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BY ELECTRONIC DELIVERY

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule [CMS-1612-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule regarding payment policies under the physician fee schedule (PFS), clinical laboratory fee schedule, and other revisions to Part B for calendar year (CY) 2015 (the "Proposed Rule").¹ BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new vaccines and 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. To that end, BIO is greatly concerned that physicians once again face a substantial, negative update to the conversion factor after March 31, 2015. This cut in physician payment rates, in addition to payment reductions due to sequestration, simply cannot be implemented without dire consequences for patient care. We agree with CMS that a long-term solution to avert future negative updates is critical,² and we urge CMS to work with Congress to reform the methodology. Until such reform is enacted, CMS should do anything in its power to mitigate these cuts and ensure that Medicare beneficiaries continue to have access to high quality care in 2015 and beyond.

¹ 79 Fed. Reg. 40,318 (July 11, 2014).

² *Id.* at 40,522.

With the goal of ensuring patient access to necessary vaccines, treatments, and therapies, our comments also:

- Urge CMS to continue to work with stakeholders to set rates under the PFS based on high-quality data specific to services provided within that system rather than substituting data from other systems;
- Support CMS's effort to understand the trend toward hospital-based physician practices, but urge CMS to ensure that the proposed approach is broad enough to capture the full extent of this trend;
- Urge CMS, in reviewing potentially misvalued codes under the PFS, to ensure that adequate reimbursement is provided for all physician services based on the actual time, work, and cost that physicians incur;
- Strongly support the proposal to adopt values for new, revised, and potentially misvalued codes through full notice-and-comment rulemaking prior to the values becoming effective;
- Support CMS's creation and continued development of a G-code for provision of chronic care management (CCM) services;
- Support the proposal to revise the definition of "colorectal cancer screening tests" to include medically appropriate anesthesia separately furnished in conjunction with a screening colonoscopy;
- Ask CMS to implement section 216 of the Protecting Access to Medicare Act (PAMA) in a manner that takes full account of the factors behind variation in Clinical Laboratory Fee Schedule (CLFS) payment rates and the costs of developing innovative diagnostic tests;
- Support the proposed data collection for purposes of the Center for Medicare and Medicaid Innovation (CMMI) models, but urge CMS to adopt safeguards against inappropriate use or disclosure of patient data;
- Urge CMS to ensure that the local coverage determination (LCD) process for clinical diagnostic laboratory tests allows for sufficient stakeholder input, including adequate time to submit comments and opportunity to participate in public meetings, as well as timely notice of decisions;
- Encourage CMS to retain the Open Payments program's continuing medical education (CME) exception or revise the indirect payment exception to clearly exclude payments where the manufacturer does not select or influence individual recipients, even with actual knowledge of the recipient;
- Urge CMS to retain current language allowing manufacturers to report up to five related products and refrain from extending the marketed name reporting requirements to non-covered drugs under the Open Payments program;
- Support CMS's proposals to expand the information available on Physician Compare and encourage CMS to provide the information in a streamlined manner with access to further detail on the information provided;
- Support CMS's proposal to include several important cross-cutting measures in the Physician Quality Reporting System (PQRS) measures set for 2015 and beyond, including three existing immunization measures, and encourage CMS to consider future inclusion of adult immunization measures recommended in a recent report from the National Quality Forum (NQF);

- Support the proposed inclusion of a new adolescent immunization measure in the PQRS measure set for 2015 and beyond, and urge CMS to also add additional measures for pneumococcal immunization and nephropathy screening;
- Support the inclusion of immunization and asthma-control measures in various PQRS measures groups, and request that CMS reconsider removal of the Age-Related Macular Degeneration (AMD) and lipid-control measures, as well as the Chronic Obstructive Pulmonary Disease (COPD) measures group from the PQRS measures set;
- Continue to support implementation of the new Qualified Clinical Data Registry (QCDR) reporting mechanism, subject to those registries meeting important standards of transparency and flexibility;
- Support CMS's continued refinement of the Medicare Shared Savings Program (MSSP), including the proposed provision of bonus points for improvement over time, but caution against overreliance on certain outcomes measures or inappropriate alignment with other quality programs;
- Commend CMS for its continued engagement with stakeholders in implementing the Value-Based Payment Modifier (VM) under the PFS, but urge CMS to ensure that the modifier reflects meaningful differences in cost and quality performance and incentivizes high-quality patient care over the long term, including through the appropriate use of drugs and biologicals; and
- Strongly urge CMS to refrain from using the total per capita cost measure for purposes of the VM until concerns raised by NQF have been addressed and the NQF endorses the measure.

I. Using Medicare Hospital Outpatient Data in Developing PFS Rates – BIO urges CMS to continue to work with industry and other stakeholders to set rates under each of the Medicare payment systems, including the PFS, based on high-quality data specific to services provided within that system, rather than substituting potentially flawed data from another system.

The Proposed Rule explains that CMS is exploring ways to exercise its authority under section 220 of PAMA, which permits CMS to use alternative approaches to establish practice expense (PE) relative value units (RVUs), including using data from other suppliers and providers of services. In particular, CMS seeks comment on the possible uses of Medicare hospital outpatient cost data in potential revisions to the PFS PE methodology.³

Similar to many other stakeholders, BIO is concerned about the possibility of using hospital outpatient cost data in developing PE RVUs under the PFS. As we noted in our comments on the CY 2014 proposed rule—which proposed a specific cap on certain PFS payments based on Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) rates—there are several reasons that hospital outpatient data are inappropriate for use in determining PFS payment rates. To begin with, as CMS notes, OPPS rates are grouped into rates that reflect a range of services, while PFS rates reflect a single item or service. Moreover, the data used to calculate annual OPPS payment

³ Id. at 40,322.

rates represent a different set of costs than the PE inputs used to calculate RVUs under the PFS. In addition, as CMS has recognized, the standard methodology for estimating hospitals' costs associated with providing drugs and biologicals to Medicare beneficiaries under the OPFS is susceptible to instability and errors. BIO urges CMS to work with stakeholders to improve the quality of the data available for rate-setting under the PFS and not to substitute unsuitable and potentially flawed data from other payment systems.

II. New Modifier to Track Services Furnished in Off-Campus Provider-Based Outpatient Departments – BIO applauds CMS's effort to understand the trend toward hospital-based physician practices but urges CMS to ensure that its proposed approach is broad enough to capture the full extent and effects of this trend.

In the Proposed Rule, CMS notes the recent and growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, which can substantially affect payment under the PFS as well as beneficiary cost-sharing for services provided at those locations.⁴ The Proposed Rule reiterates CMS's interest in understanding the extent of this trend toward hospital-based physician practices and how it is affecting Medicare. To that end, CMS proposes to create a Healthcare Common Procedure Coding System (HCPCS) modifier to be reported with every code for a physician or hospital service furnished in an off-campus provider-based department of a hospital.⁵

BIO applauds CMS's recognition of the growing trend toward hospital-based physician practices and the significant impact that this trend has on patients, both in terms of where and from whom they receive care, as well as the impact on their out-of-pocket costs. For example, an April 2014 report from the Berkeley Research Group (BRG)⁶ found that hospital acquisition of physician-based oncology practices increased significantly between 2009 and 2012 and resulted in a large shift of drug purchases from the physician setting to the hospital setting, with considerable implications for how those drugs are reimbursed. We agree that CMS needs a mechanism to track the extent of the shift toward hospital-based physician practices and that a HCPCS modifier would be a useful way to track this trend.

BIO believes that CMS should make two minor adjustments to its proposed approach, however. First, the proposal does not appear to track utilization prior to the acquisition of a physician-based practice; therefore, to the extent the physician-based practice changed its National Provider Identifier (NPI) as a result of its acquisition by a hospital, there would be no way to link the prior physician practice to the new hospital-based practice. Accordingly, we would urge CMS to employ additional tools to facilitate making such linkages, such as a requirement that hospitals register each practice acquisition, including the NPI of the acquired entity both pre- and post-acquisition. CMS could also consider modifying the existing Place-of-Service (POS) codes to seek more

⁴ *Id.* at 40,333.

⁵ *Id.* at 40,334.

⁶ Berkeley Research Group, *340B Covered Entity Acquisitions of Physician-Based Oncology Practices* (Apr. 22, 2014). Available at: <http://www.brg-expert.com/publications-vandervelde-340B-oncology.html>.

granularity than currently available.⁷ For instance, CMS could modify current POS code 22 (Outpatient Hospital) to allow the Agency to capture information on such entities as clinics, chemotherapy infusion centers, and other locations that furnish services like those furnished in physicians' offices.

Second, BIO is concerned that CMS's proposal to limit applicability of the proposed modifier to "provider-based" departments may not fully capture the extent and effects of the shift to hospital-based physician practices. BRG's research indicates that hospitals are acquiring physician-based practices that do not meet the definition of "provider-based," for example, because they are located more than 30 miles from the parent hospital. We further understand that these child sites nonetheless are included on hospital cost reports because they are subsequently registered as child sites of the hospital in the 340B covered entity database, and it is the Health Resources and Services Administration's (HRSA's) policy that a site must be included on the parent hospital's most recent Medicare cost report in order to be listed as a child site for purposes of 340B. CMS should therefore require use of the modifier by all physician practices included on Medicare cost reports filed by hospitals, regardless of whether the practice meets the definition of "provider-based."

Once CMS has developed a suitable mechanism for tracking practice acquisitions, BIO recommends that CMS gather and analyze information on the types of hospitals that are driving this trend to determine if common characteristics exist that would help to explain those hospitals' rationales and incentives and to assess the effect of these changes on the quality and cost of care for patients receiving physician-administered drugs for chronic diseases and serious illnesses, such as cancer. Moreover, we urge CMS to use information obtained through the proposed HCPCS modifier to compare the quality of services provided across settings. CMS currently collects significant amounts of quality data⁸ that, if combined with the HCPCS modifier, would help reveal whether there are meaningful differences in quality of care that relate to whether a practice is part of a hospital or remains community-based. For these purposes, the agency should consider developing cross-setting quality measures to derive an "apples to apples" comparison of the quality of care furnished across these practice sites.⁹ For example, certain PQRS measures could already be applicable across settings and could be used in such a comparative quality reporting system,¹⁰ while other measures could be modified or developed through a collaborative stakeholder feedback process.

