” based on criteria inherently inapplicable to biologics, such as the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” publication, i.e., the “Orange Book.”).

- B. The Affordable Care Act established a Medicare Part B reimbursement framework for biosimilar products based on the principle of equity to ensure that patients receive the most medically appropriate medicine for their condition; blending the ASP for multiple biosimilars with the same reference product undermines this principled approach by potentially pushing patients to one non-interchangeable biosimilar over another based on price.

Unlike small-molecule generics, a biosimilar is, by definition, not an exact copy of the innovator. Indeed, as part of the Affordable Care Act (ACA), Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which recognizes that the legal and regulatory construct of a generic drug is inappropriate for biosimilar products due to scientific differences between the two classes of products.³¹ By way of background, in order to receive regulatory marketing approval, a generic drug application (Abbreviated New Drug Application (ANDA)) must, by statute and regulation, contain certain information to show that the proposed drug product is the same as a previously-approved brand drug.^{32,33} Specifically, a drug approved under an ANDA must be bioequivalent to the brand drug, and generally must be pharmaceutically equivalent thereto (i.e., it must have the identical amount of the same active ingredient in the same dosage form and with the same route of administration).³⁴ Based on this information, it can be assumed that two generics of the same brand drug are substitutable with each other from the FDA's perspective, subject to state pharmacy substitution laws.

By contrast, biosimilars are not, by definition, direct copies of the reference product. Due to the complex structure of biologics and the associated manufacturing processes, the regulatory assessment of biosimilars is predicated on demonstrating—through analytical non-clinical and clinical data—that the biosimilar is “highly similar” to an innovator/reference biologic in terms of structural characteristics with an absence of clinically meaningful differences.^{35,36,37} Moreover, since biosimilars are approved on the grounds that they are

³¹ Pub. L. No. 111-148 (March 23, 2010) (Patient Protection and Affordable Care Act, Title VII – Improving Access to Innovative Medical Therapies, Subtitle A—Biologics Price Competition and Innovation) (codified as Public Health Service Act § 351(k)). Also see Woodcock, J., et al. 2007 (April). The FDA's Assessment of Follow-on Protein Products: A Historical Perspective. *Nature Reviews Drug Discovery* 6:437-442.

³² FFDCA § 505(j); 21 U.S.C. § 355(j).

³³ In this context, it is important to note that the FDA Orange Book and the FDA Purple Book are distinct. The Orange Book identifies drug products approved under section 505 of the Federal Food, Drug, and Cosmetic Act and contains therapeutic equivalence evaluations for approved multisource prescription drug products. Biosimilar products are not listed in the Orange Book. The FDA Purple Book lists biological products approved under section 351 of the Public Health Service Act, including any biosimilar and interchangeable biological products licensed by FDA (in the Purple Book, these products are listed under the reference product to which biosimilarity or interchangeability was demonstrated). For more information, see FDA. 2014. *Orange Book, 34th Edition, Preface and Introduction*, available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>; Also see: FDA. 2015. *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>.

³⁴ There is a narrow, and rarely granted, exception under “suitability petitions” for a generic drug that is similar, but not identical in terms of its “pharmaceutical equivalence.” See 21 U.S.C. § 505(j)(2)(C). See also 21 C.F.R. § 314.93.

³⁵ In testimony before Congress, FDA Deputy Commissioner Janet Woodcock described the scientific challenges of demonstrating biosimilarity as (but not limited to): “It is the combination of the protein’s amino acid sequence and its structural modifications that give a protein its unique functional characteristics. Therefore, the ability to predict

highly similar, but not identical to, a given reference product, interchangeability with the reference product cannot be assumed. In fact, FDA may affirmatively designate a biosimilar as interchangeable with a reference product *only* after an additional determination that: (1) it can be expected to produce the *same* clinical results as the reference product *in any given patient*; and (2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without alternating or switching.³⁸ Finally, as described in greater detail, below, there is no assessment in the biosimilar approval process to establish a biosimilar's similarity to other biosimilars, even for those that share a reference product. Instead, each product is approved based solely on whether it is "highly similar" to the reference product (or interchangeable with the reference product, in the case of interchangeables). In the absence of any data that directly compare the quality, safety, and efficacy attributes of biosimilars to one another, there can be no assumption of biosimilarity—let alone interchangeability—between biosimilars, and it cannot be assumed that a biosimilar is identical to its reference product, let alone that multiple biosimilars of the same reference product are identical to each other.³⁹

The differences between a biosimilar and its reference product can impact how an individual responds to a therapy—biologics, as large protein molecules synthesized in living cells, have increased structural complexity that can affect a product's function and clinical safety, efficacy, and immunogenicity, as compared to small-molecule drugs, which are chemically synthesized. As a result, the ACA established a Medicare Part B reimbursement framework for biosimilar products that enables patients to receive the most medically appropriate medicine for their condition. Specifically, to ensure that financial considerations did not incentivize the use of one product over another, under the ACA formula, both the innovator and each biosimilar receive the same dollar amount in the "+6%" added to their respective ASP reimbursement (i.e., each product is paid at its individual plus 6% of the reference biologic's ASP).⁴⁰ Further, Congress had good reasons for requiring that each biosimilar be paid based on its own ASP (plus 6% of the reference product's ASP), because the blending approach that CMS now proposes could hurt patients by potentially pushing them to one biosimilar over another based on price.

the clinical comparability of two products depends on our understanding of the relationship between the structural characteristics of the protein and its function, as well as on our ability to demonstrate structural similarity between the follow-on protein and the reference product. Although this currently may be possible for some relatively simple protein products, technology is not yet sufficiently advanced to allow this type of comparison for more complex protein products." See Janet Woodcock, Deputy Commissioner, Chief Medical Officer, FDA, testimony before the Subcommittee on Health, Committee on Energy and Commerce, May 2, 2007, at http://energycommerce.house.gov/cmte_mtgs/110-hehrg.050207.Woodcock-testimony.pdf.

³⁶ For additional details on the scientific challenges of demonstrating biosimilarity, see Congressional Research Service. 2010. *FDA Regulation of Follow-On Biologics*. CRS 7-5700, RL34045, pp. 7-12, available at: https://primaryimmune.org/advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf.

³⁷ See Shepherd, J. M. 2014. *Biologic Drugs, Biosimilars, and Barriers to Entry*. Emory University School of Law, Emory Legal Studies Research Paper No. 14-284.

³⁸ Public Health Service Act § 351(k)(4).

³⁹ Under the BPCIA, a reference product is defined as a product approved under section 351(a) of the Public Health Service Act. A biosimilar, on the other hand, is approved under section 351(k) of that Act. Therefore, a product approved as a biosimilar cannot be used as a reference product in a subsequent biosimilar application. See Public Health Service Act § 351(i)(4).

⁴⁰ See SSA § 1847A(a)(8)(B).

Specifically, to the extent that CMS blends the ASP of two biosimilars that share a reference product, this blended ASP would exceed the acquisition cost of the less expensive biosimilar and fall below the acquisition cost of the more expensive product. This would undercut Congress' plan that each biological product (whether biosimilar or reference biological) have the same dollar markup over that product's ASP, and also could result in a total payment that fell below the ASP for the more expensive product—thus creating a real financial incentive for physicians to prescribe the less expensive biosimilar.

Yet, there is no guarantee that this particular product would be medically appropriate for the patient in question, merely based on the fact that it shares a reference product with the other biosimilar in question. Indeed, as noted above, the regulatory approval process for a biosimilar in no way focuses on the relationship among biosimilars of the same reference product. For example, the regulatory approval pathway does not require that multiple biosimilars of the same reference product demonstrate similarity to each other in any respect. Nor does this pathway include an assessment of similarity between or among these products. Instead, each of these products is approved based only on whether it is "highly similar" to the reference product. Determinations of interchangeability are made by the FDA and are solely based on the comparison of an individual biosimilar with the reference product, not between biosimilars of the same innovator. In the absence of data that directly compare the quality, safety, and efficacy attributes of multiple biosimilars sharing the same reference product, there can be no expectation or conclusion of biosimilarity—let alone interchangeability—between or among these products.

- C. The absence of a distinct HCPCS code for each and every biosimilar, including those that share a reference product, would create confusion for providers and dispensers and could potentially harm patients.

CMS's proposal also suggests that biosimilar products that share a reference product will be grouped into the same Healthcare Common Procedure Coding System (HCPCS) code. As articulated in our comments submitted in response to the May 7 CMS Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals ("Public Meeting Agenda"),⁴¹ BIO strongly disagrees with this approach.

As an initial matter, we note that SSA § 1847A appears to envision the creation of separate HCPCS codes for each biosimilar product. Specifically, the statutory text describes the inclusion of multiple products within a given billing and payment code only to the extent that such products meet the definition of "multiple source drug." Indeed, with the exception of single-source drugs or biologics included in the same code before October 1, 2003 (which the statute treats "as if" they were multiple source drugs⁴²), the only references to the "same" billing and payment codes throughout 1847A refer to the "same *multiple source*

⁴¹ Centers for Medicare and Medicaid Services (CMS). 2015. Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals, available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/May-7-2015-DrugAgenda.pdf>.

⁴² SSA § 1847A(c)(6)(C)(ii). Notably, this exception has no application to biosimilars, as there was no biosimilars approval pathway on or before October 1, 2003.

billing and payment code.”⁴³ Biologicals—including biosimilars—do not fall within the statutory definition of a “multiple source” drug (which only applies to drugs with a therapeutic equivalence rating in the FDA’s Orange Book⁴⁴), and thus cannot be combined into a single “multiple source” code. This comports with the Agency’s own coding policy, which assigns a unique HCPCS code to each drug or biologic that is the subject to a New Drug Application (NDA) or Biologics License Application (BLA),⁴⁵ a category that includes biosimilars approved under the BPCIA.⁴⁶

Further, the scientific and regulatory differences between biosimilars and generics described previously, including the fact that the biosimilars approvals pathway does not establish any degree of similarity among multiple biosimilars of the same reference product, counsel for assigning each biosimilar a distinct HCPCS code. Distinct HCPCS codes are necessary in order to prevent confusion among providers and dispensers for the following three reasons.

First, because biologicals are generally physician-administered, rather than dispensed at pharmacies, HCPCS codes, and not NDCs, are generally the mechanism used to report the utilization of these therapies on Medicare claims forms. Even in the Medicaid context, where the use of NDCs on claims forms for physician-administered drugs is required by federal statute, these codes are not uniformly used,⁴⁷ in part as a result of litigation brought by 340B hospitals, which argued, among other things, that the use of NDC codes on claims forms would be unduly burdensome and costly—impossible, in some cases—for providers to execute in light of the lack of the necessary infrastructure (e.g., bedside bar-coding) and the difficulty of identifying NDCs for compounded drugs or drugs provided in combination.⁴⁸ Thus, without distinct HCPCS codes, it will be difficult to specify exactly which therapy was administered to an individual patient and thus ensure that the patient continues to receive the same therapy. Switching a biologic medication, even with products in the same therapeutic class, can destabilize the patient, as the switched product may not adequately respond to the needs of that patient.

⁴³ See SSA §§ 1847A(b)(3); 1847A(b)(6)(A) (emphasis added).

⁴⁴ SSA § 1847A(c)(6)(C)(i).

⁴⁷ The Medicaid program requires that NDCs are reported on claims forms (see Deficit Reduction Act of 2005, Pub. L. No. 109-171, Sec. 6002(a)), but there is evidence to suggest that NDC reporting is inconsistent despite this requirement, for example, see CMS. 2012. *Important Information Concerning the Medicare Crossover Process and State Medicaid Agency Requirements for National Drug Codes (NDCs) Associated with Physician-Administered Part B Drugs*. MLN Matters®, Number: SE1234, available at: <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se1234.pdf>. Moreover, as a result of the litigation brought by 340B hospitals and a settlement reached with CMS, the Agency issued an October 2009 transmittal to state Medicaid programs acknowledging that hospitals billing Medicaid for physician-administered drugs at their “purchasing costs as determined under the state plan” cannot be mandated under federal law to submit National Drug Codes. Yet accurate reporting of exactly which biopharmaceutical was used is crucial to tracking Medicaid utilization of these products, including for purposes of program integrity and compliance within the Medicaid Drug Rebate Program. While there is a mechanism in place to crosswalk HCPCS codes to NDCs, to function accurately, this crosswalk would rely on the availability of distinct HCPCS “J” codes for each and every biosimilar. For more information on the Medicaid Drug Rebate Program, see CMS. 2015. *Medicaid Drug Rebate Program Data*, available at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html>.

