Biotechnology Industry Organization

September 6, 2013

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 & Other Revisions to Part B for CY 2014 [CMS-1600-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) 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) 2014 (the "Proposed Rule").[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we continue to monitor changes to Medicare's reimbursement rates and payment policies for their potential impact on innovation and patient access to drugs and biologicals. Toward this end, BIO is greatly concerned that physicians once again face a substantial, negative update to the conversion factor. The estimated cut of 24.4 percent in physician payment rates,[2] in addition to payment reductions due to sequestration, simply cannot be implemented without dire consequences to patient care. We agree with CMS that a long-term solution to avert future negative updates is critical,[3] 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 2014 and beyond.

[1] 78 Fed. Reg. 43282 (July 19, 2013).
[2] CMS, Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2014, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/Downloads/sgr2014p.pdf.
[3] 78 Fed. Reg. at 43511.

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

- Support the goal of analyzing the trend of hospital acquisition of physician practices and resulting provision of physician services in an outpatient setting and support the proposed methods of studying this trend;
- Urge CMS, in reviewing potentially misvalued codes under the PFS, to ensure that adequate reimbursement is provided for all services based on the actual time, work, and cost physicians incur, particularly for drug and biological administration services;
- Ask CMS to reconsider the proposed payment cap for codes with a higher total Medicare payment in the non-facility setting than in the facility setting, in light of serious concerns that the proposed cap will result in inadequate reimbursement for physician offices that provide drug administration and other vital services;
- Recommend that CMS implement the required update to the Geographical Practice Cost Indices in a manner that ensures rural providers receive adequate reimbursement to continue providing high quality care to rural communities;
- Support CMS's proposal to create new G-codes for complex chronic care management services;
- Support CMS's effort to ensure that Clinical Laboratory Fee Schedule (CLFS) payment rates appropriately reflect new laboratory testing technologies and urge CMS to ensure its review of the CLFS codes would be in a manner that takes account of input from stakeholders and maintains access to innovative diagnostic laboratory tests;
- Commend CMS for its deliberate approach and continued engagement with stakeholders in implementing the value-based payment modifier under the PFS, but urge CMS not to include the Medicare Spending per Beneficiary measure in the cost composite, and instead to ensure that the modifier incentivizes high quality patient care over the long term, including the appropriate use of drugs and biologicals;
- Recommend that CMS cover Hepatitis C and lung cancer screening for the Medicare population in CY 2014 with an appropriate commensurate increase in reimbursement;
- Support CMS's proposal to include several immunization measures under the Physician Quality Reporting System (PQRS) including IMM-1, the pneumococcal immunization measure, and recommend ways CMS can help increase uptake of immunizations through the modification and development of quality measures;
- Support the implementation of the new qualified clinical data registry reporting mechanism while recommending that these registries meet important standards of transparency and flexibility; and,
- Urge CMS to include patient-reported outcomes and measures of patient satisfaction across the PQRS measures groups.

I. <u>Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments</u> – BIO supports the goal of analyzing the trend of hospital acquisition of physician practices and resulting provision of physician services in an outpatient setting and supports the proposed methods of studying this trend.

In the Proposed Rule, CMS notes the increased trend toward hospital acquisition of physician practices and integration of those practices as a department of the hospital, with a resulting increase in furnishing of physicians' services in a hospital outpatient setting. CMS requests recommendations on how it can study the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

BIO applauds CMS's recognition of this growing trend and the significant impact it has on patients both in terms of where and from whom they receive their care, as well as the impact on patients' out-of-pocket costs. It is especially important to understand 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. BIO supports the methods CMS has considered to study this trend as each has the potential to yield detailed data. BIO also 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.

II. <u>Misvalued Codes</u> – BIO urges CMS, in reviewing potentially misvalued codes under the PFS, to ensure that adequate reimbursement is provided for all services based on the actual time, work, and cost physicians incur.