⁷ Current POS codes include, for example: 11 – Office (Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.); and 22 – Outpatient Hospital (A portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.)

⁸ For example, the Physician Quality Reporting System ("PQRS"), the Hospital Outpatient Quality Data Reporting Program ("OQR"), the Medicare Shared Savings Program ("MSSP"), and the Physician Value-Based Modifier ("VBM") program.

⁹ The Secretary has the authority to do so pursuant to Social Security Act (SSA) § 1833(t)(17)(C)(1) ("The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties . . .").

¹⁰ See, e.g., Oncology: Medical and Radiation – Plan of Care for Pain. Measure #133 (NQF 0383) ("Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.").

III. Evaluation of Potentially Misvalued Codes – BIO urges CMS, in reviewing potentially misvalued codes under the PFS, to ensure that adequate reimbursement is provided for all physician services based on the actual time, work, and cost that physicians incur.

Under section 1848(c)(2)(K) of the Social Security Act (SSA), CMS is required to identify potentially misvalued HCPCS codes periodically using criteria specified by statute and to review and make appropriate adjustments to the relative values used to calculate payment for those services under the PFS. Section 220(c) of PAMA added nine additional criteria for CMS to use in identifying potentially misvalued codes. In the Proposed Rule, CMS again proposes to evaluate a number of HCPCS codes as potentially misvalued. CMS proposes to use a subset of one of the new statutory categories – “codes that account for the majority of spending under the physician fee schedule” – to identify approximately 65 codes as potentially misvalued, including some drug administration procedures.¹¹ CMS also proposes to evaluate a number of other individual codes as potentially misvalued for a variety of reasons.¹²

As an initial matter, we urge CMS to refrain from finalizing any revaluations of these codes until CMS finalizes the revised procedure for valuing new, revised, and potentially misvalued codes, described below. Moreover, in line with BIO’s comments on CMS’s assessment of potentially misvalued codes in previous rulemakings, we continue to urge CMS to reimburse each physician service 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.

IV. New Procedures for Valuing New, Revised, and Potentially Misvalued Codes – BIO strongly supports the proposal to adopt values for new, revised, and potentially misvalued codes through full notice-and-comment rulemaking prior to the values becoming effective.

CMS proposes to revise the process for valuing new, revised, and potentially misvalued codes so that proposed changes to the codes and code valuations are announced in a proposed rule and are subject to full notice-and-comment rulemaking prior to becoming effective.¹³ Under the proposed policy, CMS would announce most proposed values for new, revised, and potentially misvalued codes in the PFS proposed rules, beginning in CY 2016. If CMS does not receive the recommendation of the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) by January 15th of a given year, CMS would delay changing the valuation of the code for one year (or until the first year that CMS receives the RUC recommendation for the code by January 15th) and then include the

¹¹ 79 Fed. Reg. at 40,335.

¹² Id.

¹³ Id. at 40,363.

proposed values for the code in the following year's proposed rule. In the interim, CMS proposes to "adopt coding policies and payment rates that conform, to the extent possible, to the policies and rates in place for the previous year."¹⁴ As a result, CMS would "include proposed values prior to using the new code (in the case of new or revised codes) or revising the value (in the case of potentially misvalued codes)."¹⁵ CMS also proposes to establish interim rates for codes that describe wholly new services (as opposed to new or revised codes for services already included in the PFS).

BIO strongly supports the proposed revisions to the process for valuing new, revised, and potentially misvalued codes and believes this would represent a significant improvement over the current process. Currently, the results of coding reviews are announced in a final rule, meaning that the public cannot meaningfully comment on the proposed changes before they become effective. As CMS notes in the Proposed Rule, even in instances where the relevant medical specialties are aware that a particular code is under review by the RUC, they may not be "specifically aware of how those changes would affect the values and payment rate."¹⁶

We also support CMS's proposal to establish interim rates for wholly new services. Timely adoption of adequate reimbursement rates for codes that describe new items and services is particularly critical for ensuring uptake of innovative new therapies and treatments. Nonetheless, we strongly urge CMS to provide as much detail regarding a code's proposed reimbursement rate in the proposed rule, even for codes that describe wholly new services. Furthermore, for the reasons cited above, we would urge CMS to follow the same proposed full public comment process with respect to these codes during the first year that the Agency has the applicable RUC recommendation by January 15th. We also encourage CMS to strongly urge the RUC to schedule their meetings and reviews in a manner that ensures that CMS will get the information it needs well in advance of this deadline.

In the Proposed Rule, CMS also notes that it has been increasing the level of scrutiny that it gives to the recommended code valuations it receives from the AMA RUC. BIO supports this increased scrutiny. As CMS notes, the Agency's own review of the RUC recommendations has "increasingly found cause to modify the values recommended by the RUC in establishing interim final values under the PFS."¹⁷ Although we understand that the RUC is a valuable source of information in establishing values for services under the PFS, CMS should be the ultimate arbiter of code valuations and should do what is necessary to ensure Medicare beneficiary access to important services.

¹⁴ Id.

¹⁵ Id. (emphasis added).

¹⁶ Id. at 40,361.

¹⁷ Id.

V. Complex Chronic Care Management (CCM) Services – BIO continues to support CMS’s creation and development of a G-code for the provision of CCM services.

In the final rule for CY 2014, CMS adopted a new G-code to describe provision of complex CCM services under certain circumstances.¹⁸ In this year’s Proposed Rule, CMS proposes new RVUs for the G-code and refines the scope of and restrictions on billing for CCM services under it.¹⁹ The Proposed Rule also would add to the existing scope of service requirements a requirement that CCM services must be furnished with the use of certified electronic health record technology and an electronic care plan accessible to all providers in the practice.²⁰

In last year’s comments, BIO supported creation of the G-code for CCM services because we agree with CMS that care management is “one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth.”²¹ We continue 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 proposed inclusion of a new scope of service requirement for electronic health records and care planning capabilities. 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.

We also urge CMS to consider including comprehensive medication management (CMM) within the scope of services covered under the new G-code for CCM services. 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 are appropriate for the patient, effective for the condition being treated, safe given the patient’s health and other medications being taken, and able to be taken by the patient as intended.²² A growing body of evidence demonstrates the potential for CMM to maximize the benefits of appropriate medication use.²³

¹⁸ 78 Fed. Reg. 74,230, 74,414-23 (Dec. 10, 2013).

¹⁹ 79 Fed. Reg. at 40,364.

²⁰ *Id.* at 40,367.

²¹ *Id.* at 40,364.

²² 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>.

²³ 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. Assoc. 203-14 (2008).

VI. Revised Definition of “Colorectal Cancer Screening Tests” – BIO supports CMS’s proposal to revise the definition of “colorectal cancer screening tests” to include medically appropriate anesthesia separately furnished in conjunction with a screening colonoscopy.

CMS proposes to revise the applicable definition of “colorectal cancer screening tests” at 42 C.F.R. § 410.37(a)(1) to include anesthesia that is separately furnished in conjunction with screening colonoscopies, as this has become a prevalent practice in the United States.²⁴ BIO supports this proposal and believes it will expand access to screening colonoscopies by ensuring that beneficiaries will not be charged cost-sharing for medically appropriate anesthesia services that are furnished in conjunction with screening colonoscopies. Congress recognized the potential for patient cost-sharing to present a barrier to access in adopting section 4104 of the Affordable Care Act (ACA), which waives the deductible and coinsurance for important preventive services such as screening colonoscopies. Without the proposed change to the regulations, however, beneficiaries who receive medically appropriate covered anesthesia services from a different professional than the one furnishing the colonoscopy would incur costs for any coinsurance and unmet deductible for this component of the service. As CMS notes, if adopted, this proposal “will encourage more beneficiaries to obtain a screening colonoscopy, which is consistent with the intent of the statutory provision to waive Medicare cost-sharing for certain recommended preventive services, and is consistent with the authority delegated to the Secretary in section 1861(pp)(1)(D) of the Act.”²⁵ We encourage CMS to clarify that this change should not be construed to impact established local coverage decisions on monitored anesthesia services.

VII. Changes to the CLFS – BIO urges CMS to implement section 216 of PAMA in a manner that takes full account of the factors behind variation in CLFS payment rates and the costs of developing innovative diagnostic tests.

In the Proposed Rule, CMS notes that section 216 of PAMA requires the Agency to implement a new Medicare payment system for clinical diagnostic tests based on private payor rates and rescinds the statutory authority for adjustments based on technological changes for tests furnished on or after PAMA’s effective date of April 1, 2014. As a result, CMS is not proposing any revisions to payment for CLFS codes based on technological changes and proposes to remove the regulatory provision that it finalized prior to PAMA’s enactment that outlines the process by which CMS would reexamine possible payment revisions based on such technological changes. Instead, CMS proposes to implement section 216 of PAMA through separate rulemaking that would establish the parameters for collection of private payor rate information and other requirements necessary to implement the statute.²⁶

BIO urges CMS, in issuing future rules to implement section 216 of PAMA, to ensure that CMS is collecting data that enables the Agency to take into account the factors behind

²⁴ 79 Fed. Reg. at 40,369.

²⁵ *Id.*

²⁶ *Id.* at 40,376.

variation in reimbursement rates for clinical diagnostic tests (e.g., due to regional variations in cost), as well as the costs associated with developing innovative diagnostic tests, and the value these tests provide to the management of patients. In gathering data to implement this section, CMS also should be sure not to exclude too many laboratories through creation of a low-volume or low-expenditure threshold, so that CMS collects data from a broad array of laboratories, including smaller laboratories that provide critical services on behalf of Medicare beneficiaries. We look forward to working with CMS on this future rulemaking.

VIII. Access to Identifiable Data for the CMMI Models – BIO supports the proposed data collection for CMMI, but urges CMS to adopt safeguards against inappropriate use or disclosure of patient data.