⁴⁸ See Safety Net Hospitals for Pharmaceutical Access, CMS Clarifies NDC Reporting Requirements (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

Second, unique HCPCS codes will be necessary given that biosimilar products—even those that share a reference product—likely will diverge in terms of their approved and/or extrapolated indications. As noted previously, each biosimilar will be approved by the FDA based on product-specific data demonstrating that product's similarity to a given reference product. It is based on these product-specific data that the indications for use will be identified for purposes of inclusion in the product's FDA-approved label. Because there is no requirement or mechanism under the biosimilar approval pathway for demonstrating similarity across or among various biosimilar products—including among those that share a reference product—such approved indications may vary from biosimilar to biosimilar.

The indications for use that may be extrapolated from clinical data also may vary among biosimilars, including among those that share a reference product. Extrapolation of clinical data demonstrating that a product is biosimilar to the reference product with regard to one indication to support the licensure of another indication may be acceptable if the mechanism(s) (and sites) of action for both indications are very well understood and are the same; if there are no significant differences between the pharmacokinetics and bio-distribution of the product in the indication and patient population(s) studied clinically and the new indication and patient population(s); and if the study in original indication is highly sensitive to potential differences that might emerge in the new indication. That said, many biologics have several potential mechanisms of action (MOA) and the importance of potential mechanisms may be unknown. Additionally, it is common that, in a new indication, the drug may be sensitive to differences that may not have been observed in the studied indication (due to differences with regard to, e.g., concomitant medications, levels of immunocompetence, underlying disease, or patient factors such as age, tissue penetrated, dose, dosing regimen and/or route of administration). Given that the approved and/or extrapolated indications may vary across biosimilar products, it is important to have a mechanism—i.e., unique HCPCS codes—in order to be able to identify which biosimilar product has been prescribed for a given patient.

Third, the implication of multiple biosimilar products sharing the same HCPCS code—namely, that these therapies are somehow equivalent and/or interchangeable—would be confusing for prescribers and dispensers, as no such relationship would have been established during the regulatory approval process. In fact, as noted above, FDA has identified the scientific need to distinguish between biological products, including between biosimilars utilizing the same reference product. Thus, any policy that introduces confusion rather than clarity in this regard may, in turn, negatively impact patients because the differences between biosimilars can impact how an individual patient responds to a therapy, also as described above.

Moreover, the absence of distinct HCPCS codes also will create confusion for Medicare Administrative Contractors (MACs) in implementing their local coverage determinations (LCDs). Since biosimilars of the same reference product can differentially impact patients and/or patient subpopulations, a different LCD may be in place for a specific biosimilar product than is in place for other biosimilars that share the same reference product. Thus, the absence of unique HCPCS codes for each biosimilar would prove at least confusing, if not problematic for MACs in implementing LCDs.

In addition, the absence of a distinct HCPCS code for each and every biosimilar, including those that share a reference product, can also jeopardize patient safety by hindering effective pharmacovigilance. Adverse events associated with biologics, including immunogenicity risks, can have significant clinical consequences. FDA staff has noted that “[t]racking adverse events associated with the use of reference and biosimilar products will be difficult if the specific product or manufacturer cannot be readily identified, and appropriate strategies must be developed to ensure the implementation of robust, modern pharmacovigilance programs for biologics.”⁴⁹ Distinct HCPCS codes for biosimilars of the same reference product are integral to ensuring that adverse events are traced to the correct product and facilitate the collection of more timely and accurate adverse event data in order to inform critical clinical decisions about the use of biologics.

The complexity of biologics described previously also can have important pharmacovigilance implications. Where minor differences are found between two biologic products, there are limits to the certainty that such differences will not have clinical consequences. Additionally, clinical trials may not be sufficiently powered to detect the rare adverse events associated with new products.⁵⁰ These two realities, taken together, mean that, as more patients use products in less controlled post-approval settings, critical safety and efficacy information is learned through post-market safety surveillance and outcomes research.⁵¹ In these settings, the ability to distinguish between products—including two or more biosimilars of the same reference product—is necessary to promote efficient data aggregation and disaggregation, and to ensure that events observed through post-market safety surveillance and outcomes research are accurately attributed to the specific product that was used. As noted previously, given that biologics are often physician-administered, HCPCS codes are generally relied on to bill for these products. Thus, a distinct HCPCS code for each and every biosimilar, including for biosimilars of the same reference product, is critical to ensure a robust pharmacovigilance infrastructure. Assigning a shared HCPCS code to multiple biosimilars would be an imprudent strategy that gives up an important opportunity to improve the traceability of adverse events and reduce the risks of misattribution. Moreover, HCPCS coding information linked to a specific biosimilar is particularly valuable today, as FDA’s “mini-Sentinel” initiative seeks to mine patient health records for safety signals using data that include billing codes.⁵²

Finally, a cornerstone of patient safety, the combined ability to prevent prescribing errors (including inappropriate substitution) and accurately attribute adverse events, depends upon the ability of patients, prescribers, and dispensers to accurately identify

⁴⁹ Kozlowski, S., et al., 2011. Developing the Nation’s Biosimilar Program. *New England Journal of Medicine* 365: 385-38.

⁵⁰ Jesse Berlin, et al., Adverse Event Detection in Drug Development: Recommendations and Obligations Beyond Phase 3, *Am. J. Public Health*, Vol. 98, No. 8, 1366–1371 (August 2008). Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2446471/pdf/0981366.pdf>.

⁵¹ Examples of biological products that have exhibited immunogenicity issues include Factor VIII, interferon-alpha, interferon-beta, interleukin-2, erythropoietin, granulocyte macrophage colony stimulating factor, calcitonin, growth hormone, denileukin-diftitox, and megakaryocyte derived growth factor. See Schellekens, H. 2002 (June) Bioequivalence and the Immunogenicity of Biopharmaceuticals. *Nature Reviews Drug Discovery* 1(6):457-62, Table 1.

⁵² See, e.g., Mini-Sentinel, Overview and Description of the Common Data Model v.4.0, http://www.mini-sentinel.org/work_products/Data_Activities/Mini-Sentinel_Common-Data-Model.pdf.

specific products. To further such efforts to promote and enhance patient safety, each biosimilar must be assigned a distinct HCPCS code.

- D. BIO urges CMS to apply the same payment policies to biosimilar products as currently are applied to all innovative drugs and biologicals for quarters in which there are no manufacturer data.

With respect to payment for new-to-market biosimilar products, CMS proposes that, until sufficient sales data have been collected, payment limits should be determined based on the product's wholesale acquisition cost (WAC). The Agency goes on to propose that, if no manufacturer data are collected, "prices will be determined by local contractors using *any available pricing information*, including provider invoices."⁵³ BIO is concerned that allowing contractors to rely on "any available pricing information" would introduce unpredictability into reimbursement for new biosimilar products, as different local contractors could establish their own payment limits based on different information inputs. This unpredictability, in turn, could lead to market distortions and disruptions. Additionally, while the reliance on WAC to calculate payment in the absence of ASP data is consistent with current CMS payment policy for innovative drugs and biologicals, allowing local contractors to use "any available pricing information" for new biosimilars in the absence of WAC is not. Rather, in the case of an innovative therapy for which WAC has not been published, CMS specifically directs local contractors to use invoice pricing. Aligning payment for biosimilars with existing policy only partially could introduce confusion with respect to payment for biosimilar products in the months immediately following their launch. Thus, in the absence of evidence that the current payment policy for new innovative drugs and biologicals is insufficient, inadequate, or impractical for application to new biosimilar products, BIO urges CMS to clarify in the Final Rule that, as with CMS's payment policy for innovative drugs and biologicals generally, payment for a new biosimilar must be based on WAC or, if WAC has not been published, only invoice pricing until ASP data become available.

X. Physician Compare Website

As a general matter, BIO supports CMS's phased-approach to adding additional measures for public reporting of performance and other data to Physician Compare, and urges the Agency to ensure such measures are selected based on feedback from a diverse group of stakeholders and provide useful information, together with appropriate context, to consumers. In addition, as described in greater detail in the comments that follow, with respect to the specific proposals included in the Proposed Rule, we would like to take this opportunity to:

- Express concern about CMS's proposal to add an indicator related to the Physician Value-Based Payment Modifier (VM) to Physician Compare profile pages;
- Support CMS's proposed inclusion of an indicator on Physician Compare for providers who satisfactorily report the new Cardiovascular Prevention measures group, if finalized;

⁵³ 80 Fed. Reg. at 41,802 (emphasis added).

- Urge CMS to consider alternatives to the ABC™ benchmarking tool for purposes of Physician Compare, or, at a minimum, to evaluate including a risk-adjustment component into the methodology;
 - Support the inclusion of patient-experience data on Physician Compare, but note our continued concerns with respect to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure “Stewardship of Patient Resources”;
 - Express concern with CMS’s proposals to include additional VM data on the Physician Compare website;
 - Support the addition of utilization data to the Physician Compare downloadable database;
 - Support CMS’s proposal to add additional board certification information to Physician Compare; and
 - Urge CMS to consider providing a link to the Open Payments website on Physician Compare, if such information is included at all, and to work with stakeholders to ensure that Open Payments data are provided with sufficient context.
- A. BIO supports CMS’s phased-approach to adding additional measures for public reporting of performance and other data and urges the Agency to ensure such measures are selected based on feedback from a diverse group of stakeholders and provide useful information, together with appropriate context, to consumers.

As an initial matter, BIO would like to express our support for CMS’s continued efforts to implement the public reporting of performance information on the Physician Compare website in a phased manner, including the Agency’s use of concept testing to ensure that Medicare patients understand and are benefitting from the posted information.⁵⁴ We further support the Agency’s efforts to obtain stakeholder feedback for this purpose. However, in addition to seeking feedback from physicians to ensure that measures under consideration for public reporting remain clinically relevant and accurate, BIO continues to urge the Agency to reach out to manufacturers and patients for feedback on new and existing measures under consideration and review for inclusion on this website.

BIO also supports CMS’s proposal to continue to expand public reporting on Physician Compare by making an even broader set of measures available on the website in CY 2016.⁵⁵ BIO supports expanding the number of measures currently available on the Physician Compare website, as we believe this is an effective way to provide more information to consumers in order to allow for more effective decision-making. However, it is important that this information is provided in such a way that is helpful, rather than overwhelming for Medicare beneficiaries, and other consumers. To these ends, we urge CMS to ensure that the data be provided with appropriate and helpful context. For example, CMS should make clear that the data have not been adjusted to take into account changes in Medicare coding and billing rules that may be different over time and across regions of the country (e.g., Local Coverage Determinations), or by site of service (e.g., facility or non-facility), and that the data are not risk-adjusted to account for differences in the underlying disease severity of the patient population. Without such risk adjustment, physicians that treat sicker, and thus costlier, patient populations may be mischaracterized. CMS also should note for users

⁵⁴ 80 Fed. Reg. at 41,808.

⁵⁵ 80 Fed. Reg. at 41,810.

that the dataset excludes important context about treatment decisions and patient patterns of care impacting Medicare payments.

Additionally, as we stated in last year's comments, it is essential for CMS to ensure that the specific measures chosen for inclusion on the profile page—which are the most likely to inform medical decision-making—are appropriately selected with input from a diverse group of stakeholders. Finally, BIO recommends that CMS propose a mechanism for providers to review and correct their information.

B. BIO does not support CMS's proposal to add an indicator related to the Physician Value-Based Modifier to Physician Compare profile pages.

In the Proposed Rule, CMS proposes to expand the section on each individual EP and group practice page that indicates Medicare quality program participation by adding a green check mark to include the names of those individual EPs and group practices who received an upward adjustment under the Physician Value-Based Payment Modifier (VM).⁵⁶

BIO does not support this proposal. While we agree that a green check mark, in theory, is a clear way to indicate a physician's positive performance, we believe that this proposal is overly simplistic and may, in fact, be misleading for Medicare patients. First, given that Medicare providers have found the VM program to be complex and difficult to understand, we question whether patients will understand what this proposed check mark is meant to symbolize. Second, and more importantly, given BIO's ongoing concerns with the VM program, described in greater detail, below, we are concerned with proposals to expand the use of this program such that it not only informs provider payment amounts, but also influences whether a given patient visits that provider in the first instance.