Under Section 1848(c)(2)(K) of the Social Security Act (SSA), added by the Affordable Care Act (ACA) in 2010, CMS is required to periodically identify potentially misvalued codes using seven criteria specified by the statute and to review and make appropriate adjustments to the relative values used to calculate the payment that Medicare makes for those services under the PFS. In past years, CMS has identified and reviewed individual codes or groups of potentially misvalued codes using each of the criteria specified in the statute. In the Proposed Rule, CMS states that it "plan[s] to continue [its] work examining potentially misvalued codes in these areas over the upcoming years."[4] CMS also proposes to further expand its review of potentially misvalued codes by soliciting the input of Medicare contractor medical directors on codes that may be misvalued.

BIO urges CMS, in all such reviews of potentially misvalued codes, to provide adequate reimbursement for all physician services, including for drug and biological administration, that reflects the totality of time and work required to furnish the service and 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 on a growing number of drugs and biological products by the Food and Drug Administration (FDA). REMS requirements often obligate physicians to spend more resources on each administration than is accounted for by measuring only the time and work of the drug administration itself, such as reviewing a medical guide with each patient or providing other mandatory patient education each time the physician administers the treatment. More complex REMS require physicians and others to obtain special training and enter patients into registries to facilitate periodic monitoring and provide documentation of "safe use" conditions, all of which require

[4] *Id*. at 43303.

considerable additional time and effort by physicians and their staff. In addition, some recent surveys have suggested that physicians are less likely to prescribe products that carry REMS requirements,[5] making it all the more important that CMS recognize the additional work and physician time in the reimbursement for drug administration procedures in order to maintain patient access to vital drug and biological therapies.

Similarly, the list of practice expense input codes subject to payment reductions under this proposal includes certain codes for companion diagnostic tests used to guide the appropriate use of molecularly targeted cancer agents that are part of current clinical practice guidelines. The proposed payment reductions are both substantial and sudden and BIO is concerned that this may impact the ability of laboratories and physicians to provide such critical tests to a patient population in need. As such, this reduction could be harmful to the Medicare program, devastating to the target beneficiary, and sends a negative signal to those investing in the science of companion diagnostic development. BIO urges CMS to consider the impact of such dramatic payment reductions on a healthcare provider's willingness and ability to deliver patient-centered, evidence based, guideline driven care. We recommend that CMS not finalize this proposed change and to work through existing mechanisms and processes to set appropriate values for these codes.

The Proposed Rule also notes that CMS has entered into two contracts with outside entities to develop validation models for the relative value units (RVUs) used to value services under the PFS, as required by ACA. As CMS works with these entities, it should include as criteria of any proposal the inclusion of robust stakeholder engagement and a comprehensive mechanism to assess the work and time required to furnish a service.

III. Using Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Rates in Developing Practice Expense (PE) Relative Value Units (RVUs) – BIO urges CMS to reconsider the proposed payment cap for codes with a higher total Medicare payment in the non-facility setting than in the facility setting, in light of serious concerns that the proposed cap will result in inadequate reimbursement for physician offices that provide drug administration and other vital services.

Beginning in CY 2014, CMS proposes to limit the non-facility PE RVUs for individual codes so that the total non-facility PFS payment amount would not exceed the total combined amount Medicare would pay for the same code in the facility setting (PFS facility payment plus payment under OPPS/ASC). CMS identifies approximately 200 codes as potentially misvalued because the total PFS payment for those codes in a non-facility setting would exceed the total Medicare payment when the service is furnished in a facility. This proposal is based on CMS's belief that when the total non-facility payment exceeds the total facility payment, the difference is not the result of appropriate payment differentials between the services furnished in different settings. CMS believes instead that the

[5] *See, e.g.*, Slevin, K.A., and M. A. Ashburn.2011. Primary Care Physician Opinion Survey on FDA Opioid Risk Evaluation and Mitigation Strategies. *Journal of Opioid Management* 7(2):109-115; Johnson, P.E. et al. 2010. NCCN Oncology Risk Evaluation and Mitigation Strategies White Paper: Recommendations for Stakeholders. *Journal of National Comprehensive Cancer Network* 8: S-7-S-27.

difference is the result of anomalies in the data used under the PFS and the application of the PE methodology to particular services. In particular, CMS expresses concerns about inaccuracies in the data due to low survey response rates and outdated data.