In the Proposed Rule, CMS proposes to collect certain individually identifiable health information necessary for CMMI to carry out assessments of certain innovative payment and service delivery models.²⁷ Among other reasons, this information is needed to enable CMMI to construct “control groups against which model performance can be compared” and “to determine whether the observed impacts are due to the model being tested and not due to differences between the intervention and comparison groups.”²⁸

BIO is encouraged that CMMI aims to thoroughly assess its demonstrations and generally supports the proposed data collection, as the construction of control groups and assessment of impacts are both standard practices in the evaluation of any intervention. We urge CMS to adopt all available safeguards to ensure that these data are protected from inappropriate use or disclosure, however. Specifically, we urge CMS to ensure that beneficiaries are notified of the data collection and have the opportunity to opt out of having their data provided to CMS. This opt-out should apply to CMMI demonstrations that happened in the past, as well as to current and future demonstrations. We also urge CMS to refrain from using these data for purposes other than those articulated in the Proposed Rule. Finally, the proposed assessments should comply with the applicable statutory requirements, meaning that: (1) the assessments should take into account all of the factors outlined under section 1115A(b)(4) of the SSA (i.e., quality of care, including patient-level outcomes and patient-centeredness criteria); (2) the assessments should be made publicly available; and (3) CMMI should pursue notice-and-comment rulemaking before any of the CMMI demonstrations are expanded based on these assessments, as required by section 1115A(c) of the Act.

IX. LCD Process for Clinical Diagnostic Laboratory Tests – BIO urges CMS to ensure that the LCD process for clinical diagnostic laboratory tests allows for sufficient stakeholder input, including adequate time to submit comments and opportunity to participate in public meetings, as well as timely notice of decisions.

In the Proposed Rule, CMS notes that section 216 of PAMA requires all coverage policies for clinical diagnostic laboratory tests to be made “in accordance with the process

²⁷ Id.

²⁸ Id.

for making a local coverage determination.”²⁹ Accordingly, CMS proposes to establish a specific process that Medicare Administrative Contractors (MACs) must follow when developing clinical diagnostic laboratory test LCDs that would apply to all new clinical diagnostic laboratory test draft LCDs issued on or after January 1, 2015.³⁰ The proposed process mirrors the current LCD process with the following modifications: (1) the public comment period would be shortened to a minimum of 30 days; (2) the Carrier Advisory Committee (CAC) meeting would be optional, at the discretion of the MAC, and there would be no public comment period; (3) the MAC would publish the final LCD 45 days after the close of the public comment period; and (4) the LCD would become effective immediately upon the date of publication.

BIO is deeply concerned that the proposed LCD process for clinical diagnostic laboratory tests will not provide sufficient opportunity for stakeholder input. Section 216 of PAMA gives CMS the discretion to move to a system in which one to four regional administrative contractors would be designated to establish LCDs for clinical diagnostic laboratory tests. Although BIO is not opposed to the consolidation of contractors for the purpose of administering coverage and payment for diagnostic laboratory tests, we are concerned that this consolidation could create a system that in essence is a national coverage decision but that lacks an appropriate process to ensure transparency, accountability, and stakeholder input. This is inconsistent with the Agency’s recent statements that it intends to bring greater uniformity, transparency, and engagement with stakeholders to the process.

Although we appreciate that CMS and its contractors are challenged by the large volume of tests that must be evaluated, we urge CMS to make the following revisions to its proposed process. First, we urge CMS to retain the 45-day public comment period. The additional 15 days are important for stakeholders to be able to provide meaningful input and would not slow the LCD development process in any meaningful way. Second, individual stakeholders should be able to request CAC meetings in addition to the MACs making this determination. CMS should also articulate criteria that MACs must consider in deciding whether or not to host a CAC meeting on a given topic, and these criteria should be released for public comment before they are finalized. When CAC meetings are not held, stakeholders should be given other opportunities to meet with the MAC and share input about the coverage policy under consideration. Finally, we believe that the notice period is an important component of the LCD process. This notice period provides time for test developers and laboratories to adjust their billing advice or practices. We therefore recommend that CMS maintain a notice period for finalized LCDs. We urge CMS to make these changes in the final rule.

²⁹ Id. at 40,378.

³⁰ Id. at 40,379.

X. Revisions to the Open Payments Program

- A. BIO urges CMS to retain the CME exclusion or revise the indirect payment exception to clearly exclude payments where the manufacturer does not select or influence individual recipients, even with actual knowledge of the recipient.

With respect to the Open Payments program, under which certain manufacturers of covered products are required to report payments and other transfers of value to covered recipients, CMS proposes to remove the language at 42 C.F.R. § 403.904(g) stating that payments or transfers of value provided at a CME program need not be reported if three specific conditions are met.³¹ The Proposed Rule notes that this proposal was motivated in part by CMS's view that the CME-specific exclusion is "redundant with the exclusion in § 403.904(i)(1)" — the "indirect payment exclusion" — which excludes indirect payments or transfers of value from reporting if the applicable manufacturer is "unaware" of (i.e., "does not know") the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.³²

BIO supports CMS's continued recognition that payments for CME programs should be excluded from the otherwise applicable reporting obligations. These programs provide important opportunities for physicians to further their medical education, and the absence of such an exclusion could reduce educational opportunities for physicians, potentially limiting their exposure to new practices and advancements in patient care. That said, we also acknowledge that CMS has concerns that the existing regulatory text of § 403.904(g)(1)(i) may give the appearance that CMS endorses or supports specific organizations. We further appreciate CMS's stated intention and apparent belief that the indirect exclusion is redundant with the current CME exclusion, rendering the CME exclusion unnecessary. This is a clear statement of CMS's continued support for the principle of the CME exclusion.

We are concerned, however, that the indirect payment exclusion, as reflected in the regulatory text itself, is not, in fact, redundant with the CME-specific exclusion that CMS proposes to eliminate. Reliance, on the indirect payments exclusion could therefore achieve the opposite result from what CMS intends, as it likely would require the reporting of most applicable manufacturer provision of funds to a CME provider. This is because the indirect payment exclusion's knowledge standard, and the extended time period for such knowledge, makes this exclusion very difficult to apply to CME funding in practice.

To illustrate, a manufacturer providing funding support typically would have no role in selecting or directing choice of physician speakers for accredited CME events, consistent with CME accreditation standards as well as the OIG compliance guidance for pharmaceutical manufacturers. CMS appears to intend that such payments appropriately are excluded from reporting, given the Agency's stated intent to exclude payments "[w]hen an applicable manufacturer or applicable [group purchasing organization] GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set

³¹ Id. at 40,383.

³² Id. at 40,384.

of covered recipients to be considered as speakers for the continuing education program.”³³ However, CME providers routinely publicize names of speakers for their programs once they are selected, as part of their efforts to attract attendees for the program. Such names may appear in brochures, online publicity, or other means. It is highly likely, therefore, that in practice an applicable manufacturer’s employees will at some point become aware of the identity of those speakers chosen by the CME provider, and it is also highly likely that this awareness will occur within the specified time period for such knowledge (i.e., by the end of the second quarter of the following reporting year). This would occur even if, at the time of deciding to fund a CME program via its grant making process, the grant committee or other relevant decision makers at the manufacturer had no awareness of the CME provider’s planned speakers and, more importantly, the applicable manufacturer had no role in the CME provider’s selection of speakers.

As written, however, the indirect payment exclusion could be read to require the reporting of indirect transfers of value, where an applicable manufacturer’s employee *eventually* learns of the recipient’s identity, even if the manufacturer has no input whatsoever on the selection of the recipient. This would have the effect of either eliminating CME provider program publicity, or requiring the reporting of nearly all applicable manufacturer funding of CME. This is clearly not the intention of CMS, which, as noted in the Proposed Rule, intends merely to continue to exclude CME funding via a believed redundancy with the indirect payments exclusion without seeming to endorse particular CME accreditation bodies.

In addition, while CMS has reiterated in the preamble to the Proposed Rule that “if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments are outside the scope of the rule,” regardless of any eventual knowledge obtained by the manufacturer,³⁴ we believe this will be a very difficult standard to apply with sole reliance on the indirect payment exclusion. Specifically, it may be confusing to provide, as CMS now proposes, that a certain category of payments (i.e., payments that qualify for the current CME speaker payment exclusion) inherently qualifies for the indirect payment exclusion, notwithstanding the possibility that a manufacturer may become aware of the covered recipient’s identity during the applicable knowledge time period. For example, it is unclear whether CMS similarly would take the position that other types of indirect payments as to which the applicable manufacturer learns the covered recipient’s identity within the knowledge time period likewise would qualify for the indirect payment exclusion.

Moreover, the regulatory text of the indirect exclusion does not expressly recognize this special treatment of CME payments. As noted previously, BIO is concerned that if CMS eliminates the CME exclusion without modifying the indirect exclusion, as proposed, the net effect may be a reduction in received or allocated support for CME programs. Applicable manufacturers may request that CME providers eliminate the allocation of manufacturer CME funding to faculty fees, due to the difficulty in capturing or tracking the indirect transfer. Further, physicians may decline CME faculty positions to avoid the misperception that they are receiving payments or transfers of value from manufacturers for influential

³³ Id.

³⁴ Id. at 40,384 (citing 78 Fed. Reg. 9458, 9492 (Feb. 8, 2013)).

purposes, when in fact these funds are determined without knowing the identity of the CME faculty, and without influence on the faculty or content of the program.

Accordingly, in order to meet CMS's stated desires to continue to exclude from the Open Payments program manufacturer funding of CME providers that may indirectly transfer value to a CME program speaker, BIO urges CMS either to: (a) retain the CME-specific exclusion but replace the list of organizations in § 403.904(g)(1)(i) with articulated standards that would allow manufacturer funding support of a CME program to qualify for the exclusion if the applicable manufacturer did not influence the CME provider's choice of speaker(s), regardless whether the manufacturer later becomes aware of the identity of the faculty or speakers; or (b) revise the text of the indirect payment exclusion to explicitly exclude payments to CME providers when the manufacturer has no role in choosing or recommending the ultimate recipient of funds from that payment, regardless of whether the manufacturer's employees later become aware of the indirect recipient's identity.