To the extent that CMS nonetheless moves forward with its proposal to add VM data to Physician Compare, we do support CMS's proposal to include all VM data on the Physician Compare downloadable database. We agree with CMS that "adding this information to the downloadable file promotes transparency and provides useful data to the public." We believe, however, that this should be the only VM-related information added to Physician Compare "while [CMS] conduct[s] consumer testing to ensure VM data beyond the indication for an upward adjustment . . . can be packaged and explained in such a way that it is accurately interpreted, understood, and useful to average consumers."⁵⁷

C. BIO supports CMS's proposed inclusion of an indicator on Physician Compare for providers who satisfactorily report the new Cardiovascular Prevention measures group, if finalized.

In support of the HHS-wide "Million Hearts initiative," CMS proposes to include on Physician Compare annually an indicator for individual EPs who satisfactorily report the new Cardiovascular Prevention measures group being proposed under Physician Quality Reporting System (PQRS), should this measures group be finalized.⁵⁸ BIO supports the

⁵⁶ 80 Fed. Reg. at 41,811.

⁵⁷ 80 Fed. Reg. at 41,811.

⁵⁸ 80 Fed. Reg. at 41,811.

inclusion of this indicator and CMS's intent to improve reporting of the specific "ABCS" (Appropriate Aspirin Therapy for those who need it, Blood Pressure Control, Cholesterol Management, and Smoking Cessation) measures.

Given the prevalence of heart disease among Medicare beneficiaries, this indicator is likely to be of importance for consumers using the Physician Compare website. Additionally, providing an easily identifiable indicator for those providers who satisfactorily report on these new measures creates an added incentive for them to not only report, but to improve the management and treatment of these conditions among their patients. BIO believes this can be an effective way to help achieve the aim of the Million Hearts initiative to decrease the incidence of heart disease and stroke.

- D. To the extent that CMS includes benchmark data on Physician Compare, such data should be provided with appropriate context, and should be risk-adjusted.

CMS proposes to publicly report on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABCTM) methodology annually based on the PQRS performance rates most recently available. The benchmark would only be applied to those measures deemed valid and reliable that are reported by enough EPs or group practices to produce a valid result.⁵⁹

As noted in prior BIO comments with respect to CMS's benchmarking proposal, BIO supports providing consumers with information to more easily evaluate the data provided on Physician Compare. However, we urge CMS to provide appropriate context around the proposed benchmark and quality scores, including how they were calculated and any applicable limitations. Merely providing summary information without any context may ultimately be more misleading than helpful for consumers.

BIO also is concerned that the particular benchmarking methodology proposed by CMS does not risk-adjust for the underlying health status of a providers' patients, which will unfairly penalize those providers who treat a disproportionate number of sick and vulnerable patients, by lowering their scores relative to other providers. We therefore urge CMS to consider alternatives to the ABCTM benchmarking tool, or to evaluate including a risk-adjustment component into the methodology.

- E. BIO supports the inclusion of patient-experience data on Physician Compare, but continues to have concerns with respect to the CAHPS measure "Stewardship of Patient Resources."

CMS proposes to continue to make available for public reporting all patient-experience data for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified Consumer Assessment of Healthcare Providers and Systems (CAHPS) vendor, annually in the year following the year that the measures are reported. The specific patient experience data that CMS proposes to

⁵⁹ 80 Fed. Reg. at 41,811.

make available for public reporting are the CAHPS for PQRS measures, which include the CG-CAHPS core measures.⁶⁰

BIO supports the reporting of patient-experience data on Physician Compare, as other patients' assessments of their experience with a given provider are no doubt helpful to the healthcare decision-making process. We also are particularly supportive of certain CAHPS measures that may be of particular interest to patients suffering from complex, chronic diseases—namely "Access to Specialists," "Care Coordination," and "Helping You Take Medication as Directed." That said, as articulated in prior BIO comments, we continue to have concerns with respect to the CAHPS measure "Stewardship of Patient Resources." We note that the underlying question for this measure hinges on whether the "care team talked to you about cost of your prescription medications." This question concerns us not only because we are unsure that providers should be directing care based on cost, but also because prescription drug costs are only one part of a patient's costs and therefore only one part of holistically managing patient healthcare expenditures. Moreover, we note that there are other barriers, apart from costs, that can impede patient access to care that are similarly not addressed by this measure.

We therefore urge CMS to exclude this measure for purposes of the Physician Compare website. To the extent that CMS nonetheless decides to include a measure of this nature, we urge the Agency to consider using an alternative measure that asks whether the care team had consulted with patients about all barriers the patient faces to access care (e.g., patient education level, language barriers, distance traveled to care, work/family commitments, and inability to pay coinsurance).

F. BIO does not support the inclusion of additional VM data on the Physician Compare website.

In the Proposed Rule, CMS is seeking comment on including additional VM cost and quality data on Physician Compare, such as an indicator for downward and neutral VM adjustment, the VM quality composite, or other VM quality performance data (either on the profile page or downloadable database).⁶¹ CMS also seeks comment on including the VM cost composite or other VM cost measure on Physician Compare group practice and individual EP profile pages and/or the downloadable database.

For the reasons articulated in section (X)(B), above, BIO is very concerned with respect to CMS's proposals to include data from the VM on Physician Compare, particularly in the absence of sufficient context. We strongly urge CMS to address our larger concerns with respect to the VM program before VM data are posted on Physician Compare, particularly on practitioners' profile pages.

G. BIO supports the addition of utilization data to the Physician Compare downloadable database.

⁶⁰ 80 Fed. Reg. at 41,813.

⁶¹ 80 Fed. Reg. at 41,813.

Per section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),⁶² which requires CMS to integrate utilization data information on Physician Compare, CMS is proposing that utilization data generated from Medicare Part B claims, by HCPCS code, be added to Physician Compare's downloadable database.⁶³ BIO supports CMS's proposal to add this information to the downloadable database, as opposed to the consumer-focused website profile pages. We agree that these data are "less immediately usable in their raw form by the average Medicare consumer" and that inclusion of these data on the profile page would serve only to confuse and/or overwhelm patients.

H. BIO supports CMS's proposal to add additional board certification information to Physician Compare.

CMS is proposing to add additional Board Certification information to the Physician Compare website. Specifically, in addition to the American Board of Medical Specialties (ABMS) data, CMS is now proposing to add to the website board certification information from the American Board of Optometry (ABO) and the American Osteopathic Association (AOA).⁶⁴ BIO supports this proposal, as it does fill a gap in the current board-certification information available on the Physician Compare website. As CMS notes, the ABMS does not certify Optometrists and only certain types of DOs are covered by ABMS Osteopathic certification.

I. BIO urges CMS to consider providing a link to the Open Payments website on Physician Compare, if such information is included at all, and to work with stakeholders to ensure that Open Payments data are provided with sufficient context.

CMS is proposing to make Open Payments data available on individual EP profile pages.⁶⁵ BIO continues to express our longstanding support for the goals of the Physician Payments Sunshine Act.⁶⁶ While we do not have a position with respect to whether CMS should include Open Payments data on Physician Compare, we would like to take this opportunity to make certain suggestions with respect to how this information should be made available via Physician Compare, should CMS move forward with this proposal.

Specifically, to the extent that CMS ultimately moves forward with the inclusion of Open Payments information on Physician Compare, we urge the Agency not to make this information directly available on the Physician Compare site. Instead, the Agency should consider including a statement, where applicable, along the lines of the following: "One or more drug, device, or medical supply companies have reported a payment or transfer of value to this physician. Click [here] to see Open Payments data submitted for this physician." This link would then take users to the home page of the Open Payments website, where they could then use the search function to view payments and transfers of value made to their physician.

⁶² Pub. L. No. 114-10, § 104 (Apr. 16, 2015).

⁶³ 80 Fed. Reg. at 41,813.

⁶⁴ 80 Fed. Reg. at 41,814.

⁶⁵ 80 Fed. Reg. at 41,815.

⁶⁶ ACA § 6002 (SSA § 1128G).

This approach is consistent with the rather spare content and format of the information currently presented on the physician profiles of Physician Compare. It also avoids the need to determine how best to present the necessary context on Physician Compare to help users understand the voluminous and potentially confusing information available on CMS's Open Payments website. Although BIO continues to urge the Agency to provide more robust contextual information on the Open Payments website, the information currently available on the home page of the Open Payments site provides at least some critical background information for consumers. We believe that it would be difficult to incorporate this information into Physician Compare and that, without this contextual information, the Open Payments data would have little value for purposes of patient decision-making, particularly given that these are not the type of data generally included on Physician Compare.⁶⁷

Finally, regardless of whether CMS moves forward with this proposal, BIO continues to encourage CMS to honor its statutory obligation to engage all stakeholders in a public process to develop important context with respect to the Open Payments website, including to ensure that the information is presented in a way such that patients do not form mistaken impressions that all payments to physicians are suspect.

XI. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)—BIO generally supports CMS's efforts to align requirements across quality-reporting programs and to emphasize reporting of outcomes and patient-experience measures, as well as measures reported through registries, but urge the Agency not to use the Value-Based Payment Modifier (VM) attribution methodology for purposes of the PQRS program.

As an initial matter, we would like to voice our support for CMS's efforts, in developing PQRS-related proposals, to "focus[] on aligning [the Agency's] requirements, to the extent appropriate and feasible, with other quality reporting programs, such as the Medicare Electronic Health Record (EHR) Incentive Program for EPs [Eligible Professionals], the Physician Value-Based Modifier (VM), and the Medicare Shared Savings Program."⁶⁸ BIO supports CMS's efforts to align these programs, and appreciates CMS's statement that such alignment will extend only to those circumstances that are "appropriate and feasible."

BIO also generally supports CMS's efforts to "emphasize the reporting of certain types of measures, such as outcome measures . . ." across the various Medicare quality programs.⁶⁹ That said, a sole reliance on quality measures is not necessarily appropriate.

⁶⁷ Open Payments data do not relate to the quality or efficiency of care provided by a given physician, which is the type of information Congress intended would appear on Physician Compare, and thus the type of information patients expect to see on this website. *See* ACA § 10331. The specific information that Congress identified for inclusion on Physician Compare in enacting the Sunshine Act include: (1) measures collected under the Physician Quality Reporting Initiative; (2) an assessment of patient health outcomes and the functional status of patients; (3) an assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use; (4) an assessment of efficiency; (5) an assessment of patient experience and patient, caregiver, and family engagement; and (6) an assessment of the safety, effectiveness, and timeliness of care.

⁶⁸ 80 Fed. Reg. at 41,816.

⁶⁹ 80 Fed. Reg. at 41,816.

Accordingly, we urge CMS to continue to recognize the importance of having a combination of both process and outcomes measures for purposes of the PQRS.⁷⁰ For instance, we believe it is critically important for Medicare physicians to continue to be evaluated for their performance on immunization measures to ensure that Medicare beneficiaries continue to receive these important services.

In addition, and as articulated in greater detail in the following comments, BIO would like to take this opportunity to:

- Support CMS's efforts to implement reporting via Qualified Clinical Data Registries (QCDRs) and qualified registries, but urge CMS to require the qualified registries to collect data and quality measures through a scientifically robust, transparent, and validated process;
- Support CMS's proposal to include patient-experience data for purposes of PQRS, but express concern with respect to the CAHPS "Stewardship of Patient Resources" measure;
- Urge CMS not to use the attribution methodology used for the VM for the purposes of the Group Practice Reporting Option (GPRO) web interface beneficiary assignment methodology;
- Support CMS's proposal to add three new measures groups for reporting in the PQRS beginning in CY 2016: Multiple Chronic Conditions Measures Group; Cardiovascular Prevention Measures Group; Diabetic Retinopathy Measures Group;
- Urge CMS to include additional pneumococcal vaccination measures or a more comprehensive measure in the PQRS; and
- Commend CMS for proposing to retain a number of immunization measures in the PQRS, and encourage CMS to include additional immunization measures recommended in a recent report from the National Quality Forum (NQF).

- A. BIO supports CMS's efforts to implement reporting via QCDRs and qualified registries, but urges CMS to require these registries to collect data and quality measures through a scientifically robust, transparent, and validated process.