BIO is concerned that the proposed payment cap would arbitrarily set values for non-facility PE in the RVU calculation to achieve the goal of equalization instead of the goal of adequately reimbursing for services furnished in non-facility settings. By working backward from the premise that payments in the non-facility setting never should exceed payments in the facility setting, regardless of the particular circumstances of the procedure at issue, CMS undermines its stated goal of maintaining relativity within the RVU payment methodology, based on the principle that services should be reimbursed according to the "direct and indirect physician practice resources involved in furnishing each service."[6]

Moreover, the reasons for which CMS would depart from this basic principle of reimbursement under the PFS are faulty. BIO strongly disagrees with CMS's assumption that non-facility costs are always inherently less than those incurred in the facility setting, and believes that higher total non-facility payments often are justified by legitimate differences in the cost of providing services between the two settings. For example, in many cases facilities are able to reduce costs in ways that individual physician offices cannot, by exercising increased purchasing power to obtain supplies at lower cost and to spread fixed costs such as storage and inventory management costs over several departments. In contrast, physician offices often must bear the full brunt of such costs and rely on adequate reimbursement under the PFS to ensure that they can provide those services. In particular, physician offices incur significant costs associated with use of physician-administered drugs and biological products, such as the costs of shipping, storing, handling, preparing, and managing inventory, as well as the significant staff time spent on administration and counseling patients about use of these physician-administered drugs. All of these costs are appropriately incorporated into the RVUs and payment amounts in the non-facility setting under the PFS, and should not be discounted simply because they happen to lead to a higher non-facility payment for one code or another.

In addition, BIO disagrees with CMS's proposed use of OPPS data as a basis for setting a cap on payment in the non-facility setting. The data used to calculate annual OPPS payment rates represent a different set of costs than the PE inputs used to calculate RVUs under the PFS. Medicare's global payment periods under the PFS and packaging policies under the OPPS often result in different services being included in the payment rates for the same service under each payment system. Comparing OPPS and PFS payment rates is comparing apples to oranges, and therefore, it would not be appropriate to use these rates. Moreover, as CMS has recognized, the standard methodology for estimating hospitals' costs associated with providing drugs and biologicals to Medicare beneficiaries under the OPPS is susceptible to instability and errors. BIO urges CMS to continue to work to improve the quality of data available for rate-setting under all of the payment systems, and not to substitute potentially flawed data from one system for data under another system.

[6] 78 Fed. Reg. at 43296.

Finally, we note that CMS bases its non-facility payment cap proposal in part on a March 2012 report to Congress by the Medicare Payment Advisory Commission (MedPAC), that evaluated the cost of delivering evaluation and management services in different payment settings. MedPAC's analysis in fact recommended certain codes' rates be capped at the PFS payment amount, citing that amount as the "best proxy for the cost of efficiently delivering E&M services" rather than the OPPS amount.[7] Notably, MedPAC's recommendation against using the OPPS as the basis for a payment cap was partly in response to the trend of "a shift of services from offices" to hospital outpatient departments that the Proposed Rule itself identifies as a potential concern in driving up Medicare expenditures. BIO notes that this trend only would be exacerbated by insufficiently reimbursing physicians for services provided in the non-facility setting. As just one example, if finalized, this provision could decrease reimbursement rates by 25 to 60 percent for fluorescence *in situ* hybridization and immunohistochemistry tests that are commonly used to assess the human epidermal growth factor 2 (HER2) status of tumors. The presence of this tumor characteristic is important in guiding treatment options for patients with early- and late-stage breast cancer. Such drastic cuts could impact patient access to these tests entirely, or limit access to test kits with the highest quality components to ensure reliable results. In turn, this may impact the ability of thousands of patients a year to make informed decisions about their treatment that could significant impact the chance of cancer recurrence.[8] On a broader scale, finalizing this proposal will potentially force physician offices either to cease providing such services or to follow the long line of physician practices joining hospitals as outpatient departments.[9]

IV. Geographical Practice Cost Indices (GPCIs) – CMS should implement the required update to the GPCIs in a manner that ensures rural providers receive reimbursement adequate to maintain full access to quality care for patients in rural communities.