To the extent that CMS pursues option (a), we ask CMS refer to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers,³⁵ the FDA's guidance on industry sponsorship of CME, and Codes of conduct or accreditation standards promulgated by the CME industry as useful starting points for making the recommended revision. We also recognize, as CMS has noted in the preamble to the Proposed Rule, that enforcement of accreditation standards could be difficult on an ad hoc basis, and to that end would suggest that CMS publish a list of organizations that it deems to meet the standards for the following calendar year, perhaps based on information that CMS requires the organizations to submit. If CMS does not pursue either our proposed option (a) or option (b) above, we ask that CMS retain the CME-specific exclusion as it currently stands, in order to preserve in the regulatory text CMS's intent to exclude such payments from reporting.

As a final note, BIO is concerned with the potential for the CMS proposal to be misinterpreted to affect the reporting of CME funding being used by CME providers to subsidize registration fees for all physicians attending a given CME event. In the final rule implementing the Open Payments program, CMS stated that it does "not intend to capture" within the Education reporting category, "the attendees at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer."³⁶ BIO is concerned that, by removing a reporting exclusion with specific reference to accredited CME events, CMS's current proposal may be misinterpreted as altering the reporting of registration fees for physician attendees at CME events as well. BIO therefore suggests it would be useful for CMS to confirm that changes made to the reporting exclusion for indirect manufacturer funding of CME faculty do not alter prior CMS statements on the treatment of CME attendees.

³⁵ 68 Fed. Reg. 23,731, 23,738 (May 5, 2003).

³⁶ 78 Fed. Reg. at 9481.

B. BIO urges CMS to retain current language allowing manufacturers to report up to five related products and refrain from extending the marketed name reporting requirements to non-covered drugs.

With respect to CMS's proposed revisions to the requirement to report related product names, BIO asks that CMS revise the proposed language to retain the current regulatory language allowing manufacturers to report "*up to five* covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value."³⁷ CMS does not explain why it proposes to remove this language. We note that it is often difficult for a manufacturer to establish a single related product for a given transfer of value, and we ask CMS to retain the language allowing manufacturers the flexibility to report up to five related products in such cases. As CMS previously correctly observed, "many financial relationships are not specific to one product only."³⁸

In addition, BIO is concerned with the impact to applicable manufacturers of expanding the reporting to include the marketed name for *non-covered* drugs. CMS, in its final regulations implementing the Open Payments program, provided some flexibility to manufacturers regarding how to report the marketed name for non-covered drugs. Thus, manufacturers likely have already interpreted and implemented these instructions differently depending on their products, processes, and systems capabilities, and therefore have built their reporting systems based on that flexibility. The resources and burden required should CMS change its existing policy on non-covered drugs could be significant, including the need to adopt new business processes and provide further employee training necessary to ensure compliance.

In addition to costs, CMS may not have considered that this proposal, if finalized, could have the unintended effect of disclosing proprietary or commercial information associated with pre-clinical or clinical research. Both Congress and the Agency put in place specific safeguards to avoid such disclosure; namely, eligibility for delayed publication up to four years. Manufacturers frequently conduct pre-clinical and early phase research without a name for the molecule, referring to the product by the project name or otherwise. Under CMS's proposal, manufacturers would apparently be required to establish a name for such a product. This could cause manufacturers additional patent, copyright, or trademark expenses. Moreover the new requirement to reveal names of non-covered products could expose information that does not now have to be revealed about products that have not matured past the pre-clinical stage, which could result in confidential information about a company's pipeline being revealed. For the reasons described above, we therefore strongly urge CMS to withdraw its proposal to report the marketed name for non-covered drugs and retain its existing requirements with respect to these products.

If CMS does not rescind its proposal, we ask the Agency to provide further rationale for requiring this change. While we acknowledge and understand CMS's interest in making reporting requirements consistent across product types, we do not believe that this reasoning alone justifies the significant investment that would be necessary for compliance. Furthermore, we believe this proposal is inconsistent with the intent of the

³⁷ 42 C.F.R. § 403.904(c)(8).

³⁸ 78 Fed. Reg. at 9474.

statute: as CMS itself acknowledged in the Open Payments Program final rule, requiring manufacturers to report the name of the associated non-covered products “may be misleading to consumers and would provide information that is beyond the goal of the statute.”³⁹ Finally, should CMS retain its proposal, we ask that CMS clarify the intended use of the “non-covered” field and provide additional guidance regarding the related changes to the reporting template so that manufacturers can further assess the impact and effort associated with this change. We ask that CMS create a workable framework to exempt the reporting of a product name associated with pre-clinical or early phase research, particularly when no Investigational New Drug Application (IND) has been filed with the Food and Drug Administration (FDA).

XI. Physician Compare Website – BIO supports CMS’s proposals to expand the information available on Physician Compare and encourages CMS to provide the information in a streamlined manner with access to further detail on the information provided.

The Proposed Rule describes several proposals to continue expansion of public reporting of physician data on the Physician Compare website. Notably, CMS is proposing to: (1) expand public reporting of group-level measures by making all 2015 Physician Quality Reporting System (PQRS) group practice reporting option (GPRO) measure sets across group reporting mechanisms available for public reporting on Physician Compare in CY 2016 for groups of two or more eligible professionals (EPs); (2) make all measures reported by MSSP Accountable Care Organizations (ACOs) available for public reporting on Physician Compare; (3) expand reporting by individual EPs; and (4) make available on Physician Compare 2015 Qualified Clinical Data Registry (QCDR) measure data collected at the individual level or aggregated to a higher level of the QCDR’s choosing. CMS also seeks comments on including specialty society measures on Physician Compare.

BIO believes that the Physician Compare website is an important means of providing consumers with quality-of-care information to help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. Accordingly, BIO supports the inclusion of data from all Medicare physicians and reporting mechanisms. We also support the inclusion of specialty care measures that will provide the opportunity for more EPs to have measures included on Physician Compare. Our comments on certain specific proposals with respect to Physician Compare are below.

A. BIO supports providing information on Physician Compare in a streamlined manner that also allows consumers to access further information, if desired.

CMS proposes to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file.⁴⁰ CMS proposes that not all of these measures would be included on the Physician Compare profile pages, however.

³⁹ Id.

⁴⁰ 79 Fed. Reg. at 40,385.

BIO supports providing information on Physician Compare in a manner that is informative, but does not overwhelm Medicare beneficiaries and other consumers. CMS's proposal appears to strike that balance by aiming to create profile pages that are streamlined and easy to understand, while affording consumers the option to download additional information. We further support the use of consumer and concept testing for purposes of designing these resources in a consumer-friendly manner. We are concerned, however, that the specific measures chosen for inclusion on the profile page — which are the most likely to inform medical decision-making — will be selected without input by a diverse group of stakeholders. Specifically, CMS proposes to reach out only to “stakeholders in the professional community, such as specialty societies, to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.”⁴¹ We urge CMS to consult a broader array of stakeholders, including both patients and manufacturers, for this purpose.

- B. BIO asks CMS to implement its proposal to create composite measures for group practices and individual EPs in a manner that does not place too much emphasis on a particular measure and allows consumers to access further information, if desired.

CMS seeks comment on its proposal to create composites using 2015 PQRS data and publishing composite scores in 2016 by grouping measures based on the PQRS GPRO measure groups, if technically feasible.⁴² For group practices, these composites include, but are not limited to: care coordination/patient safety (CARE) measures; coronary artery disease (CAD) disease module; diabetes mellitus (DM) disease module; and preventive (PREV) care measures. For individual practitioners, the composites include CAD; DM; general surgery; oncology; PREV; Rheumatoid Arthritis (RA); and Total Knee Replacement (TKR).

BIO supports providing information to consumers in a manner that is easy to understand. However, we urge CMS to ensure that grouping measures into composites does not have the unintended effect of over- or under-emphasizing performance on a particular measure. We also urge CMS to ensure that consumers retain the ability to obtain more comprehensive information about the measures within each composite measure, such as through the Physician Compare downloadable file.

- C. BIO asks CMS to implement its proposal to calculate and post benchmarks and quality scores on Physician Compare in a manner that provides sufficient context for consumers to understand the benchmarks and scores for a particular provider.

CMS proposes to calculate benchmarks based on PQRS GPRO data, using the same methodology currently used under the MSSP, and to report group practices' and individual EPs' performance against these benchmarks on Physician Compare in 2016.⁴³ For each measure, CMS would establish a benchmark and then develop a quality scoring points system that would award points based on the provider's actual performance on each measure. The total points earned for measures in each measure group would be summed

⁴¹ Id. at 40,389.

⁴² Id.

⁴³ Id.

and divided by the total points available for that measure group to produce an overall measure group score of the percentage of points earned versus available. The percentage score for each measure group would then be averaged together to generate a final overall quality score.

BIO supports providing consumers with information to more easily evaluate the data provided on Physician Compare. We urge CMS to provide appropriate context around the proposed benchmarks and quality scores, however. Specifically, Physician Compare should provide clear information about how the benchmarks and quality scores were calculated and any applicable limitations. Merely providing summary information without any context may ultimately be more misleading than helpful for consumers.

D. BIO supports CMS's proposal to publicly report patient experience data on Physician Compare, but urges CMS to exclude the problematic measure for "Stewardship of Patient Resources."

CMS proposes publicly reporting in CY 2016 patient experience data from 2015 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.⁴⁴

BIO supports this proposal, in particular CMS's proposal to include patient-reported information on "Access to Specialists," "Care Coordination," and "Helping You to Take Medication as Directed." We are concerned, however, about the proposed inclusion of the measure entitled "Stewardship of Patient Resources."⁴⁵ We note that the underlying question for this measure hinges on whether the "care team talked with you about cost of your prescription medicines." This question concerns us not only because we do not believe it is a physician's role to manage a patient's pocketbook, 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 from inclusion on the Physician Compare website. To the extent that CMS insists on including a measure of this nature, we urge CMS to consider including a measure that asks whether a physician had consulted with patients about all barriers the patient faces to access care, including patient education level, patient language barriers, distance traveled to receive care, patient work/family commitments, and inability to pay coinsurance.