CMS makes certain proposals to change the QCDR and qualified registry reporting mechanisms for purposes of the PQRS program.⁷¹ BIO continues to support CMS's efforts to implement reporting via QCDRs and qualified registries, and we appreciate CMS's continued efforts to implement these new reporting mechanisms through the Proposed Rule. We continue to believe, however, that it is critical for CMS to require these registries to collect data and quality measures through a scientifically robust, transparent, and validated process.

⁷⁰ 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.").

⁷¹ 80 Fed. Reg. at 41,817-19.

We reiterate here the recommendations included in our previous comment letters in terms of specific requirements that CMS should impose on QCDRs to ensure that the inclusion of these registries achieves the intended expansion of physician participation in the PQRS and improvement in the quality of care. Specifically, BIO urges CMS to require qualified registries to:

- Transparently develop and update data elements and quality measures with stakeholder input by making all review processes open to the public, reviewing and regularly updating data elements and quality measures, and encouraging that all included quality measures are endorsed by a multi-stakeholder process equivalent to that used by the National Quality Forum (NQF);
 - Allow for flexibility in data collection methods, including opportunities to collect patient-reported outcomes;
 - Capture data longitudinally, not just at a single time interval;
 - Employ a transparent, peer-reviewed risk-adjustment methodology;
 - Supply meaningful feedback to providers to inform their clinical decision-making; and
 - Provide for adequate patient protections and consent procedures.
- B. BIO supports CMS's proposal to include patient-experience data for purposes of the PQRS, but continue to have concerns with respect to the CAHPS "Stewardship of Patient Resources" measure.

CMS is proposing to require the reporting of the CAHPS for PQRS survey for groups of 25 or more EPs who register to participate in the PQRS Group Practice Reporting Option (GPRO) and select the GPRO web interface as the reporting mechanism.⁷² BIO supports the use of patient-reported outcomes for purposes of the PQRS and Medicare's other quality programs. However, as noted in prior BIO comments, as well as in section (X)(E), above, we have serious concerns with respect to the "Stewardship of Patient Resources" measure included in the CAHPS measures set.

- C. BIO urges CMS not to use the attribution methodology used for the VM for the purposes of the GPRO web interface beneficiary assignment methodology.

For assignment of patients for group practices reporting via the GPRO web interface, CMS proposes to continue to use the attribution methodology used for the VM for the GPRO web interface beneficiary assignment methodology for the 2018 PQRS payment adjustment and future years.⁷³ As described in prior BIO comments and engagement with the Agency, we believe there are substantial flaws with the beneficiary attribution methodology used for purposes of the VM modifier.

Specifically, we believe that the attribution methodology used in the VM for cost measures in particular penalizes providers for costs that may be beyond their control. This is because *all* costs for a given beneficiary are assigned to the practice group/EP. However,

⁷² 80 Fed. Reg. at 41,821.

⁷³ 80 Fed. Reg. at 41,823.

studies of such attribution methodologies indicate that between 45 percent and 63 percent of the total spending on physician services are billed by physicians *other* than the physician to whom a beneficiary is assigned.⁷⁴ Reasons for this include, for example, that the EP/group may not have the appropriate resources, expertise, or authority to manage all of a patient's conditions and services.⁷⁵ Alternatively, the patient may have incurred costs *before* entering into the care of the EP/group, making it impossible for the EP/group to control these costs. Because the VM's attribution methodology penalizes providers for costs that may be beyond their control, it may discourage them from seeing the sickest patients. We therefore do not support its application for purposes of the VM, in other contexts, including here.

- D. BIO supports CMS's proposal to add three new measures groups for reporting in the PQRS beginning in CY 2016: Multiple Chronic Conditions Measures Group; Cardiovascular Prevention Measures Group; Diabetic Retinopathy Measures Group.

CMS proposes to add three new measures groups that will be available for reporting in the PQRS beginning in 2016: Multiple Chronic Conditions Measures Group; Cardiovascular Prevention Measures Group; and Diabetic Retinopathy Measures Group.⁷⁶ BIO supports the inclusion of each of these measures groups in the PQRS for CY 2016.

In particular, BIO supports the inclusion of the Multiple Chronic Conditions Measures Group in the PQRS for CY 2016. Patients with multiple chronic conditions often are more difficult to treat and the providers who are responsible for their care must juggle several treatment plans in order to appropriately care for this patient population. Furthermore, as CMS acknowledges, these providers often are not recognized for their efforts and the complexities involved in treating patients with multiple chronic conditions. For this reason, BIO believes that this is an important measure group, which could be beneficial to the Medicare patients suffering from multiple conditions.

BIO is especially supportive of the inclusion of the "Preventive Care and Screening: Influenza Immunization" measure (NQF #0041) within the Multiple Chronic Conditions Measures Group. Immunization measures help ensure that healthcare providers routinely discuss and offer recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system. Furthermore, ensuring this patient population receives an influenza vaccination is especially important given that patients with multiple chronic conditions are immunocompromised at a rate higher than the general population, and are therefore at an increased risk of developing serious influenza-associated complications. Additionally, we believe the "Documentation of Current Medications in the Medical Record" measure (NQF #0419) is an especially vital measure with regards to this patient population, as patients with multiple chronic conditions often take multiple medications. However, we would encourage CMS to include additional measures that specifically address medication adherence as part of care transitions and

⁷⁴ A. Mehrotra, J. Adams, J.W. Thomas, E.A. McGlynn, *The Effect of Different Attribution Rules on Individual Physician Cost Profiles*, 152 J. Ann. Intern. Med. 649-654 (2010).

⁷⁵ Center for Healthcare Quality & Payment Reform, *Measuring and Assigning Accountability for Healthcare Spending* (2014).

⁷⁶ 80 Fed. Reg. at 41,872.

otherwise. Adherence to a medication protocol is critical in order to reduce unnecessary care and expenditures that can result from non-adherence.

- E. BIO urges CMS to prioritize development of outcomes measures in asthma; building upon PQRS measure 398, "Optimal Asthma Control."

BIO was supportive of the 2015 PQRS measure 398, "Optimal Asthma Control," which measures patient-reported outcomes for asthma. BIO believes that there is an opportunity to build upon this measure and for CMS to adopt other similar measures to improve asthma. Notably, asthma is a common comorbidity for patients with multiple costly chronic conditions in the Medicare program; indeed, disabled beneficiaries are 1.8 times more likely than the general population to have asthma. While the Centers for Disease Control and Prevention (CDC) reports outcome measures for states related to daily symptom burden (e.g., limitations in activity, hospitalizations, emergency, or urgent care), a major stumbling block has been how to account for differences in patient asthma severity. We further believe that CMS should develop an approach to adjust for asthma severity pursuant to MACRA, as described in section (XII)(E), below.

- F. BIO commends CMS for proposing to retain a number of important immunization measures in the PQRS and encourages the Agency to develop and include additional adult immunization measures.

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#183, Hepatitis A Vaccination in Patients with Hepatitis C Virus
- NQF#1407, Immunizations for Adolescents
- NQF#0038/PQRS#240, Childhood Immunization Status

Three of these measures—Childhood Immunization Status, Preventive Care and Screening: Influenza Immunization, and Pneumonia Vaccination Status for Older Adults—are also included in the cross-cutting measure set. BIO commends CMS for recognizing the importance of immunization measures and continuing to include immunization measures in the PQRS.

Immunization measures help ensure that healthcare providers routinely discuss and offer recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system. This 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.⁷⁷

Beyond the immunization measures that are currently included in the PQRS measure sets, BIO encourages CMS to consider including additional adult immunization measures to address gaps identified by the NQF in the previously mentioned report, "Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations."⁷⁸ The committee identified four age-specific priorities for measurement:

- HPV vaccination catch-up for females ages 19-26 years and for males ages 19-21 years;
- Tdap/pertussis-containing vaccine for ages 19+ years;
- Zoster vaccination for ages 60-64 years; and
- Zoster vaccination for ages 65+ years.

The committee identified a number of composite measure priorities and the following three were highlighted as most important among them:

- Composite of Tdap and influenza vaccination for all pregnant women (including adolescents);
- Composite measures that include immunization with other preventive care services; and
- Composite measures for healthcare personnel of all Advisory Committee on Immunization Practices (ACIP)/CDC recommended vaccines.

Additionally, the committee noted that 60 measures have been developed to address pneumococcal immunization and that to reduce the burden and improve the value of measurement, measures should be harmonized and consolidated and "at a minimum, all measures should be up to date with current ACIP/CDC recommendations." To that goal, through its Health and Well-Being Standing Committee, NQF has proposed and approved standard specifications for pneumococcal vaccination to enable measure stewards for the existing measures (CMS and National Committee for Quality Assurance (NCQA))) to assess, and presumably modify, their measures based on the revised standardized specifications.⁷⁹ We encourage CMS to work with relevant stakeholders, including NQF, to implement the recommended Pneumococcal Vaccination Standard Specifications, which align to the current ACIP recommendation for PCV13 and PPSV23 vaccination in adults age 65 and older as well as at risk adults 19-64 years old, for the PQRS and across CMS programs.^{80,81}

⁷⁷ 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).

⁷⁸ National Quality Forum, *Final Report: Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations* (2014). Available at: http://www.qualityforum.org/Publications/2014/08/Priority_Setting_for_Healthcare_Performance_Measurement_Addressing_Performance_Measure_Gaps_for_Adult_Immunizations.aspx

⁷⁹ National Quality Forum, *Health and Well-Being, Phase 2 Draft Report for Comment*, pp. 11-13 and 35-37, May 29, 2015

⁸⁰ Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2014;63(37):822-825.

Finally, the committee also prioritized composite measures to help manage chronic diseases (e.g., diabetes, end stage renal disease) prevalent in the Medicare population. We strongly encourage CMS to incorporate measures reflective of the NQF report's priority recommendation in future updates to the PQRS, as the addition 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.

XII. Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

In the Proposed Rule, CMS is seeking public input on the provisions related to the new Merit-based Incentive Payment System (MIPS) established by MACRA, applicable beginning with payments for items and services furnished on or after January 1, 2019. While CMS is seeking feedback on any of the MIPS-related provisions, the Agency is particularly interested in two provisions: (1) the low-volume threshold; and (2) clinical practice improvement activities. As articulated in greater detail in our comments below, with regard to MIPS development and implementation, including these two areas, BIO would like to take this opportunity to:

- Support the consideration of distinct low-volume thresholds for different MIPS-eligible provider specialties;
- With respect to CMS's implementation of the MIPS program, ask the Agency to consider the feedback of patient advocates, in particular, when considering how to operationalize the definition of clinical practice improvement activities;
- Ask CMS to implement more robust requirements for QCDRs to ensure data are collected and quality measures developed through a scientifically robust process, before relying on this reporting mechanism in implementing the MIPS;
- Urge CMS to establish a robust risk-adjustment process to ensure MIPS-eligible providers are not unduly penalized for treating sicker patients and/or those in need of more complex care;
- Caution CMS against including quality measures used in other payment systems in the MIPS without a robust assessment, incorporating stakeholder feedback, of the appropriateness of such measures for MIPS-eligible providers;
- Urge CMS to consider the specific inclusion of metrics in the MIPS that assess patient access to the most appropriate therapy;
- Caution CMS against the use of global measures to assess provider performance in the MIPS unless there is evidence to suggest such measures can appropriately capture the quality and effectiveness of the care individual Medicare beneficiaries receive;
- Encourage CMS to directly engage stakeholders, such as patient advocacy organizations, involved in measures development as the Agency implements the MIPS; and

⁸¹ Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2012;61(40):816-819.

- Urge CMS to establish performance standards for purposes of MIPS based on existing evidence of what constitutes high quality, effective care for individual beneficiaries, and not overly rely on historical performance metrics or measures of improvement.

But, as an initial matter, we begin by articulating some general considerations that we urge CMS to take into account as the Agency works towards implementing MIPS and other value-based payment and payment reform initiatives under development by the Agency.