Pursuant to its statutory obligation under Section 1848(e)(1)(C) of the SSA, CMS proposes to update the GPCIs that account for differences in the cost of resources between localities in calculating each of the three fee schedule components (physician work, PE, and malpractice). In calculating the payment for each physician service under the PFS, CMS is required by the statute to adjust the components of the fee schedule (work, PE, and malpractice RVUs) using the GPCIs to reflect geographical variations in the costs of furnishing the services. The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component. CMS is required to review the GPCIs and update them as necessary at least every three years. CMS proposes

[7] MedPAC, *2012 Report to Congress: Medicare Payment Policy: Chapter 3: Hospital Inpatient and Outpatient Services*, at 32, available at http://www.medpac.gov/chapters/Mar12_Ch03.pdf.
[8] Danese, M.D., D. Lalla, M. Brammer, Q. Doan, andK. Knopf. 2010. Estimating recurrences prevented from using trastuzumab in HER-2/neu-positive adjuvant breast cancer in the United States. *Cancer* 116(24):5575-5583. See also: Heitz, F., J. Barinoff, O. du Bois, R. Hils, A. Fisseler-Eckhoff, P. Harter, J. Heitz, et. al. 2013. *Oncology* 84(6):319-325.
[9] MedPAC, *2012 Report to Congress: Medicare Payment Policy: Chapter 3: Hospital Inpatient and Outpatient Services*, at 31, available at http://www.medpac.gov/chapters/Mar12_Ch03.pdf.

adjustments to the GPCIs in Addendum E to the Proposed Rule and proposes to phase in these adjustments over two years as required by statute.

BIO urges CMS to reconsider the method used to calculate the proposed GPCI updates. Although we recognize that CMS is required by statute to update the GPCIs, we are deeply concerned that the method CMS has used to implement the proposed update will decrease reimbursement to rural physicians and threaten patient access in these communities to critical physician services, including physician-administered drugs and biologicals for patients with cancer, multiple sclerosis, rheumatoid arthritis, and other serious illnesses requiring complex treatment.

As required by ACA, the proposed update to the PE GPCI retains the required 1.0 floor for frontier states, defined as those states in which at least 50 percent of counties have a population per square mile that is less than six. The list of five qualifying states has not changed for CY 2014 (Montana, Nevada, North Dakota, South Dakota, and Wyoming). However, there are many rural and very rural areas across the country that face similar challenges to patient access to physician-furnished services that were the impetus to institute this PE floor for frontier states, but that do not fall within the statutory definition of a frontier state. BIO is concerned that the proposed GPCI updates for CYs 2014 and 2015 will adversely impact many of these communities if they are finalized, and we urge CMS to reconsider the proposed PE GPCI using a method that takes full account of the particular difficulty and cost of ensuring patient access to care in rural areas of states not defined as frontier states.

Likewise, BIO believes that the expiration of the 1.0 work floor at the end of 2013, reflected in the proposed work GPCI update, will negatively impact access to care in rural areas. We recognize that the expiration of the work floor requires a legislative rather than an administrative response. Even if the work floor were extended by Congress, however, the proposed GPCI updates to the PE and malpractice components of the fee schedule would, if finalized, still disadvantage rural providers, especially in the provision of drugs and biologicals administered in a physician's office. Their low purchasing power and the unique costs associated with rural practice (e.g., shipping and storage requirements, patient volume) already cause many to operate at a loss when providing these critical therapies. Decreasing GPCIs will exacerbate this financial stress and threaten patient access to critical physician administered drugs and biologicals in these communities where the next available site of care could be prohibitively far. We urge CMS to ensure adequate access to physician services in rural areas by implementing a GPCI update that fully recognizes the significant costs of providing health care in those communities.