⁴⁴ Id. at 40,390.

⁴⁵ Id.

XII. Physician Quality Reporting System – BIO appreciates CMS’s proposal to include several important cross-cutting and other quality measures; opposes the removal of the measures related to AMD, lipid control, and COPD; recommends the inclusion of certain additional quality measures; and continues to support implementation of the new qualified clinical data registry reporting mechanism subject to those registries meeting important standards for transparency and flexibility.

The Proposed Rule describes several proposals to continue expansion of reporting on quality measures under the PQRS. Our comments on some of the specific proposals follow.

A. BIO supports the inclusion of certain cross-cutting measures for 2015 and beyond.

Under the Proposed Rule, satisfactory reporting under the PQRS would require some EPs to report on one or more of cross-cutting measures. For this purpose, CMS proposes to include 18 new cross-cutting measures for 2015 and beyond.⁴⁶ BIO supports the inclusion of many of these measures.

First, BIO supports the inclusion of two NQF-endorsed medication-specific measures: “Documentation of Current Medications in the Medical Record” and “Medication Reconciliation.”⁴⁷ We also support the intention behind CMS’s proposal to replace “Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility” with “Documentation of Medications in the Medical Record” for purposes of the GPRO Reporting Option Web Interface beginning in 2015, as we agree with other commenters that Medication Reconciliation should be performed at all office visits and not just those occurring after an inpatient discharge.⁴⁸ However, as discussed in more detail in section XIII.A, below, we recommend that CMS retain the “Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility” measure for a defined period to ensure the “Documentation of Medications in the Medical Record” measure is able to adequately capture medication reconciliation during care transitions, as a physician visit does not always immediately follow a discharge from a hospital or rehabilitation facility. We further encourage CMS to include additional cross-cutting measures that specifically address medication adherence as part of care transitions and otherwise. BIO views the inclusion of these measures as critical given the important role that adherence to a medication protocol can have in reducing unnecessary care and expenditures.

Second, BIO supports the inclusion of cross-cutting measures that assess care coordination between specialists and other providers, including “Closing the Referral Loop: Receipt of a Specialist Report” (PQRS#374),⁴⁹ which we believe will encourage communication between specialists and other care providers, a critical component to ensure that patients receive appropriate, coordinated care. However, we urge CMS to obtain endorsement for this measure from the NQF or a similar consensus-based entity in order to support its continued inclusion in the PQRS. We also support the inclusion of the cross-

⁴⁶ Id. at 40,402-09.

⁴⁷ Id. at 40,405-06.

⁴⁸ Id. at 40,469.

⁴⁹ Id. at 40,406.

cutting measure entitled "CAHPS for PQRS Clinician/Group Survey" (NQF#0005&0006/PQRS#321) that enables patients to have a say in how their physician is rated.⁵⁰ As noted above, we are particularly supportive of the questions related to access to specialists, shared decision making, care coordination, and helping to take medication as directed. We reiterate our concerns, however, about the survey question related to stewardship of patient resources, articulated in Section XI.D, above.

Third, BIO supports the inclusion of three immunization-specific cross-cutting measures, namely:⁵¹

- Childhood Immunization Status (NQF#0038/PQRS#240)
- Preventive Care and Screening: Influenza Immunization (NQF#0041/PQRS#110)
- Pneumonia Vaccination Status for Older Adults (NQF#0043/PQRS#111)

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.⁵²

Beyond the three immunization measures proposed for inclusion in the PQRS cross-cutting measure set, BIO encourages CMS to consider the future inclusion of the adult immunization measures identified by the NQF in a recently published report titled, "Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations."⁵³ The details and rationale for the NQF report's measure development recommendations are discussed on pages 2-3 and in Table 1 of the report. Several of the priority areas for age-specific immunization and preventive services composite measure development are relevant for the Medicare population, including pertussis-containing and zoster vaccine measure development for adults of various ages, as well as outcomes-oriented composite measures that would include immunizations in a set of preventive services recommended by age and gender, and composites 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

⁵⁰ *Id.* at 40,408.

⁵¹ *Id.* at 40,404, 40,406-07.

⁵² 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).

⁵³ 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

diseases among the Medicare population, facilitate better management of individuals with chronic conditions, and therefore improve the health of the Medicare population.

Finally, BIO supports the inclusion of the cross-cutting measure entitled "Screening for Hepatitis C Virus (HCV) for Patients at High Risk,"⁵⁴ as well as two related, non-cross-cutting measures in the PQRS beginning in 2015: "Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users,"⁵⁵ and "Screening for Hepatitis C Virus (HCV) for Patients at High Risk."⁵⁶ Given the prevalence of HCV in the baby boomer population that is, or will soon become, eligible for Medicare, there are recognized public health benefits to proactively screening this population, as screening and earlier detection of infected persons will help to mitigate the projected burden of HCV-related chronic disease and its consequences. However, we urge the Agency to seek endorsement of these measures by NQF or a similar consensus-based entity to support their continued inclusion in the program.

B. BIO supports the proposed inclusion of one new immunization measure in the PQRS measure set for 2015 and beyond and urges CMS to consider inclusion of a pneumococcal immunization measure and a nephropathy screening measure.

BIO supports CMS's proposal to include one new immunization measure in the PQRS measure set for CY 2015 and beyond:⁵⁷

- Immunizations for Adolescents (NQF#1407)

As CMS notes in the preamble to the Proposed Rule, this measure complements existing childhood immunization measures already in the program. In addition to any catch-up childhood vaccines and an annual influenza vaccine, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommends that adolescents receive one dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine, two doses of meningococcal conjugate (MenACWY) vaccine, and three doses of human papillomavirus (HPV) vaccine. According to recent data reported by the CDC, vaccination coverage rates among adolescents continue to lag behind *Healthy People 2020* goals. In 2013, *Healthy People 2020* vaccination targets for adolescents aged 13–15 years were reached in 42 states for ≥1 Tdap dose and 18 states for ≥1 MenACWY dose. No state met the target for ≥3 HPV doses. Vaccination rates for HPV have been particularly low with only 57.3 percent of females and 34.6 percent of males receiving ≥1 HPV dose in 2013.⁵⁸

The inclusion of this measure in the PQRS will help ensure that adolescents receive all of the immunizations recommended for them by the ACIP and are therefore fully

⁵⁴ While this measure is not NQF-endorsed, as CMS notes, it is complementary of other Hepatitis C measures currently in the program and represents a clinical gap not currently captured in the PQRS. 79 Fed. Reg. at 40,409.

⁵⁵ While this measure is not NQF-endorsed, as CMS notes, this measure addresses a clinical gap in PQRS by targeting active injection drug users. *Id.* at 40,411.

⁵⁶ While this measure is not NQF-endorsed, as CMS notes, this measure is complementary of other Hepatitis C measures currently in the program and represents a clinical gap not currently captured. *Id.* at 40,417.

⁵⁷ *Id.* at 40,414-15.

⁵⁸ Centers for Disease Control and Prevention, *National, Regional, State and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 years—United States, 2013*, 63 Morb Mortal Wkly Rep. 625-33 (2014).

protected from vaccine-preventable infections and cancers. Further, since the ACIP recommends administration of all three age-appropriate vaccines during a single office visit, the inclusion of a composite measure rather than individual measures for each of the immunizations is the best approach. Physicians will be encouraged to administer all recommended vaccines to adolescents rather than select vaccines. BIO supports the inclusion of this measure in the PQRS and encourages CMS to finalize its proposal.

In addition to the adolescent immunization measure, BIO urges CMS to consider including the following measure in the PQRS set for CY 2015 and beyond:

- Pneumococcal Immunization (NQF#1653)

In the CY 2014 proposed rule, CMS considered including a pneumococcal immunization process measure (IMM-1c, Pneumococcal Immunization (PPV23) for High Risk Populations Age 5 through 64 years) in PQRS.⁵⁹ However, CMS did not finalize this proposal citing the fact that a similar pneumococcal immunization measure had been suspended from the Hospital Inpatient Quality Reporting System for FY 2014, as well as reports of difficulties implementing this measure in PQRS.⁶⁰ Specifically, CMS had stated that the measure should be removed from IQR due to “new guidelines on the administration of pneumococcal vaccination for various populations” released by the ACIP in October 2012.⁶¹

BIO opposed removal/suspension of the pneumococcal immunization measure from the PQRS and IQR programs, as did the Department of Health and Human Services (HHS’s) National Vaccine Advisory Committee (NVAC). On June 25, 2013, Dr. Howard Koh, Assistant Secretary for Health, transmitted to Administrator Tavenner the NVAC’s recommendation to retain the measure, as its removal would “drive down pneumococcal immunization rates.”⁶²

Vaccination is the primary method for preventing pneumococcal disease, and it can also prevent the need for antibiotic treatments and the subsequent spread of antibiotic resistance, a problem that has been recently identified by the White House as a priority.⁶³ Pneumococcal disease is common in adults and is associated with significant morbidity, mortality, and healthcare costs. Each year, approximately 175,000 people are hospitalized with pneumococcal pneumonia in the U.S., and these patients are at increased risk for concurrent cardiac events such as myocardial infarction, arrhythmia, or congestive heart failure.⁶⁴ In 2012, the total costs for Medicare beneficiaries during, and one year following, a pneumonia hospitalization were approximately \$15,682 higher than those patients without

⁵⁹ 78 Fed. Reg. 43,282, 43,427 (July 19, 2013).

⁶⁰ See 78 Fed. Reg. at 74,687.

⁶¹ 78 Fed. Reg. 27,486, 27,680 (May 10, 2013).

⁶² Letter from the National Vaccine Advisory Committee to Dr. Howard Koh, Assistant Secretary for Health (2013). Available at: <http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/nvac-memo-koh-2013.pdf>.