A. General considerations for CMS to address in implementing MIPS.

Congress, in enacting MACRA, envisioned that CMS would establish a MIPS program that would incorporate and build on existing value-based reporting and payment programs. To do so, BIO strongly urges CMS to address existing and outstanding issues with respect to the programs incorporated into MIPS, including the PQRS and the VM. Specifically, and as articulated in greater detail in the following sections of this letter, we urge CMS to: utilize quality measures that are disease-specific and meaningful to patients and providers; employ a robust risk-adjustment methodology that does not unduly penalize providers based on the underlying health of their patients; ensure patient access to the most appropriate therapies for them, including new-to-market therapies; and utilize robust monitoring of patient and provider experiences to support continuous program refinement. We further urge CMS to work with an array of stakeholder groups as the Agency moves forward with this process, and take into account feedback received through the notice-and-comment process, including as outlined in this letter.

B. BIO supports the consideration of distinct low-volume thresholds for different MIPS-eligible provider specialties.

MACRA requires the Secretary to develop a threshold to apply for purposes of excluding certain eligible professionals from the definition of a MIPS-eligible professional.⁸² While the specific definition is left to the discretion of the Secretary, statute directs the Secretary to consider one or more of the following three metrics: (1) enrollees treated by the provider; (2) items and services furnished to Part B-enrolled individuals; and/or (3) allowed charges billed. While BIO is not offering specific recommendations with regard to which, if any, of these metrics should be used to establish the low-volume threshold, or whether several should be used in concert, we note the need for CMS to consider employing different low-volume thresholds for different provider specialties. The use of any of the three metrics above will have a different impact on which providers are excluded from MIPS requirements, and can preferentially exclude certain provider specialties based on the nature of their practices and/or patient populations: for example, use of “allowed charges billed” 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 low-volume thresholds for different provider types—or the requirement that a provider must meet a multi-pronged threshold utilizing two or more of the identified metrics—is necessary since the accuracy of defining “low volume” will vary depending on the type of patients a provider treats.

⁸² Id. at 41,879.

- C. BIO asks the Agency to consider the feedback of patient advocates, in particular, when determining how to operationalize the definition of clinical practice improvement activities.

CMS requests feedback on activities that could be classified as clinical practice improvement activities according to the statutory definition.⁸³ Under MACRA, clinical practice improvement activities are defined as activities that relevant stakeholders have identified as improving clinical practice or care delivery and that the Secretary determines are likely to result in improved outcomes when effectively executed.⁸⁴ As an initial matter, BIO asks the Agency to put forward additional detail on how CMS intends to operationalize the definition of clinical practice improvement activities in order for stakeholders to be able to provide more specific, relevant feedback. Additionally, when identifying “activities that relevant stakeholders have identified as improving clinical practice or care delivery,” we urge the Agency to consider a diverse range of stakeholders including patient advocacy organizations that are increasingly collecting data from their members that can help improve patient experiences and health outcomes for numerous diseases/conditions.

- D. BIO asks CMS to implement more robust requirements for QCDRs, to ensure data are collected and quality measures developed through a scientifically robust process, before relying on this reporting mechanism in implementing the MIPS.

In implementing the MIPS, MACRA directs the Secretary to encourage the use of qualified clinical data registries (QCDRs).⁸⁵ BIO reiterates our concerns with the process utilized by QCDRs expressed in our response to CMS’s proposal to change the QCDR and qualified registry reporting mechanisms for purposes of the PQRS program (see Section (XI)(A) above). This includes that CMS has not established sufficiently robust requirements to ensure that these registries collect data and quality measures through a scientifically robust, transparent, and validated process.

- E. BIO urges CMS to establish a robust risk-adjustment process to ensure MIPS-eligible providers are not unduly penalized for treating sicker patients and/or those in need of more complex care.

MACRA directs the Secretary to assess appropriate adjustments to providers’ scores for the MIPS performance categories, composite score, and payment adjustments based on an individual’s “health status and other risk factors” as identified by the Secretary on an ongoing basis.⁸⁶ Robust risk-assessment is crucial to ensure that MIPS-eligible providers are not unduly penalized for providing care to patients who are sicker or in need of more complex care. The risk factors accounted for in the adjustment should at least reflect: patient demographic characteristics and clinically distinguishable disease characteristics that are predictive—based on peer-reviewed evidence—of prognosis, disease progression, and/or how well an individual may respond to a specific type, or types, of therapy. For example, “stage of cancer” must be included in the risk-adjustment methodology applied to MIPS-

⁸³ Id. at 41,879.

⁸⁴ MACRA § 1833(z)(3)(C).

⁸⁵ MACRA § 101(c)(1)(E).

⁸⁶ MACRA § 101(c)(1)(G).

eligible oncologists. Especially with regard to treating complex conditions, manufacturers are developing increasingly targeted therapies to specific stages of a disease or for specific patient subpopulations. Without a risk-adjustment methodology that accounts for the appropriate differences in total expenditures and health outcomes between different types of patients, these changes in payment policy may slow and/or discourage patient access to these personalized medicines by unduly penalizing providers who prescribe them.

As another example, we ask that CMS encourage the development of an approach to adjust for asthma severity in order to fairly measure practices with active management and response to asthma that is not controlled (e.g., improvements after a switch in medication). Without such an approach, it is difficult to measure the relative improvement for different severity levels. Doing so will facilitate MACRA's objective for patient-centered care, as well as the outcomes measures provisions of the MIPS program.

- F. BIO cautions CMS against including quality measures used in other payment systems in the MIPS without a robust assessment, incorporating stakeholder feedback, of the appropriateness of such measures for MIPS-eligible providers.

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.⁸⁷ 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 quality care in all care settings. Thus, we urge CMS to request stakeholder feedback on the applicability of metrics used in other settings, like the hospital inpatient setting, to MIPS-eligible providers before finalizing any such quality measures for a performance period.

- G. In considering quality measures for inclusion in the MIPS, BIO urges CMS to consider the specific inclusion of metrics that assess patient access to the most appropriate therapy for them and inform patient/provider decision-making.

BIO understands that CMS is in the beginning stages of identifying quality measures and performance standards for incorporation in the MIPS, and we applaud the Agency's effort in the Proposed Rule to solicit preliminary stakeholder feedback to inform its thinking and to express a commitment to developing these measures through a process that is inclusive of stakeholder input. While BIO looks forward to participating in future opportunities to comment on specific quality and performance measures put forward by the Agency, we would like to take this initial opportunity to recommend that CMS identify and include measures to assess, among other factors, patient access to appropriate therapies. 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

⁸⁷ MACRA § 101(c)(2)(C)(ii).

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).

1. *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 most appropriate therapies under these programs.*

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 the 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.⁸⁸ 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-eligible providers 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.

2. *As CMS develops and implements the MIPS, and related aspects of MACRA, the Agency should include quality metrics that inform appropriate clinical decision-making.*

Robust quality metrics can not only retrospectively assess the quality of care a patient received, but—if developed, implemented, and refined in a timely manner—can inform patient/provider decision-making at the point of care. They can accomplish this by reflecting the most recent advances in the standard of care for a specific disease and patient population or subpopulation. In the remainder of this section, BIO identifies two lung cancer-related examples of quality measures that can fulfill this dual role. This is by no means an exhaustive list but is meant to be illustrative to the Agency with regard to the

⁸⁸ 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.

importance of choosing and updating quality measures in a timely manner that keeps pace with emerging clinical evidence.

Lung cancer is the third most common cancer and the leading cause of cancer death in the U.S.⁸⁹ Given the burden of the disease on the U.S. population and the health care system, we support CMS's National Coverage Decision (NCD) for the Screening for Lung Cancer with Low Dose Computed Tomography (LDCT).⁹⁰ While the NCD is a significant step in improving early detection rates, we believe there is more to be done to increase the adoption of proper LDCT screening by physicians. Pursuant to the quality-metrics-related aspects of MACRA, and the MIPS specifically, we ask that CMS encourage the development of quality measures that ensure that physicians provide LDCT screening to all patients who meet the eligibility criteria. We believe this will increase the proper screening rates, thereby reducing mortality rates and the burden of disease for this population and for Medicare.^{91,92}

As a second example, we encourage CMS to support development of a measure to track timely testing for known driver mutations with available targeted therapies for patients with advanced non-small cell lung cancer (NSCLC).^{93,94} Such a measure would be consistent with current oncology and pathology practice guidelines (specifically for epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) testing in adenocarcinomas/mixed lung cancers with an adenocarcinoma component regardless of histologic grade).⁹⁵ The current College of American Pathologists (CAP)/ International Association for the Study of Lung Cancer (IASLC)/ Association for Molecular Pathology (AMP) clinical practice guidelines specify that patients should be tested at the time of diagnosis and that results should be available within 10 working days of the laboratory's receipt of the specimen (with additional specificity on the timeliness of tissue delivery for testing following histopathological diagnosis).⁹⁶ Timely testing and rapid turnaround would also allow treatment decisions that are consistent with current National Comprehensive Cancer Network (NCCN) guidelines for NSCLC.⁹⁷ According to NCCN guidelines and the American Society of Clinical Oncologists (ASCO), while patients may benefit from first-line chemotherapy followed by targeted therapies in second line, patients with EGFR and ALK

⁸⁹ American Cancer Society. Cancer Facts & Figures 2013. Atlanta: American Cancer Society; 2013. Accessed at <http://www.cancer.org/research/cancerfactsfigures/cancerfactsfigures/cancer-facts-figures-2013> This link goes offsite. Click to read the external link disclaimer on August 5, 2015.

⁹⁰ Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT), 2015. Accessed at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274> on August 5, 2015

⁹¹ Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, et al.; National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. *New Engl J Med*. 2011;365(5):395-409

⁹² Pinsky PF, Church TR, Izmirlian G, Kramer BS. The National Lung Screening Trial: results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013.

⁹³ Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology; Arch Pathol Lab Med. 2013 Jun; 137(6): 828-860.

⁹⁴ See CAP/IASLC/AMP guideline for complete information on staging and recurrence.

⁹⁵ Molecular testing guideline, CAP/IASLC/AMP, 2013, Recommendation 1.2.

⁹⁶ Molecular testing guideline, CAP/IASLC/AMP, 2013. Expert Consensus Opinion 3.3.

⁹⁷ National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Non-Small Cell Lung Cancer; Version 7.2015.

mutations show superior outcomes with first-line administration of targeted therapies.^{98,99} Pursuant to the quality metrics-related aspects of MACRA, and the MIPS specifically, BIO recommends CMS encourage the development of a measure of timely diagnosis and testing to enable providers and patients to make the most appropriate clinical decisions in NSCLC.

- H. 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-eligible providers. 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-eligible provider 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 to prevent, diagnose, and/or treat. While this 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, are receiving. 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.

- I. BIO encourages CMS to directly engage stakeholders, such as patient advocacy organizations, involved in measures development as the Agency implements the MIPS.

In identifying and finalizing quality measures to apply to MIPS-eligible providers, MACRA directs the Secretary to allow input from “eligible professional organizations and other relevant stakeholders,” where the former is defined as “a professional organization as defined by nationally recognized specialty boards of certification or equivalent certification boards.” In section 101(c)(2)(D)(viii), MACRA again references “relevant eligible professional and other relevant stakeholders, including State and national medical societies” directing the Secretary to consult with these stakeholders in developing and finalizing the list of quality measures that will apply during a given performance year to MIPS-eligible providers. BIO appreciates the statute’s recognition of the important place professional societies have in identifying quality measures that are relevant to clinical practice and accurately reflect aspects of clinical care over which providers have control. As CMS implements MACRA, we urge the Agency to specifically engage other stakeholders including

⁹⁸ Keedy VL, Temin S, Somerfield MR, et al. American Society of Clinical Oncology provisional clinical opinion: epidermal growth factor receptor (EGFR) mutation testing for patients with advanced non-small-cell lung cancer considering first-line EGFR tyrosine kinase inhibitor therapy. J Clin Oncol. 2011;29(15):2121–2127.

⁹⁹ NCCN Clinical Practice Guidelines, Version 7.2015.

patient advocacy organizations and manufacturers, both of which are increasingly engaging in measures development and have important perspectives to inform the Agency's process.

- J. BIO urges CMS to establish performance standards based on existing evidence of what constitutes high quality, effective care for individual beneficiaries, and not overly rely on historical performance metrics or measures of improvement.

Under the MIPS, the Secretary must establish performance standards with respect to specified measures and standards for a performance period. In doing so, the Secretary is directed 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 in the context of the following concerns. First, historical performance standards may not be relevant to the population served by MIPS-eligible professionals 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-eligible providers' 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).