V. <u>Complex Chronic Care Management Services</u> – BIO supports CMS's proposal to create new G-codes for complex chronic care management services as a meaningful step toward promoting effective coordination of care.

CMS proposes to create two new separately payable G-codes to reflect the provision of complex chronic care management services to patients with multiple chronic conditions: GXXX1 for services within an initial 90-day period, and GXXX2, for services provided in

subsequent 90-day periods. These codes would include services such as provision of 24-hour-a-day, 7-day-a-week access to care; systematic assessment of the patient's medical, functional, and psychosocial needs, including a plan of care; and management of care transitions.

BIO strongly supports separate payment for provision of complex chronic care management services and the creation of new G-codes to allow providers to bill for such services. We applaud CMS's continued recognition of the importance of coordinated care to patient outcomes and believe that the proposed G-codes will promote effective coordination for patients with multiple complex chronic conditions, who are among those patients most in need of coordinated care. We particularly appreciate that these new codes will not require services to be delivered in face-to-face interactions, supporting access to high-quality, convenient care that takes into account patient preferences and the realities of the different environments in which patients seek care today.

VI. Proposals Regarding the Clinical Laboratory Fee Schedule – BIO supports CMS's effort to ensure that CLFS payment rates appropriately reflect the resources required to provide laboratory tests and urges CMS to carry out its review in a manner that takes account of input from stakeholders and maintains access to innovative diagnostic laboratory tests.

In the Proposed Rule, CMS notes that the payment rates for diagnostic laboratory tests under the CLFS are the only rates among the Medicare payment schedules and systems that are not subject to an established mechanism for adjusting payment amounts. As a result, the Medicare payment for a laboratory test generally will remain the same even when the cost of the test changes, for example due to new technological developments. To regularly account for such changes in cost, CMS proposes to review payment rates for all diagnostic lab tests currently paid under the CLFS as part of the annual PFS update, beginning in CY 2014. In particular, CMS cites the need to adjust CLFS payment amounts to account for advancements in technology that have occurred since the implementation of the CLFS, leading to changes in the resources and personnel required to perform certain tests, the frequency and volume of testing, and the site of service.

BIO agrees that CMS should take the necessary steps to ensure that innovative diagnostic laboratory tests are appropriately reimbursed under the CLFS. We urge CMS, in carrying out the proposed review of CLFS payment rates, to subject both the potential review process, and the criteria on which current and future diagnostics will be reviewed, to public comment. Throughout the process, CMS should actively seek diverse stakeholder input to improve the transparency of the rate-setting process.

CMS should take into account not only the costs of performing these tests, but also the costs associated with developing innovative diagnostic tests and the value they provide to the management and treatment of patients. Incorporation of these factors in the analysis is necessary to maintain a robust, accurate payment system that supports and sustains continued diagnostic innovation. The analysis should not be presumed to only result in potential decreases in rates for particular tests; rather, the analysis should take into

account all factors (not just changes in technological advances) when determining adjustments in payment rates. CMS should explore whether different diagnostic laboratory tests require variable criteria to ensure adequate and appropriate reimbursement. Ultimately, it is critical that CMS consider and explain how its review will affect access to high-quality diagnostic tests that are crucial to ensuring the right patient gets the right medicine at the right time, and what impact the review may have on incentives for continued innovation in this space. Therefore, we would recommend CMS provide another opportunity for public comment after providing more detail about its proposed process.

VII. Value-Based Payment Modifier (VBPM) and Physician Feedback Program – BIO commends CMS for its deliberate approach and continued engagement with stakeholders in implementing the VBPM under the PFS but urges CMS to ensure that the modifier incentivizes high quality patient care over the long term, which includes the appropriate use of drugs and biologicals.