⁶³ The White House, Fiscal Year 2016 Budget Guidance for Combatting Antibiotic Resistant Bacteria Resource Priorities (July 18, 2014). Available at: <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2014/m-14-13.pdf> (“The President has stated that combatting antibiotic resistance bacteria (CARB) is an Administration priority and actionable recommendations to advance this priority are in development through the process established in Presidential Policy Directive-1.”).

⁶⁴ National Foundation for Infectious Diseases, *Pneumococcal Disease Call to Action* (2012). Available at: http://aahivm.org/Upload_Module/upload/Provider%20Resources/Pneumococcal%20CTA%20HCP%20Roles%20AAHIVM%20Partner.pdf.

pneumonia.⁶⁵ Despite the health and economic benefits, pneumococcal immunization rates are still suboptimal. In 2011, pneumococcal vaccination coverage among adults age 65 and older was only 62 percent, and among high-risk adults age 19-64, it was only 20 percent.⁶⁶ HHS' *Healthy People 2020* targets for these populations are 90 percent and 60 percent vaccination coverage, respectively.

During a meeting on August 13, 2014, the ACIP voted to recommend that naïve adults 65 and older receive the pneumococcal conjugate vaccine (PCV13) followed by the pneumococcal polysaccharide vaccine (PPSV23) to ensure the broadest protection against pneumococcal disease and the greatest health benefits. With this recommendation finalized, CMS' concerns about the guidelines should be allayed and implementation of a pneumococcal immunization measure should be feasible in all healthcare settings.

Further, the National Quality Forum (NQF) is currently considering a new version of measure #1653, of which CMS is the steward. The revised draft measure is still specific to the hospital setting and references the measure population as "inpatients." To fulfill CMS's goal of aligning measures throughout the reporting programs, the measure should be properly integrated so it is applicable across programs, healthcare settings, and patient populations. This will allow for more relevant application within the PQRS, in particular.

Given the significant public health and economic impact of pneumococcal disease, the continued opportunities for improvement in vaccination rates, and the ACIP's new recommendation, BIO strongly encourages CMS to consider updating and adding NQF 1653, Pneumococcal Immunization, to the PQRS measure set for CY 2015 and beyond.

In addition, BIO suggests that CMS add a measure to assess the percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy (NQF#0062) to the PQRS measures set. Diabetes mellitus is the leading cause of chronic kidney disease (CKD)—a growing global public health problem.⁶⁷ The rapidly increasing prevalence of diabetes worldwide—and in the Medicare population in particular—makes it particularly critical to assure that diabetes patients are assessed for their susceptibility of developing CKD as a comorbidity.

- C. BIO supports the inclusion of immunization and asthma-control measures in the PQRS measures groups for reporting in 2015 and beyond and urges CMS not to remove the existing PQRS measures for Age-Related Macular Degeneration (AMD) or lipid control, or the Chronic Obstructive Pulmonary Disease (COPD) measures group.

CMS proposes to include the following 11 immunization measures across various PQRS measures groups for reporting in 2015 and beyond and BIO strongly supports the inclusion of these measures:⁶⁸

⁶⁵ Thomas CP, Ryan M, Chapman JD, et al., *Incidence and Cost of Pneumonia in Medicare Beneficiaries*, 142 *Chest*. 973-81 (2012).

⁶⁶ Centers for Disease Control and Prevention, *Noninfluenza vaccination Coverage Among Adults – United States*, 2011, 63 *Morb Mortal Wkly Rep*. 66-72 (2013).

⁶⁷ Centers for Disease Control and Prevention, 2014 National Chronic Kidney Disease Fact Sheet, <http://www.cdc.gov/diabetes/pubs/factsheets/kidney.htm#2>.

⁶⁸ 79 Fed. Reg. at 40,458-66.

- Influenza Immunization (NQF#0041/PQRS#110) - Asthma Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Chronic Kidney Disease Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Diabetes Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Heart Failure Measures Group
- Hepatitis A Vaccination in Patients with Hepatitis C Virus (NQF#0399/PQRS#183) - Hepatitis C Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Inflammatory Bowel Disease (IBD) Measures Group
- Pneumonia Vaccination Status for Older Adults (NQF#0043/PQRS#111) - IBD Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Oncology Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Preventive Care Measures Group
- Pneumonia Vaccination Status for Older Adults (NQF#0043/PQRS#111) - Preventive Care Measures Group
- Influenza Immunization (NQF#0041/PQRS#110) - Rheumatoid Arthritis Measures Group

BIO also supports CMS's proposal to replace Assessment of Asthma Control: Ambulatory Care Setting (NQF#0001) with the measure Optimal Asthma Care, Control Component, as the latter is a superior clinical measure to assess patient control.⁶⁹ Heightened assessment of control and medication management is essential to improving patient outcomes and preventing hospitalizations. Indeed, uncontrolled asthma patients cost nearly \$3,500 more in direct medical costs than their counterparts who have well-controlled asthma.⁷⁰

BIO urges CMS to reconsider its proposed removal of certain measures, however. First, beginning in 2015, CMS proposes to remove the existing PQRS measure on AMD (NQF#0087/PQRS#0014) on the grounds that EPs are consistently meeting performance on this measure with performance rates close to 100 percent, suggesting that there is no gap in care. We believe this move is premature. First, we are concerned that there is a lack of access to ophthalmology care, and as the healthcare community works to reduce disparities in care, a provider's performance on this AMD measure will be a critical barometer of quality of care. Second, we do not believe performance on the existing measure means that there is no gap in care for AMD. It is not known how many retinal specialists are participating in the PQRS at the current time, so even a very high rate of performance on this measure may not reflect performance across the population of relevant specialists, as opposed to those who have reported. Meanwhile, two external factors will increase the rate of reporting: (1) the additional penalties for not reporting PQRS and the increased penalties under the VM; and (2) the American Academy of Ophthalmology's development of the Intelligent Research in Sight (IRISTM) registry to facilitate easier reporting for PQRS.⁷¹ We therefore urge CMS to

⁶⁹ *Id.* at 40,416.

⁷⁰ R.S. Zeiger, et al., *Asthma Costs and Utilization in a Managed Care Organization*, 121 J. of Allergy and Clin. Immunol. 885-92 (2008).

⁷¹ American Academy of Ophthalmology. *IRISTM Registry*, <http://www.aao.org/iris-registry/benefits.cfm>.

delay removal of the AMD measure at least until the performance rate of these additional reporters can be determined.

Second, CMS has also proposed the removal of two lipid control measures from the existing PQRS measure set:⁷²

- Hypertension: Low-Density Lipoprotein (LDL-C) Control (PQRS#301)
- Coronary Artery Disease (CAD): Lipid Control (NQF#0074/PQRS#197)

CMS has further proposed the removal of the CAD: Lipid Control measure (NQF#0074/PQRS#197/ACO#32) and two additional lipid-control measures from the PQRS GPRO Web Interface and the MSSP for ACOs:⁷³

- Diabetes: Low Density Lipoprotein (LDL-C) Control (<100 mg/dL) (NQF#0064/PQRS#2/ACO#23)
- Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (<100 mg/dL (NQF#0075/PQRS#0241/ACO#29).

While BIO understands the need to align measures with new guidelines for cholesterol management from the American Heart Association (AHA) and the American College of Cardiology (ACC), it is important to note that there are existing guidelines that are not aligned with the AHA/ACC recommendations, such as those of the American Academy of Clinical Endocrinologists (AACE).⁷⁴ Additionally, there are other specific sub-populations that are at the highest risk for cardiovascular events (e.g., persons with familial hypercholesterolemia⁷⁵), which are not adequately considered in the new guidelines.⁷⁶ Also, we are concerned that removal of some measures without proposed replacements will create gaps in the measure set. Without suitable replacement measures, it will be difficult to ensure that cholesterol management and prevention of subsequent cardiovascular events will be handled appropriately. Finally, current evidence from interventional, large epidemiologic, and human genetic studies provide strong evidence for the role of LDL-C in cardiovascular risk.⁷⁷ This evidence has supported the pursuit of clinical programs designed

⁷² 79 Fed. Reg. at 40,433, 40,436.

⁷³ *Id.* at 40,469-70.

⁷⁴ The current AACE guidelines for lipid management in diabetic patients continue to recommend LDL-C levels less than 100 mg/dL in high-risk patients and less than 70 mg/dL in very high-risk patients. Paul S. Jellinger, Donald A. Smith, Adi E. Mehta, et al., *Association of Clinical Endocrinologists' Guidelines for Management of Dyslipidemia and Prevention of Atherosclerosis*, 18 Endocr. Pract. S1-78 (2012). Available at: <https://www.aace.com/files/lipid-guidelines.pdf>. The AACE has also noted that "failure to set targets for treatment makes the degree of risk reduction produced in these groups unknowable and eliminates proper monitoring of management." *AACE Member Alert Letter* (Nov. 21, 2013).

⁷⁵ P.N. Hopkins, P.P. Toth, C.M. Ballantyne, D.J. Rader, *Familial Hypercholesterolemias: Prevalence, Genetics, Diagnosis and Screening Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia*, 5 J. Clin. Lipidol. S9-17 (2011).

⁷⁶ Recent Agency for Healthcare Research & Quality (AHRQ) comparative effectiveness research (CER) on lipid-lowering therapy identified gaps in evidence with respect to high-risk populations and populations with greater burden of cardiovascular disease, and recommended research to determine which strategy provides better short-term improvements in lipid profile. A.K. Monroe, K.A. Gudzone, R. Sharma, et al., *Combination Therapy Versus Intensification of Statin Monotherapy: An Update*, AHRQ Publication Report No. 14-EHC013-EF (Feb. 2014).