Second, consider both the second and third factors together, we remain concerned that a focus on improvement may disadvantage providers who are already performing well. BIO also strongly urges the Secretary to take into account the variability in performance based on: a provider's specialty or subspecialty and the characteristics of a provider's patient population. Performance metrics that are not tailored to account for at least these factors may unduly penalize providers for aspects of care outside of their influence. BIO looks forward to continuing to discuss these important issues related to the development of MIPS performance standards as CMS works to implement this program.

XIII. Medicare Shared Savings Program (MSSP)—BIO supports the proposed inclusion of certain additional quality measures for purposes of the MSSP, but urges CMS to consider the inclusion of certain, additional measures, and to make certain modifications to Agency's proposal with respect to measures no longer aligning with clinical guidelines, high quality of care, or outdated measures that may cause patient harm. We also urge CMS to consider expanding the application of meaningful-use related measures to specialists under the MSSP.

- A. BIO supports the inclusion of a "Statin Therapy for the Prevention and Treatment of Cardiovascular Disease" measure to the MSSP's Preventive Health domain, once the measure is endorsed by NQF.

CMS is proposing to add a “Statin Therapy for the Prevention and Treatment of Cardiovascular Disease” measure to the Preventive Health domain to the MSSP.¹⁰⁰ While BIO supports the inclusion of a measure of this nature, we believe it is important for the measure to first be approved by NQF, or another similar consensus organization, before it is implemented. Because quality performance plays such an important role in the Shared Savings Program insofar as it is tied to an accountable care organization’s (ACO’s) eligibility for shared savings and the amount of shared savings to which it may be entitled, BIO believes that it is especially important that the measures used in this program are endorsed by a national, consensus-based organization, such as the NQF. In addition, CMS should also strive to incorporate additional cardiovascular outcome measures that address this patient population into the measure set. By way of example, the MACRA legislation prioritizes the development and use of outcome measures for the new MIPS program. The addition of cardiovascular outcome measures to the measure set will provide a more comprehensive view of hospital and provider performance with respect to the management of cardiovascular disease than is possible with this process measure alone, and their use will help to support continued quality improvement by MSSP ACOs as they aim to provide care more efficiently.

- B. BIO commends CMS for proposing to retain the influenza immunization and pneumococcal vaccination measure in the MSSP and encourages CMS to develop and add other adult immunization measures.

CMS proposes to include the following two measures for use in establishing quality performance standards that ACOs must meet for shared savings: Preventive Care and Screening: Influenza Immunization (NQF #0041); and Pneumonia Vaccination Status for Older Adults” (NQF #0043).¹⁰¹ It is critically important that CMS include immunization measures in the MSSP to ensure that ACOs continue to provide these valuable services. We commend CMS for retaining the Influenza Immunization (ACO#14) measure and the Pneumonia Vaccination Status for Older Adults measure (ACO#15) in the MSSP’s Preventive Health Domain. As previously discussed in our comments, these measures help ensure that healthcare providers routinely discuss and offer recommended influenza and pneumococcal vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and ultimately cost savings for the healthcare system. BIO urges CMS to finalize the proposal to include these two NQF-endorsed measures. In addition, we encourage CMS to develop and include additional immunization performance measures and composite measures for preventive services recommended for adults in future updates to the ACO measure set, as described in the 2014 NQF report discussed fully in Section (XI)(F) above of our comments.

- C. BIO urges CMS to include certain additional measures for purposes of the MSSP that were not proposed.

BIO encourages CMS to include certain additional measures for purposes of the MSSP that are not proposed, namely: measures that specifically address medication adherence as part of care transitions and otherwise; a Comprehensive Medication Management (CMM)

¹⁰⁰ 80 Fed Reg. at 41,886.

¹⁰¹ 80 Fed. Reg. at 41,887.

measure to help maximize the benefits of appropriate medication use by patients treated by MSSP participants; measures that assess continuity of care between ACOs and medical specialists; "Hospital 30-Day All-Cause Readmission Rate following a COPD Hospitalization" (NQF #1891); "Hospital 30-Day All-Cause Risk Standardized Mortality Rate Following a COPD Hospitalization" (NQF #1893); and "Pharmacotherapy Managements of COPD Exacerbation" (NWF #0549).

- D. BIO urges CMS to make certain modifications to the proposed policy for measures no longer aligning with clinical guidelines, high quality of care, or outdated measures that may cause patient harm.

In the Proposed Rule, CMS notes the frequency of changes that occur in scientific evidence and clinical practice, as well as that a measure owner may determine—between rulemaking cycles—that their measure no longer meets best clinical practices due to clinical guidance updates or when clinical evidence suggests that continued measure compliance and collection of the data may result in harm to patients. CMS is therefore proposing that, if a guideline update is published during a reporting year and the measure owner determines that the measure specifications do not align with the updated clinical practice, CMS would have the authority to maintain a measure as pay-for-reporting, or revert a pay-for-performance measure to pay-for-reporting, and finalize changes in the subsequent MPFS final rule with comment period, by either retiring the measure or maintaining it as pay for reporting.¹⁰²

BIO supports CMS's efforts to ensure that measures used for purposes of the MSSP are "up-to-date."¹⁰³ We further support efforts to immediately remove measures that are found to result in harm to patients. We are concerned, however, that the removal of measures, particularly mid-reporting year without the opportunity for stakeholder comment, may create gaps in the measures set against which providers are evaluated. Accordingly, we urge CMS to modify the proposed regulatory text at 42 C.F.R. § 425.502(a)(5) to provide that this proposed authority would be used only in instances in which there is evidence that continued use of the retired measure would result in harm to patients. We further urge CMS to continue to work with the measures development community such that the Agency can better anticipate measures likely to be retired, in order to facilitate the development of strategies to mitigate and minimize potential gaps in available measures. Finally, to ensure that providers remain aware of the standards against which they will be evaluated, we urge the Agency to establish clear notification standards with respect to any changes made pursuant to the proposed provision, if finalized.

- E. CMS should consider expanding the application of meaningful use-related measures to specialists.

CMS is seeking comment on how the measure "Percent of PCPs who Successfully Meet Meaningful Use Requirements" might evolve in the future to ensure CMS is incentivizing and rewarding providers for continuing to adopt and use more advanced health IT functionality, and broadening the set of providers across the care continuum that have

¹⁰² 80 Fed. Reg. at 41,889.

¹⁰³ 80 Fed. Reg. at 41,885.

adopted these tools. Among other questions, CMS specifically asks for feedback as to whether this measure should be expanded in the future to include all EPs, including specialists.¹⁰⁴ BIO believes that CMS should consider expanding use of this measure beyond primary care providers to include specialists. Specialists are important members of the care team, particularly for patients suffering from complex, chronic conditions. Incentivizing specialists to incorporate data into patient EHRs in accordance with CMS's Meaningful Use requirements will help ensure that such patients' care can be properly coordinated across their care team.

XIV. Value-Based Payment Modifier and Physician Feedback Program—BIO supports CMS's proposal to continue to monitor the VM, as well as CMS's proposals to both exempt certain groups from the VM and increase the reliability of the VM's cost and quality measures, but urges the Agency to make certain critical improvements to the VM program going forward.

As CMS is aware, BIO has overarching concerns with respect to the VM program, described throughout these and prior BIO comments, as well as through our engagement with the Agency, which fall into the following seven categories:

- (1) the quality measures used in the program are inadequate, particularly for purposes of assessing the quality of care furnished by medical specialists, and do not capture the benefits of appropriate use of drugs and biologics (e.g., retention of vision acuity);
- (2) the cost measures used in the program are based on an incomplete cost profile and thus distort the weightings of different costs in the overall market basket, in turn, obscuring true changes in costs that may reflect the provision of high-quality, efficient care;
- (3) the attribution methodologies for cost measures may assign costs to providers who had no ability to control the care provided;
- (4) provider benchmarks may not adequately compare providers to their peers;
- (5) the risk-adjustment methodology may fail to adequately take into account the underlying health of a provider's patient population, which can have very real cost implications (e.g., as a result of the failure to model extensive atherosclerosis);
- (6) the model that assigns quality and cost measures to tiers includes arbitrary breakpoints and may not have been adequately assessed by CMS; and
- (7) quality and resource use reports (QRURs) issued to providers are confusing and do not provide actionable information.

BIO also has some specific concerns and recommendations related to certain proposals made in the Proposed Rule. Specifically, related to BIO's overarching concerns, and as articulated in greater detail in the following sections, BIO would like to take this opportunity to:

- Support the proposed modification of the VM's future application to non-physician eligible professionals;

¹⁰⁴ 80 Fed. Reg. at 41,890.

- Support CMS's proposal to rely on the highest numerical quality composite score among the various ACOs in which a given tax identification number (TIN) participates for purposes of the VM, but urge the Agency to re-evaluate aspects of applying the VM to MSSP participants;
- Support CMS's proposal to exempt certain CMMI demonstrations from the VM and urge the Agency to go further by exempting all such models;
- Support CMS's proposal to extend upward payment adjustments for treatment of high-risk patients to Shared Savings Program ACOs under the VM;
- Urge CMS to reduce the amount of payment at risk for physicians participating in the VM;
- Support the continued use of an upward adjustment for practices that serve high-risk beneficiaries under the VM, but also urge CMS to apply these payments to all providers that serve high-risk patients, regardless of their quality score;
- Support the proposed inclusion of all PQRS quality measures in the VM, but urge the Agency to monitor use of these measures and ensure that quality measures in the VM adequately capture the benefits and appropriate use of drugs and biologicals, as well as the care provided by specialists;
- Support the use of patient experience data for purposes of the VM, but continue to express concern with respect to the "Stewardship of Patient Resources" measure used in the CAHPS survey;
- Urge CMS to remove the Medicare Spending Per Beneficiary (MSPB) measure from the VM program, but support the Agency's efforts to improve the measure's reliability to the extent that CMS continues to use the measure;
- Support CMS's proposal to classify practitioners as "average" for purposes of their cost or quality measures, to the extent that they do not have at least one such measure that can be calculated reliably, but reiterate our serious concerns with respect to the cost and quality metrics used in the VM generally;
- Agree with CMS that the benchmark for each cost measure should be based only on performance rates that meet the minimum number of cases for that measure and continue to support the use of the VM's specialty adjustment, but express concern that the adjustment does not adequately account for subspecialty practice differences; and
- Urge CMS to consider replacing the CMS hierarchical condition categories (CMS-HCC) as the risk-adjustment methodology under the VM.

In light of these overarching concerns, together with our specific concerns and recommendations, we would like to articulate our support for CMS's proposal to "continue to monitor the VM program and continue to examine in the VM Experience Report the characteristics of those groups and solo practitioners that would be subject to an upward or downward payment adjustment under [the Agency's] quality-tiering methodology to determine whether [the Agency's] policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups." We strongly support CMS's efforts to monitor the VM program to identify, and hopefully correct, any unintended consequences with respect to the program going forward, particularly those identified here.

A. BIO supports the proposed modification of the VM's future application to non-physician EPs.

For the CY 2018 payment adjustment period, CMS proposes to apply the VM only to non-physician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups and those who are solo practitioners.¹⁰⁵ BIO supports CMS's efforts to expand the VM program to non-physician providers, as these providers do furnish services to Medicare beneficiaries and thus, like physicians, should be incentivized to provide high-quality care. We further support this particular proposal, which aims to streamline the transition from the VM to MIPS in 2019.

As CMS notes in the Proposed Rule, section 1848(p)(7) of the SSA provides CMS with the express authority to expand application of the VM to certain non-physician providers, beginning in 2017. However, as CMS also notes, beginning in 2019, MACRA replaces the VM with MIPS, yet provides that MIPS will not apply to non-physician providers that are not PAs, NPs, CNSs, and CRNAs until 2021. We believe that CMS's proposal appropriately reconciles this discrepancy, by extending the VM to all non-physician providers who will be transitioned directly from the VM to MIPS, while also ensuring that the remaining non-physician providers are transitioned to a value-based payment program only once.

B. BIO supports CMS's proposal to rely on the highest numerical quality composite score among the various ACOs in which a given TIN participates, but urges the Agency to re-evaluate aspects of applying the VM to MSSP participants.

CMS proposes that, beginning with the CY 2017 payment adjustment period, TINs that participate in multiple Shared Savings Program ACOs in the applicable performance period would receive the quality composite score of the ACO that had the highest numerical quality composite score. BIO supports this proposal. We believe that using the highest quality composite is the fairest approach for MSSP-participating providers. That said, we continue to note our concern that CMS has failed to model the results of any benchmark changes so that physicians and other providers under the MPFS can determine the impact of adding these large, multi-specialty, highly resourced entities into the VM quality metrics.