In the Proposed Rule, CMS proposes several significant changes to the VBPM, including expanding the modifier from groups of physicians with 100 or more eligible professionals for the CY 2015 modifier to groups with 10 or more eligible professionals for the CY 2016 modifier; increasing the amount of payment at risk due to the modifier from one percent of total Medicare payment to a practice for the CY 2015 modifier to two percent for the 2016 modifier; expanding the mandatory application of the quality-tiering methodology for groups subject to the modifier; and refining other methodologies used in calculating the VBPM adjustment. BIO appreciates CMS's continued engagement with stakeholders in implementing the VBPM, but we continue to have several concerns about specific aspects of the VBPM's implementation in the Proposed Rule, discussed in detail below.

A. The cost and quality measures used to calculate the VBPM should capture the short and longer term benefits of the appropriate use of drugs and biologicals.

Although we applaud CMS's efforts to align the quality measures used in other quality reporting programs with the quality measures used to calculate the VBPM, we remain concerned that the current quality and cost measures used to calculate the VBPM adjustment are insufficient to fully capture the benefits of appropriate use of drugs and biologicals. Notably, a Congressional Budget Office (CBO) analysis, released in November 2012 and based on CBO's review of dozens of new studies, projected that even a modest increase in the use of prescription drugs would cause Medicare's overall spending on medical services to decrease.[10] We encourage CMS to incorporate into the VBPM calculation recommendations such as those of the Working Group on Optimizing Medication Therapy in Value-Based Healthcare that has developed a framework for integrating pharmaceuticals into value-based purchasing systems.[11] Incorporating such standards for the appropriate

[10] Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012), available at http://www.cbo.gov/publication/43742.
[11] DuBois, R.W. et al. (2012). Role of Pharmaceuticals in Value-Based healthcare: A Framework for Success. *American Journal of Managed Care, 18(7).* Available at: http://www.ajmc.com/publications/issue/2012/2012-7-vol18-n7

use of drugs and biologicals into the VBPM calculation will serve the VBPM's goal of promoting cost-effective health care by ensuring that any successful strategy for providing higher quality care at lower cost is rewarded.

Likewise, in developing quality and cost measures for purposes of calculating the VBPM, CMS should take into consideration that the impact of certain health care services may not be fully apparent over a period of six months to a year. Accordingly, BIO recommends that the quality and cost of health care given by Medicare providers should be studied over a period of time sufficient to account for the full effect of longer-term treatments and therapies. Considering the longer-term impact of innovative drugs and biologicals, for example, is crucial to sustaining improvements in quality of care and decreasing overall costs.

B. CMS should not finalize its proposal to include the Medicare Spending per Beneficiary measure in the VBPM beginning in 2014.

CMS proposes to include the Medicare Spending per Beneficiary (MSPB) measure as part of the VBPM composite cost measure to better align all Medicare quality reporting programs, incentivize lower costs associated with post-acute care, and improve care coordination between providers across care settings. While BIO appreciates the importance of these goals, we do not believe that including the MSPB measure will achieve them. While CMS notes that the MSPB measure is already utilized in the Hospital Inpatient Quality Reporting System (IQRS) and the Hospital Value-Based Purchasing (VBP) Program, this does not ensure its appropriateness when applied to the VBPM. The physician groups subject to the VBPM can differ significantly from each other in specialty composition as well as the setting in which they provide care. Applying the MSPB measure uniformly to these practices would not account for such differences and the impact on cost the clinical realities of these differences convey. Further, BIO does not believe that simple cost measures like the MSPB are the best measures of efficiency in patient care, and that instead CMS should seek to include relative resource use measures[12] in the VBPM cost composite. Reporting utilization rates alone perpetuates and rewards component management by encouraging physicians to reduce utilization rates in the short-term rather than considering what may reduce utilization for individual patients over time. BIO also notes that the MSPB measure does not necessarily reflect high quality care because it is not directly linked to improvements in clinical outcomes as a means of physician evaluation. Similarly, it is unlikely that the MSPB will be able to aid care coordination between inpatient and outpatient settings because it does not convey an infrastructure for such coordination, only offers a retrospective measure of one aspect of the provision of care: its cost. Therefore, based on the inability of the MSPB measure to promote high quality, coordinated patient care, BIO