⁷⁷ *See, e.g.*, Cholesterol Treatment Trialists' (CTT) Collaboration, *Efficacy and Safety of More Intensive Lowering of LDL Cholesterol: A Meta-Analysis of Data from 170,000 Participants in 26 Randomized Trials*, 376 Lancet 1670-81 (2010); B.V. Howard, D.C. Robbins, M.L. Sievers, et al., *LDL Cholesterol as a Strong Predictor of Coronary Heart Disease in Diabetic Individuals with Insulin Resistance and Low LDL: The Strong Heart Study*, 97 Circulation 830-5

to further lower LDL-C.⁷⁸ Given these programs, the lack of consensus and ongoing clinical dialogue around the newly proposed guidelines, the lack of consideration of specific sub-populations, and the lack of new measures to replace those proposed for removal, we recommend that CMS retain these measures unless or until new measures that are more consistent with new and existing guidelines are put in place to replace them.

Finally, CMS has proposed removal of the Chronic Obstructive Pulmonary Disease (COPD) measures group from reporting in PQRS beginning in 2015.⁷⁹ While BIO understands that the removal of this measure group is contingent on the measure steward not being able to maintain certain measures contained in this group, we are concerned that retiring the measures without any substitutes could leave COPD—a major cause of serious, long-term disability, as well as healthcare costs—severely underrepresented in the PQRS measure set. We are further concerned that removal of this group will adversely impact influenza and pneumococcal immunization among this high-risk group of patients, as the measure set currently includes measures for both influenza immunization and pneumococcal immunization. We therefore hope the COPD measures group will remain in the PQRS for 2015 and beyond. However, to the extent that CMS ultimately removes the COPD measures group due to lack of steward maintenance, BIO urges the Agency to adopt the following as free-standing measures for purposes of the PQRS:

- Influenza Immunization (NQF#0041/PQRS#110)
- Pneumonia Vaccination Status for Older Adults (NQF#0043/PQRS#111)
- Pharmacotherapy Management of COPD Exacerbation (NQF#0549)⁸⁰
- Use of Spirometry Testing in the Assessment and Diagnosis of COPD (NQF#0577)

BIO also encourages CMS to support stakeholders in developing new COPD measures—including validated Patient Reported Outcomes performance measures (PRO-PM)—that will help drive better outcomes for patients and control costs.

D. BIO supports the continued refinement and expansion of the QCDR reporting option and reiterates its recommendations on implementation of the QCDR reporting mechanism in the future.

The Proposed Rule includes several proposals related to the development and modification of the QCDR reporting option that CMS finalized in the CY 2014 final rule. BIO continues to support CMS's efforts to implement QCDR reporting, and we appreciate CMS's continued efforts to implement this new reporting mechanism through the Proposed Rule. We continue to believe, however, that it is critical for CMS to require these registries to

(2000); T.R. Penderson, A.G. Olsson, O. Faergeman, et al., *Lipoprotein Changes and Reduction in the Incidence of Major Coronary Heart Disease Events in the Scandinavian Simvastatin Survival Study*, 97 *Circulation* 1453-60 (1998); K.M. Anderson, W.P. Castelli, D. Levy, *Cholesterol and Mortality: 30 Years of Follow-Up from the Framingham Study*, 257 *JAMA* 2176-2180 (1987).

⁷⁸ These include, for instance, use of statins and other LDL-lowering medications, and lifestyle changes, particularly diet.

⁷⁹ 79 Fed. Reg. at 40,457.

⁸⁰ BIO supports the adoption of NQF#0549 because, even though it is no longer endorsed by NQF, NCQA is in the process of updating the measure. The measure is also in Meaningful Use and a display measure in the Star Rating Program and adoption in PQRS would help achieve the goal of measure harmonization across CMS programs.

collect data and quality measures through a scientifically robust, transparent, and validated process.

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 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.

XIII. Medicare Shared Savings Program – BIO supports CMS’s continued refinement of the MSSP, including bonus points for improvement over time, but cautions against reliance solely on outcomes measures and against inappropriate alignment with certain aspects of the Value-Based Payment Modifier.

The Proposed Rule describes several proposals to continue refinement and expansion of the MSSP. Our comments on some of the specific proposals are below.

- A. BIO generally supports CMS’s proposed approach to the MSSP measures but cautions CMS not to rely solely on outcomes measures and suggests that CMS include certain additional measures.

In the Proposed Rule, CMS notes its intent to incorporate more outcomes-based measures into the MSSP over time in the set used to establish quality performance standards that ACOs must meet in order to obtain shared savings. BIO generally supports the movement to include more outcomes-based measures in the MSSP. That said, a sole reliance on outcomes measures is not necessarily appropriate. Accordingly, we urge CMS to continue to recognize the importance of having a combination of both process and outcomes measures. For instance, we believe it is critically important that CMS continue to include immunization measures in the MSSP to ensure that ACOs continue to provide these valuable services.

For this reason, 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. 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 August 15, 2014 NQF report discussed fully in Section XII.A of our comments.

BIO also supports the proposed addition of a measure for "Documentation of Current Medications in the Medical Record," which CMS proposes should replace ACO #12 "Medication Reconciliation." CMS's rationale for this change is that the existing measure was designed to determine whether medication reconciliation was done immediately following a hospital discharge, whereas the medical community has indicated that it is better clinical practice to perform medication reconciliation at every office visit. As articulated previously, we support this measure and agree that medication reconciliation should be performed at every office visit. However, instead of replacing the medication reconciliation measure, BIO recommends that CMS retain both measures for at least two years to evaluate whether the "Documentation of Current Medications in the Medical Record" is able to adequately capture medication reconciliation during care transitions, as a physician visit does not always immediately follow a hospital or rehabilitation facility discharge, a critical time period in patient care. If CMS finds that medication reconciliation in the first 30 days after a care transition is adequately captured, ACO #12 can be removed.

BIO also supports CMS's proposal to include patient-reported health outcomes measures for purposes of the MSSP and to expand quality measures over time to include more caregiver experience measures. BIO agrees that "[p]atient reported outcomes . . . provide valuable information not captured by other means."⁸¹ We urge CMS to aggressively test methods to gather systematic patient and caregiver feedback as the core of quality measurement, improvement, and public reporting for care furnished to ACO beneficiaries. In addition, CMS should develop practice-pattern metrics that address the risks of inappropriate withholding of effective treatments in settings in which providers have financial incentives to reduce costs. However, we reiterate our serious concerns, articulated in Section XI.D, above, with respect to the "Stewardship of Patient Resources" measure, which BIO urges CMS not to include in the MSSP.

In addition, BIO supports the inclusion of measures that adequately address critical conditions that are contributing to poor patient health in the Medicare population, as well as costs to the healthcare system. For instance, BIO commends CMS's efforts to improve care coordination for diabetes patients, including through the continued inclusion of the Diabetes Composite, as well as CMS's efforts to update this composite measure with the addition of the Hemoglobin A1c Poor Control measure (NQF#0059/ACO#27).⁸² However, we urge CMS to retain the outcome measure of Hemoglobin A1c Control (NQF#0729), either in the new composite or as a standalone measure.⁸³ We also support the addition of the Depression

⁸¹ 79 Fed. Reg. at 40,485.

⁸² *Id.* at 40,479, 40,481.

⁸³ CMS proposes to retire this measure from the MSSP. *Id.* at 40,482.

Remission at Twelve Month measure (NQF#0710/ACO#40) because we agree with CMS that depression is a serious condition for the Medicare population that can decrease patient adherence to treatment for chronic conditions.⁸⁴

Finally, BIO encourages CMS to include certain additional measures for purposes of the MSSP. First, we urge CMS to include measures that specifically address medication adherence as part of care transitions and otherwise. As noted previously, BIO views the inclusion of these measures as critical given the important role that adherence to a medication protocol can have in reducing unnecessary care and expenditures. Second, we believe that the addition of a Comprehensive Medication Management (CCM) measure would help to maximize the benefits of appropriate medication use by MSSP patients, as described in Section V, above. Third, we urge CMS to include measures that assess continuity of care between ACOs and medical specialists. While ACOs were understandably focused on primary care during their initial years, as the MSSP program evolves, there will be an increasing need to assess the degree to which ACOs are coordinating care with specialist providers—including specialists who are not participating in the ACO—to ensure continuity and coordination of care for all ACO-aligned Medicare beneficiaries. Fourth, because of the substantial impact of Chronic Obstructive Pulmonary Disease (COPD) on quality of life and healthcare costs,⁸⁵ BIO supports the inclusion of more COPD measures into the MSSP to help address this debilitating and costly condition. Specifically, BIO suggests that CMS consider adopting the following measures (or updated versions thereof) for purposes of the MSSP in future rulemaking: 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 Management of COPD Exacerbation (NQF#0549).⁸⁶ BIO also encourages CMS to support the development of new COPD measures—including validated Patient Reported Outcomes performance measures (PRO-PM)—that will help drive better outcomes for patients and control costs.

As a final note, we support CMS's plan to modify measures in future rulemaking cycles to reflect changes in practice and improvements in quality of care, including CMS's recognition that "any suggestions for new measures would be more thoroughly discussed in a future rulemaking cycle prior to being adopted."⁸⁷ For these purposes, we encourage CMS to submit as many measures as possible to the NQF Measures Application Partnership (MAP) for purposes of seeking multi-stakeholder group input.

⁸⁴ *Id.* at 40,480.

⁸⁵ According to the Centers for Disease Control and Prevention (CDC), COPD is the third leading cause of death in the United States and causes serious, long-term disability. A recent study conducted by the CDC estimated that, in 2010, total national medical costs attributable to COPD were \$32.1 billion and total absenteeism costs were \$3.9 billion for a total burden of COPD-attributable costs of \$36 billion. Fifty-one percent of these medical costs were borne by the Medicare program. Centers for Disease Control and Prevention, *Chronic Obstructive Pulmonary Disease*, <http://www.cdc.gov/copd/> (Last visited Aug. 27, 2014); Earl S. Ford, Louise B. Murphy, Olga Kavjou, Wayne H. Giles, James B. Holt, & Janet B. Croft, *Total and state-specific medical and absenteeism costs of chronic obstructive pulmonary disease among adults aged ≥18 years in the United States for 2010 and projections through 2020*, *Chest* (June 2014); Marie Smith, Margherita R. Giuliano & Michael P. Starkowski, *In Connecticut: Improving Patient Medication Management in Primary Care*, 30 *Health Aff.* 646-54 (2011).