Moreover, as articulated in prior BIO comments, we remain concerned with respect to CMS's policy of classifying the cost component of the VM for these groups as "average cost." Indeed, BIO is deeply concerned about adjusting Medicare payment for ACOs based on the VM's cost composite at all. Although BIO understands that the VM-specific provisions of the SSA require CMS to extend the VM to all physicians beginning in 2017, we note that ACOs participating in the MSSP already are incentivized to furnish efficient care in an effort to obtain shared savings. It also is clear that introducing a new variable into the ACO demonstration could change the baseline used to measure success and would substantially bias any results. Furthermore, because ACOs already receive bonuses for reducing costs under the MSSP, CMS would be giving ACOs an unfair advantage over other Medicare

¹⁰⁵ 80 Fed. Reg. at 41,895.

providers by mathematically double-counting bonus payments and skewing the distribution of VM bonus payments and penalties in a way that may favor ACO providers. Accordingly, to the extent that the VM is extended to practitioners participating in the MSSP, we urge CMS to evaluate those practitioners only with respect to the VM's quality component.

C. CMS should exempt all CMMI demonstrations from the VM.

BIO has concerns with respect to CMS's proposal that, beginning with the CY 2017 payment adjustment period, the Agency would determine the VM for groups and solo practitioners (as identified by TIN) who participated in a Shared Savings Program ACO in the performance period in accordance with the VM policies for MSSP participants under 42 C.F.R. § 414.1210(b)(2), regardless of whether any EPs under the TIN also participated in an Innovation Center model during the performance period.

Specifically, BIO has previously expressed concerns about the fact that ACO provider participation in the VM has the potential to double-count that provider's performance—positive or negative—for purposes of calculating performance-based payment (i.e., in both the MSSP and the VM). We are concerned that this proposal has the potential to *triple*-count a provider's performance for these purposes, by factoring that performance into payment adjustments made in the MSSP, VM, *and* models operated by CMMI. Instead, we believe that CMS should use its waiver authority under 1115A(d)(1) to waive application of the VM with respect to all CMMI demonstrations, as described in section (XIV)(E), below, such that groups and solo practitioners, as identified by TIN, would be exempt from the VM to the extent that at least one EP who billed for items and services under the TIN participates in any CMMI demonstration.

D. BIO supports CMS's proposal to extend upward payment adjustments for treatment of high-risk patients to Shared Savings Program ACOs, but urges the Agency to apply this upward adjustment to all providers that treat high-risk beneficiaries, regardless of whether their practices are high-performing.

BIO supports CMS's proposal to extend the +1.0x upward payment adjustment for groups and solo practitioners with attributed beneficiary populations that have an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide to groups and solo practitioners that participated in high performing Shared Savings Program ACOs that cared for high-risk beneficiaries (as evidenced by the average HCC risk score of the ACO's attributed beneficiary population as determined under the VM methodology) during the performance period. However, for the reasons described in section (XIV)(G), below, we urge the Agency to apply this upward adjustment to all providers that treat high-risk beneficiaries, regardless of whether their practices are high-performing.

E. BIO supports CMS's proposal to exempt certain CMMI demonstrations from the VM and urges the Agency to go further by exempting all such models.

As CMS notes in the Proposed Rule, there are several models under development and testing by CMMI. CMS believes that a waiver of the VM is necessary to test five of these models—the Comprehensive Primary Care (CPC) Initiative, the Pioneer ACO Model, the Next

Generation ACO Model, the Oncology Care Model, and the Comprehensive End-Stage Renal Disease (ESRD) Care Initiative—and therefore proposes to do so for the CY 2018 and, as applicable, CY 2017 payment adjustment periods.¹⁰⁶

BIO supports this proposal. We agree that the effectiveness of these models would be “impossible to isolate from the confounding variables of quality and cost metrics and contrasting payment initiatives utilized under the VM.”¹⁰⁷ However, we believe that CMS should go further and exempt all CMMI demonstrations from the VM, as noted in section (XIV)(C), above.

F. BIO urges CMS to reduce the amount of payment at risk for physicians participating in the VM.

As with CMS’s proposal, finalized in the CY 2015 MPFS Final Rule, CMS is now proposing to set the amount of payment at risk under the CY 2018 VM to 4 percent for groups with 10 or more EPs, 2 percent for groups with between two to nine EPs and physician solo practitioners, and 2 percent for groups and solo practitioners that consist of non-physician EPs who are PAs, NPs, CNSs, and CRNAs.⁵ BIO continues to oppose this proposal as it puts too great a percentage of provider payments at risk, particularly for large practices, based on a faulty approach of combining providers’ performance on measures of quality and cost by classifying providers into performance groups.

We are deeply concerned that the approach for weighting the VM measures is arbitrary and the cut-offs for inclusion in one performance group or another are not meaningful. Even if the quality and cost measures used are reliable—which is an open question—the program will fail if the method for combining those measures and cut-off points are arbitrary. For example, having a penalty of four percent in the lowest tier versus two percent in the middle tier for providers whose performance is completely indistinguishable around the benchmark is both inequitable and an unfair standard for this program to impose. We urge CMS not to put such a high percentage of provider payments at risk unless and until the Agency has worked with stakeholders to correct the underlying approach to combining providers’ performance on appropriate quality and cost measures.

G. BIO supports the continued use of an upward adjustment for practices that serve high-risk beneficiaries, but urges CMS to apply these payments to all providers that serve high-risk patients, regardless of their quality score.

CMS also proposes to continue to provide upward payment adjustments of +1.0x to groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology and have an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores.¹⁰⁸ As described previously, BIO supports the proposal to continue the +1.0x payments to providers that serve a disproportionate share of high-risk patients. We do not, however, believe that this should be viewed as a substitute for a robust risk-adjustment methodology. We also ask CMS to consider extending the

¹⁰⁶ 80 Fed. Reg. at 41,900.

¹⁰⁷ 80 Fed. Reg. at 41,900.

¹⁰⁸ 80 Fed. Reg. at 41,902.

applicability of these payments to *all* providers that serve a disproportionate share of high-risk patients, rather than only those eligible for upwards adjustments under the quality-tiering methodology, given that a provider's high-risk patient population may be one reason that the provider fails to obtain a high risk score. As described in greater detail in section (XIV)(M), below, we are concerned that the VM's current risk-adjustment methodology is not sufficient to ensure that providers are not unduly penalized for the underlying health status of their patient population.

- H. BIO supports the proposed inclusion of all PQRS quality measures in the VM, but continues to urge the Agency to monitor use of these measures and ensure that quality measures in the VM adequately capture the benefits and appropriate use of drugs and biologicals, as well as the care provided by specialists.

CMS proposes to continue to include all of the quality measures that are available to be reported under the various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2018 to the extent the group or solo practitioner submits data on these measures.¹⁰⁹ CMS acknowledges the importance of aligning the VM for CY 2018 with the requirements of the PQRS due to the role quality reporting plays on the success of quality improvement.

BIO supports the proposal to continue to include all of the PQRS measures in the VM. We agree with CMS that "quality reporting is a necessary component of quality improvement" and that CMS should avoid placing an "undue burden" on EPs to report such data.¹¹⁰ However, while we appreciate the alignment of quality measures between programs, we note that such alignment can exacerbate issues with individual measures that are in use. Accordingly, we urge CMS to continually review measures for updates and validity in the program in which they are used, and to ensure that any measures incorporated into the VM are appropriate for any additional provider types included in the program.

We further note that variations in quality measures under the different reporting methods make meaningful comparisons difficult. For example, provider practices reporting through a GPRO report far fewer measures than those providers who report individually through the PQRS. Also, as described in section (XI)(A), above, quality measures from QCDRs are not required to be developed, evaluated, or endorsed in the same transparent manner as PQRS measures. To address these concerns, BIO urges CMS to take steps to align reporting requirements and standards across reporting options, including to require QCDRs to collect data and quality measure through a scientifically robust, transparent, and validated process, as described in greater detail above.

- I. While BIO supports the use of patient experience data for purposes of the VM, we continue to be concerned with respect to the "Stewardship of Patient Resources" measure used in the CAHPS survey.

¹⁰⁹ 80 Fed. Reg. at 41,904.

¹¹⁰ 80 Fed. Reg. at 41,904.

CMS is proposing to include the CAHPS for ACOs survey in the quality composite of the VM for TINs participating in ACOs in the Shared Savings Program, beginning with the CY 2016 performance period and the CY 2018 payment adjustment period.¹¹¹ BIO supports the collection and use of patient experience data for purposes of evaluating provider performance and believes that many of the questions in CAHPS assess meaningful aspects of a patient's care experience. However, as noted in section (X)(E), above, we have concerns with respect to the "Stewardship of Patient Resources" measure used in the CAHPS survey.

- J. BIO continues to urge CMS to remove the MSPB measure from the VM program; however, to the extent CMS continues to use this measure, we support the Agency's efforts to improve its reliability.

CMS proposes to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite from 20 to 100 beginning with the CY 2017 payment adjustment period.¹¹² As articulated in prior comments, BIO has serious concerns with respect to the MSPB measure, including that the measure has not been endorsed at the physician or group level, calling into question its reliability for purposes of a physician-specific value-based purchasing program. We also are concerned that this measure offers only a retrospective measure of one aspect of the provision of care—its cost—and thus continue to urge the Agency to replace the MSPB measure with relative resource use (RRU) measures, which make it possible to consider quality and spending simultaneously.¹¹³

However, to the extent that the MSPB measure remains in the VM program, as CMS continues to propose, BIO generally supports the Agency's efforts to improve this measure's reliability. We further agree with CMS that it is preferable to avoid a situation in which groups or solo practitioners who may have performed poorly on the MSPB measure may receive a downward adjustment on the VM measure as a result of a measure that was not reliable, even if this means that a group that would have performed well on the measure would no longer have it included in its cost composite. That said, we urge CMS to quantify for stakeholders the degree to which moving the threshold to 100 episodes improves the reliability of the measure, and consider whether a higher threshold, or other adjustments to the measure and its application, are necessary for this purpose.

- K. BIO supports CMS's proposal to classify practitioners as "average" for purposes of their cost or quality measures, to the extent that they do not have at least one such measure that can be calculated reliably, but reiterate our concerns with respect to the cost and quality metrics used in the VM generally.

CMS is proposing that, beginning with the CY 2016 payment adjustment period, the cost composite for a group or solo practitioner would be classified as "average" if there is not at least one cost measure that can be calculated reliably. The quality composite would

¹¹¹ 80 Fed. Reg. at 41,905.

¹¹² 80 Fed. Reg. at 41,906.

¹¹³ RRU measures are defined by the National Committee for Quality Assurance (NCQA) as measures that: indicate how intensively plans use physician visits, hospital stays, and other resources for the care of members identified as having one of five chronic conditions (cardiovascular disease, COPD), diabetes, hypertension, and anemia).

similarly be classified as “average” if there is not at least one quality measure that can be calculated reliably.¹¹⁴ While BIO generally supports this proposal, we would like to take this opportunity to voice our ongoing concerns with respect to the VM program’s cost and quality measures more broadly.

- 1. BIO has serious concerns with respect to the VM’s cost metrics, in particular the Total Per Capita Cost measure, which provides an incomplete cost profile.*

With respect to the VM’s cost metrics, in addition to our concerns regarding the MSPB measure articulated in the previous section, we have serious concerns with CMS’s continued use of the Total Per Capita Cost Measure. For instance, we are concerned that this measure is not endorsed by a national, consensus-based organization (e.g., NQF), meaning that its use may result in inaccurate or complete conclusions with respect to the care provided.