[12] Relative Resource Use Measures are defined by the National Committee for Quality Assurance (NCQA) as measures that: indicate how intensively plans use physician visits, hospital stays and other resources to care for members identified as having one of five chronic diseases; cardiovascular disease, COPD, diabetes, hypertension and asthma. When evaluated alongside quality measures, RRU measures make it possible to consider quality and spending simultaneously.
Source: NCQA. 2013. *Relative Resource Use Measures*. Washington, DC: NCQA, Available at: http://www.ncqa.org/Employers/RelativeResourceUseMeasures.aspx.

urges CMS not to finalize its proposal to include this measure within the VBPM beginning in the 2014 reporting year.

C. CMS should continue to study the potential for certain cost measures to incentivize inappropriate shifts in the site of care, and establish robust programs to prevent, detect, and resolve any issues prior inclusion in the VBPM.

Though CMS does not make a proposal in reference to the Total Per Capita Costs for all attributed beneficiaries measure for CY 2014, the Proposed Rule indicates that this measure continues to be studied, including its submission for a National Quality Forum review earlier this year.[13] Because this measure does not reflect spending on Medicare Part D therapies, BIO is concerned that including it, or any similar measure, in the VBPM's cost composite could change prescribing practices in order to shift drug costs from Part B to Part D. This could impact where and how patients access necessary care and potentially increase their out-of-pocket costs, which could in turn affect their medication adherence and thus their health outcomes in the short- and long-term. Inappropriate site of care shifts can also present problems in achieving the goal of decreased overall Medicare expenditures. In response to similar concerns raised regarding the Medicare Shared Savings Program,[14] CMS agreed that these were "important concerns"[15] 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."[16] BIO asks that CMS make the same commitment for cost measures that may be included in the VBPM's cost composite, and that it continue to explore the feasibility of excluding Part B data from the cost measures where there are both Parts B and D therapies.

D. BIO urges CMS to finalize its proposal to better distinguish the specialty composition of participating physician practices.

Finally, BIO applauds CMS's efforts to refine the VBPM calculation to take account of distinctions in the specialty composition of eligible physician practices beginning with the CY 2016 modifier, a refinement that BIO has suggested in previous comments on implementation of the VBPM. CMS proposes two potential mechanisms to better represent the different costs inherent in different clinical specialties: a "specialty adjustment" method in which the standardized score for VBPM cost measures is adjusted based on the average costs of care for the specialties represented in a given physician group; and a "comparability peer grouping" method in which cost measures for physician groups are calculated by comparing each group to a specialty-specific benchmark. In choosing between the specialty adjustment and comparability peer grouping method, or an alternative to both, CMS should consider which is most likely to incentivize high-quality care; prevent against underuse of appropriate care, including drugs and biologicals; and protect patient and physician decision-making. CMS also should actively identify other opportunities to incorporate the

[13] 78 Fed. Reg. at 43488.
[14] Biotechnology Industry Organization (BIO). 2011. *BIO's Comments on the CMS Accountable Care Organizations Proposed Rule*. Washington, DC: BIO, Available at: http://www.bio.org/advocacy/letters/bios-comments-cms-accountable-care-organizations-proposed-rule.
[15] 76 Fed. Reg. 67802 (November 2, 2011).
[16] Ibid.

inherent differences between the performance of different clinical specialties on quality and cost measures into other aspects of the VBPM's required measures reporting and payment adjustment calculation.