⁸⁶ BIO supports the adoption of NQF#0549 because, even though it is no longer endorsed by NQF, NCQA is in the process of updating the measure. The measure is also in Meaningful Use and a display measure in the Star Rating Program and adoption in PQRS would help achieve the goal of measure harmonization across CMS programs.

⁸⁷ 79 Fed. Reg. at 40,484.

- B. BIO supports efforts to align Medicare quality programs but cautions CMS that certain aspects of the VM program are inappropriate in the context of the MSSP.

CMS proposes to “continue to align with other Medicare quality initiatives in order to reduce ACO burden and streamline quality reporting and indicators,”⁸⁸ including the VM. Although BIO supports efforts to improve alignment between programs to reduce burdens for providers, we caution CMS that certain aspects of the VM program are not appropriate in the context of the MSSP. We believe that the VM’s total per capita cost measure would be particularly inappropriate in the MSSP context, where, as CMS notes, providers already are incentivized to provide efficient care in order to capture shared savings. For the same reason, BIO urges CMS not to pursue the inclusion of “utilization measures” in the MSSP’s quality performance standards. We believe it is sufficient for that information to be included in the aggregate quarterly reports to ACOs.

- C. BIO supports CMS’s proposal to include an additional reward for ACOs that improve from one year to the next.

CMS proposes to award “bonus points” under the MSSP to ACOs that show an improvement in quality performance over time, up to a maximum of 2 bonus points for each domain.⁸⁹ BIO supports this proposal. We agree that including an additional reward for improvement over time will place an “even greater emphasis on quality improvement, encouraging all ACOs to continue to improve quality for their patient populations over time, in addition to maintaining existing high quality levels.”⁹⁰

XIV. Value-Based Payment Modifier and Physician Feedback Program – BIO commends CMS for its continued engagement with stakeholders in implementing the VM under the PFS, but urges CMS to ensure that the modifier reflects meaningful differences in cost and quality performance and incentivizes high quality patient care over the long term, including the appropriate use of drugs and biologicals.

The Proposed Rule describes several proposals to continue refinement and expansion of the VM and Physician Feedback Program, including expanding the modifier to all groups of physicians and individual EPs; increasing the amount of payment at risk due to the modifier from two percent of total Medicare payment for the CY 2016 modifier to four percent for the CY 2017 modifier; and further expanding the mandatory application of the quality-tiering methodology. BIO appreciates CMS’s continued engagement with stakeholders in implementing the VM, but we continue to have concerns about certain specific aspects of the VM’s implementation in the Proposed Rule, discussed in detail below.

⁸⁸ Id.

⁸⁹ Id. at 40,490.

⁹⁰ Id.

A. BIO opposes the proposal to increase the maximum modifier from two to four percent.

CMS proposes to increase the maximum amount of payment at risk due to the VM for the 2017 modifier from two percent to four percent of the total Medicare payment to the group practice or individual EP.⁹¹ BIO opposes this proposal because it creates considerable financial risk for Medicare providers 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 to weighting the 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, the program will fail if the methods of 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 a government program. We urge CMS not to put a greater percentage of provider payments at risk unless and until it has worked with stakeholders to correct the underlying approach to combining providers' performance on appropriate quality and cost measures.

B. BIO is concerned that the measures currently used to calculate the VM do not adequately capture the full benefits of appropriate use of drugs and biologicals.

As noted above, BIO generally supports efforts to improve alignment between Medicare quality programs to reduce burdens for providers. In particular, BIO supports CMS's proposal to use all of the quality measures that are available under the various PQRS reporting mechanisms to create a group or solo practitioner's VM in CY 2017 to the extent the group or practitioner submits data on these measures.⁹² 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.⁹³

We remain concerned, however, that the current quality and cost measures used to calculate the VM adjustment are insufficient to fully capture the benefits of appropriate use of drugs and biologicals. We continue to encourage CMS to incorporate into the VM calculation recommendations such as those of the Working Group on Optimizing Medication Therapy in Value-Based Healthcare, which has developed a framework for integrating pharmaceuticals into value-based purchasing systems. Likewise, in developing quality and cost measures for purposes of calculating the VM, CMS should take into consideration that the impact of certain healthcare services may not fully be apparent over a period of six months to a year. As noted above, we also have concerns regarding the option for practices to include measures collected through the PQRS CAHPS survey, in particular the "Stewardship of Patient Resources" measure, as articulated in Section XI.D, above.

⁹¹ Id. at 40,493.

⁹² Id. at 40,506.

⁹³ Id.

C. BIO supports CMS's proposal to apply the VM only to assigned services under the PFS.

CMS proposes to clarify that it will apply the VM "only to assigned services and not to non-assigned services starting in CY 2015."⁹⁴ The rationale that CMS provides for this proposal is that "[i]f the VM were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the VM is positive and decreased when the VM is negative. The application of the VM to non-assigned claims would therefore directly affect beneficiaries and not physicians"⁹⁵ BIO supports this proposal because we agree that "it is important that beneficiary cost-sharing not be affected by the VM and that the VM should be applied to the amount that Medicare pays to physicians."⁹⁶

D. BIO urges CMS to apply the VM to physicians participating in the MSSP in a manner that accounts for the cost incentives already present in the MSSP.

Beginning with the CY 2017 payment adjustment, CMS proposes to apply the VM to physicians and non-physician EPs who participate in the MSSP.⁹⁷ The Proposed Rule includes detailed proposals on how CMS would modify the VM to apply to EPs who participate in the MSSP, including by automatically classifying the cost component for the VM as "average cost" for most groups and solo practitioners who participate in the MSSP.

BIO is deeply concerned about adjusting Medicare payment to ACOs based on the VM's cost composite. Although BIO understands that the SSA requires 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 is also clear that introducing a new variable into the ACO demonstration could change the baseline used to measure success and would substantially bias any results. Moreover, because ACOs already receive bonuses for reducing costs under the shared savings program, CMS could be giving ACOs an unfair advantage over other Medicare 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. CMS has also failed to model the results of any benchmark changes so that physicians and other providers under the PFS can determine the impact of adding in these large, multi-specialty, highly resourced entities into the VM quality metrics. Accordingly, to the extent 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 composite.

E. BIO urges CMS to reconsider use of the proposed total per capita cost measure unless and until concerns raised by the NQF are addressed and the NQF endorses the measure.

In the Proposed Rule, CMS proceeds with its proposal to use the total per capita cost measure, with certain modifications aimed at addressing the concerns articulated by the

⁹⁴ Id. at 40,505.

⁹⁵ Id.

⁹⁶ Id. at 40,504.

⁹⁷ Id. at 40,506.

NQF in declining to endorse the measure in September 2013.⁹⁸ CMS states that it is “choosing not to address” certain NQF concerns with respect to the total per capita cost measure, however. First, CMS is “deferring addressing the issue of whether to incorporate socioeconomic status in [its] measures until after the NQF has finalized its guidance regarding risk adjustment for resource use measures.”⁹⁹ Second, CMS is “not proposing to include Part D data in the total per capita cost measures at this time due to the complexity of the issue.”¹⁰⁰

BIO urges CMS to reconsider its continued use of the total per capita cost measure until the measure obtains endorsement by the NQF. Although we appreciate CMS’s attempt to address the NQF’s concerns—including the proposed modifications to the two-step attribution methodology to recognize the critical role of non-physician practitioners in providing primary care—we believe that the piecemeal approach articulated in the Proposed Rule is not a substitute for measure endorsement by the NQF.

Specifically, with respect to CMS’s proposal “not . . . to include Part D data in the total per capita cost measures at this time,”¹⁰¹ BIO reemphasizes its concern (and the concern of NQF) that, because the total per capita cost measure does not reflect spending on Medicare Part D therapies, including that measure (or any similar measure) in the VM’s cost composite could change prescribing practices in order to shift drug costs from Part B to Part D. This could affect where and how patients access necessary care and potentially could increase their out-of-pocket costs, which in turn could affect their medication adherence and thus their health outcomes in the short- and long-term. Inappropriate site of care shifts also can present problems in achieving the goal of decreased overall Medicare expenditures. In response to similar concerns raised regarding the MSSP, CMS agreed that these were “important concerns” and committed to ensuring that “the program’s quality measurement and program monitoring activities . . . prevent and detect any avoidance of appropriately treating at-risk beneficiaries.”¹⁰² BIO asks that CMS make the same commitment for cost measures that may be included in the VM’s cost composite and further urges CMS not to include the total per capita cost measure until it has received NQF endorsement.

Moreover, assuming that CMS nonetheless moves forward with this measure, and pending inclusion of Part D data into the total per capita cost measure, we ask that CMS exclude all Part B drugs from the total per capita cost measure. We believe that this approach would help to limit the potential negative effects on health outcomes from inappropriately shifting drug costs between different Parts of the Medicare program in the interim. While we believe most physicians will put their patients’ needs first, the current structure will reward those who act arbitrarily.

We also remind CMS that the Agency has the express statutory authority to include or exclude all of these costs (or a portion thereof) for purposes of implementing section 3007 of the ACA, as Congress gave the Secretary broad leeway to determine which

⁹⁸ Id. at 40,509.

⁹⁹ Id. at 40,511.

¹⁰⁰ Id.

¹⁰¹ Id.

¹⁰² See 76 Fed. Reg. 67,802, 67,920 (Nov. 2, 2011).

measures of costs are “appropriate” for purposes of calculating the value-based payment modifier.¹⁰³ 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.¹⁰⁴ 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. Finally, we note that reimbursement rates for all drugs—both B and D—are determined outside of the PFS structure, which further indicates that CMS can independently evaluate the appropriateness of including these costs in the VM cost measures.¹⁰⁵

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) 962-9220 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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Health Policy

¹⁰³ The applicable provision defines “costs” to mean “expenditures per individual as determined appropriate by the Secretary.” ACA § 3007(2) (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.

¹⁰⁴ SSA § 1848(p)(3).

¹⁰⁵ See SSA § 1833(a)(1)(S) (citing SSA § 1847A); SSA § 1860D-11, et seq.