This measure also is problematic because it currently captures Medicare Part A and Part B costs, but not Part D costs. This methodology is analogous to a survey for health population needs containing under-reported results for dual-eligible and the institutionalized populations, which biases the results to understate the resources required to treat these populations. Thus, not only does the measure provide an incomplete cost profile with respect to the prescription drugs prescribed by a given physician, but it also can create a financial disincentive for the provision of the best clinical care for an individual patient. To illustrate, for patients with a given disease state, one physician may prescribe predominantly therapies covered under Medicare Part B, which reflects the best line of therapy for their patient mix, while another physician may prescribe predominantly therapies covered under Part D (which also may reflect the clinical needs of their patient mix). The reasons for these prescribing patterns are numerous and include, for example, the characteristics of the prescriber’s patient population (e.g., severity of disease, failure on first-line therapies, ability to self-administer), patient cost-sharing considerations, and the physician’s own training and experience. We firmly believe that the cost measures in the VM should not penalize, based on their structure alone, physicians’ clinical decisions with regard to which therapy to prescribe for an individual patient. However, for those categories and classes of drugs that include treatment options covered under Part B and others covered under Part D, the Total Per Capita Cost Metric, as currently structured, may penalize Medicare physicians who prescribe therapies primarily covered under Part B for their treatment decisions, merely based on how those drugs are covered under Medicare. As such, the measure as constructed is clinically insensitive to optimal care given the limitation of risk adjustment with different stages of care.

Specifically, consider those drug categories that include at least one therapy covered under Part B and at least one therapy covered under Part D, but both approved to treat the same clinical indication. For drug categories where this is the case, those practices that provide primarily Part B drugs would be deemed less efficient (and subject to a potential penalty under the VM) than practices that prescribe primarily Part D drugs. Physicians treating patients who require additional lines of therapy should not be penalized for

¹¹⁴ 80 Fed. Reg. at 41,907.

prescribing clinically appropriate Part B-covered drugs that may represent the only hope for successful disease management. While we believe that most physicians will put their patients' needs first, the current structure will reward those few who act arbitrarily and inappropriately. 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 long-term.

We therefore continue to urge the Agency to either exclude the Total Per Capita Cost Measure from the VM program, or alter the measure such that this measure specifically (and the VM as a whole) does not have the potential to skew prescribing behavior, disadvantage providers who prescribe primarily Part B therapies, and/or potentially create patient access issues. Specifically, in order to create a "level playing field" across all therapies—regardless of how they are covered by Medicare—and taking into account the challenges associated with incorporating Part D costs into this measure,¹¹⁵ we strongly urge CMS to exclude Part B utilization for those drug categories and classes for which there are Part D treatments approved to treat the same clinical indication(s). Doing so would help to limit the potential negative effects on health outcomes from inappropriately shifting drug costs between different Parts of the Medicare program. BIO would be happy to work with the Agency to identify those categories and classes of therapies to which this policy would be effective.

As noted in BIO's comments last year, we continue to remind CMS that the Agency has the express statutory authority to exclude all drug costs (or a portion thereof) for purposes of implementing section 3007 of the ACA, as Congress gave the Secretary broad leeway to determine which measures of costs are "appropriate" for purposes of calculating the VM.¹¹⁶ Indeed, the statute requires CMS to evaluate costs for purposes of the VM, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary that, among other things, take into account risk factors and other factors determined appropriate by the Secretary.¹¹⁷ We urge CMS to rely on this authority to address an important factor: ensuring that all prescribing decisions are, and continue to be, driven by clinical considerations alone.

If CMS does not exclude Part B utilization, the Agency should incorporate Part D costs where there are B/D lines of therapy in the Total Per Capita Cost metric in order to level the playing field across therapies. CMS should involve all stakeholders—including BIO—in the process of identifying and refining any applicable methodologies. We and our members have conducted some research and performed some initial analyses in this area,

¹¹⁵ CMS has resisted excluding Part B costs and has taken the position not to include Part D at this time "... due to the complexity of the issue and uncertainty of how to fairly and equitably incorporate the costs." See 79 Fed. Reg. at 67,963 ("... due to the complexity of the issue and uncertainty of how to fairly and equitably incorporate the costs ... Including Part D data would incorrectly indicate higher costs for these beneficiaries with Part D coverage relative to otherwise comparable beneficiaries without such coverage and for whom prescription drug costs cannot be measured directly by CMS. Before we are able to propose inclusion of Part D data, we would need to determine an approach to address this issue.").

¹¹⁶ The applicable provision defines "costs" to mean "expenditures per individual as determined appropriate by the Secretary." ACA § 3007 (codified at SSA § 1848(p)(8)(A)). In making this determination, the law permits the Secretary to take into account the amount of growth in expenditures per individual for a physician compared to the amount of such growth for other physicians. Id.

¹¹⁷ SSA § 1848(p)(3).

which we believe would be helpful to the Agency in this regard, and we would be happy to share this information at your request. We note that these analyses may also be of use with respect to CMS's implementation of MACRA, which requires CMS to account for Part D drug costs "as feasible" when it implements the MIPS program in 2019.

Finally, we note that, although improvements to the Total Per Capita Cost metric are both important and necessary to "level the playing field" across treatment options, such improvements would not, alone, address the concerns that BIO has articulated both here and elsewhere with respect to the VM program. Accordingly, we urge CMS to pursue, in tandem with any such improvements, certain critical modifications to the VM's other cost and quality metrics, as well as to the VM's risk-adjustment and specialty-adjustment methodologies, as described throughout this section (XIV) of our letter. We also strongly urge CMS to collect data with respect to, and to what extent, the VM is driving prescriber behavior and/or creating access barriers for patients.

2. *BIO urges CMS to work with stakeholders to ensure that the VM's quality metrics fully capture the benefits of appropriate use of drugs and biologicals, and that the VM includes sufficient quality metrics for specialists.*

In addition to our concerns with the VM's cost metrics, as stated in prior comments, BIO remains concerned that the current quality measures used to calculate the VM adjustment are insufficient to fully capture the benefits of appropriate use of drugs and biologicals. CMS should therefore work with stakeholders to ensure that the VM includes quality measures that capture the short- and longer-term benefits of the appropriate use of drugs and biologicals. For this purpose, BIO continues to recommend that CMS adopt the recommendations from the Working Group on Optimizing Medication Therapy in Value-Based Healthcare.¹¹⁸ We also urge the Agency to ensure that both the quality and cost of health care are assessed over a period of time sufficient to account for the full effect of longer-term treatments and therapies.

BIO also is concerned that the VM lacks appropriate measures for certain specialists, which may result in inaccurate or incomplete conclusions regarding the quality of care. Specifically, to the extent these specialists and sub-specialists do not have quality measures relevant to their patient populations, they may be forced to report quality measures that do not reflect the nature of the care provided or the associated outcomes. CMS should therefore work with physician specialty groups and other stakeholders to ensure that there are adequate quality measures for each specialty and sub-specialty.

- L. BIO agrees that the benchmark for each cost measure should be based only on performance rates that meet the minimum number of cases for that measure; we also continue to support the use of the VM's specialty adjustment, but remain concerned that it does not adequately account for subspecialty practice differences.

¹¹⁸ R.W. DuBois, Role of Pharmaceuticals in Value-Based Healthcare: A Framework for Success, Am. J. Mg'd Care (2012), <http://www.ajmc.com/publications/issue/2012/2012-7-vol18-n7/role-of-pharmaceuticals-in-value-based-healthcare-a-framework-for-succes/1>.

CMS proposes to codify at 42 C.F.R. § 414.1255(b) that, beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated for all groups and solo practitioners that meet the minimum number of cases for that measure.¹¹⁹ BIO supports this policy, which will help ensure that only the data for those measures that are considered statistically reliable are included in the benchmarks, as with the cost and quality metrics.

We further support CMS's continued use of the specialty adjustment method finalized in the CY 2014 MPFS Final Rule.¹²⁰ We would like to reiterate our concern, however, that the specialty adjustment does not account for subspecialty practice differences to the extent that a given specialty or subspecialty lacks a Medicare specialty code. Yet these subspecialties may have substantial differences with respect to patient case mix and resource use. We therefore urge CMS to ensure there are adequate specialty codes. Moreover, as noted in the CY 2014 MPFS Final Rule, CMS should "explore ways to explain to sub-specialists the process that [the Agency has] in place to obtain a new or keep their CMS specialty designation current."¹²¹

M. BIO urges CMS to consider replacing the CMS-HCC as the risk-adjustment methodology under the VM.

CMS notes in the Proposed Rule that "stakeholders have suggested that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries." CMS "agree[s] that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and are outside of the control of the provider." However, CMS "continue[s] to believe that [the Agency's] current methodology of using HCC scores that include adjustments for Medicare and Medicaid eligibility status in addition to diagnoses, and replacing the highest 1 percent of costs with the cost of the 99th percentile for the highest cost beneficiaries, help address these concerns" together with the specialty adjustment to all cost measures.¹²² Nonetheless, CMS is considering an option to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles.

BIO echoes other stakeholder concerns with respect to the CMS-HCC risk-adjustment methodology, which is designed to predict future spending, rather than predicting current patient needs. Indeed, weights for health conditions are based on factors that affect regression-based predictions of actual spending (e.g., increased utilization unrelated to health status), as opposed to changes in clinical evidence regarding patient care. In addition, the CMS-HCC system explicitly gives zero weight to many acute conditions that, while not necessarily "predictive," are likely to result in a need for expensive services, both in the year in which they occurred and potentially in subsequent years. Moreover, the CMS-HCC is a prospective (rather than concurrent) model, meaning that health problems in the

¹¹⁹ 80 Fed. Reg. at 41,908.

¹²⁰ 78 Fed. Reg. 74,230, 74,783 (Dec. 10, 2013).

¹²¹ *Id.* at 78,784.

¹²² 80 Fed. Reg. at 41,908.

current year are ignored, resulting in risk scores that tend to over- or under-predict costs in the payment year versus the performance year used to calculate risk scores. For these and other reasons, the Medicare Payment Advisory Commission (MedPAC) has found that the HCC model explains only 11 percent of the variation in costs—only half of the variability thought to be predictable.¹²³

Moreover, according to CMS's recent report on the VM,¹²⁴ a greater proportion of the physician groups with the sickest patients received a negative adjustment compared to groups with the healthiest patients, underscoring that the VM's current risk adjustment may not be sufficient. Indeed, among the quartile of physician groups with highest average beneficiary risk, all received either no or a negative adjustment (none received an upward payment adjustment, 31% received a downward, and 69% received a neutral payment adjustment). Among the quartile with lowest risk, the majority (92%) received either a positive or no adjustment (22% received an upward adjustment, 70% neutral, and 7% downward adjustment). The average CMS-HCC risk score among groups receiving an upward adjustment was 1.02 vs 1.38 for groups receiving a downward payment adjustment.

Thus, while we believe that CMS's proposal may address some of BIO's concerns with respect to benchmarking, it is not clear that this proposal will resolve the underlying issues with the VM's risk-adjustment methodology. We therefore urge CMS to evaluate the potential for replacing the CMS-HCC entirely for purposes of the VM, and to consider either using a concurrent risk-adjustment model, or a model that uses at least two years of diagnoses (rather than just one) to identify beneficiary's conditions for this purpose.

N. Episode Costs and the Supplemental QRURs.

Section 1848(n)(9)(A) of the SSA requires CMS to develop an episode grouper and include episode-based costs in the QRURs. CMS continues to seek stakeholder feedback as the Agency develops the episode framework.

In response to this request for feedback, BIO recommends that all communication with providers, including QRURs, with respect to the episode grouper be clear and distinct from the existing VM QRURs, since the episode grouper is still in development and could be confusing to providers who already have been having difficulty understanding their QRURs.

In addition, we would like to take this opportunity to articulate some of our concerns with respect to the VM's use of QRURs more generally. Specifically, the performance information in QRURs and Supplemental QRURs could have serious unintended consequences for providers, as well as patient access to care. 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. In addition, many providers have not even received QRURs to date, making it impossible for them to take actionable steps to improve their performance under the VM. To illustrate, the 2012 QRUR

¹²³ MedPAC, Issues for Risk Adjustment in Medicare Advantage (June 2012), http://www.medpac.gov/chapters/Jun12_Ch04.pdf.

¹²⁴ CMS, 2015 Value-Based Payment Modifier Program Experience Report (June 16, 2015).

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. Of these groups 99 percent (2,894) had insufficient or no attributed Medicare fee-for-service beneficiaries.¹²⁵ We strongly urge CMS to take steps to ensure that providers are receiving information regarding their performance that is useful to them, including by conducting a survey of Medicare providers with respect to their receipt, comprehension, and use of QRUR reports.

XV. Conclusion

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to critical drug and biological therapies. Please contact me at (202) 962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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¹²⁵ 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