VIII. Coverage of Preventive Services – BIO recommends that CMS to take into account the recommendations of the U.S. Preventive Services Task Force (USPSTF) in updating the coverage of preventive services for CY 2014.

A. CMS should include Hepatitis C Virus (HCV) screening for the Medicare population in the Annual Wellness Screening with an appropriate commensurate increase in reimbursement.

In a December 2011 report entitled the *Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965*, the Centers for Disease Control and Prevention (CDC) recommended that all those born during 1945 through 1965 receive a one-time blood test for hepatitis C virus (HCV).[17] Given the prevalence of HCV in the "baby boomer" population, which is or will soon become eligible for Medicare, there are recognized public health benefits to proactively screening this population since screening and earlier identification of infected persons will help to mitigate the projected burden of HCV-related chronic disease and its consequences.

Patients who are made aware of their status and seek treatment can see a positive impact on their liver health and may be able to avoid the serious consequences of liver disease. Specifically, treatment-related sustained virologic response (SVR) is associated with a reduced risk of hepatocellular carcinoma by 75 percent[18] and a reduced risk of mortality among persons diagnosed with HCV infection by 50 percent.[19]

In June 2013, the USPSTF conferred a Grade B rating to the evidence supporting the value of screening the "baby boomer" population for Hepatitis C.[20] Therefore, BIO recommends that CMS include HCV screening as part of the Annual Wellness Visit to provide a defined opportunity to screen this population as well as improve the potential to screen a significant portion of eligible beneficiaries. If included, CMS should ensure reimbursement is commensurate with the service provided and sufficient to incentivize active screening efforts.

B. CMS should initiate coverage in anticipation of a USPSTF recommendation for lung cancer screening.

The USPSTF is currently reviewing a "Grade B" recommendation for lung cancer screening for persons at high risk. While it is possible that the USPTF recommendation will not be issued before the Proposed Rule is finalized, BIO urges CMS to recognize in the final

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[17] CDC. 2012 (August 17). Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965. *Morbidity and Mortality Weekly* 61(4). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf.
[18] Id. at 10.
[19] Id. at 5.
[20] U.S. Preventive Services Task Force (USPSTF). 2013. USPSTF A and B Recommendations. Rockville, MD: USPSTF, Available at: http://www.uspreventiveservicestaskforce.org/index.html.

rule that it anticipates USPSTF action on this issue. Further, we encourage CMS to consider incorporating into coverage USPSTF's recommendation once it is finalized, and formalize the policy through the CY 2015 PFS final rule.

IX. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System – BIO appreciates CMS's proposal to include several immunization measures under the PQRS and supports the implementation of the new qualified clinical data registry reporting mechanism, subject to these registries meeting important standards of transparency and flexibility.

A. BIO supports the proposed inclusion of immunization measures and urges CMS to finalize these provisions in the final rule.

Beginning or continuing in CY 2014, CMS proposes to include several immunization measures as individual measures or as part of measures groups available for quality reporting under the PQRS. Immunization measures help ensure that health care providers routinely discuss and offer recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the health care system. Therefore, BIO strongly supports the proposed inclusion of the following immunization measures and urges CMS to finalize their inclusion for CY 2014:

- Childhood immunization status as a PQRS Recommended Core Measure;
- Pneumococcal vaccination for patients 65 years and older in the Preventive Care Measures Group;
- Pneumococcal vaccination for patients 65 years and older in the Chronic Obstructive Pulmonary Disease (COPD) Measures Group;
- Pneumococcal immunization in patients aged 18 years and older in the Inflammatory Bowel Disease (IBD) Measures Group;
- Hepatitis A vaccination in patients with Hepatitis C Virus (HCV) in the Hepatitis C Measures Group;
- Influenza immunization in patients 6 months and older in the Preventive Care Measures Group;
- Influenza immunization in patients 6 months or older in the COPD Measures Group;
- Influenza immunization in patients 6 months or older in the Chronic Kidney Disease (CKD) Measures Group;
- Influenza immunization in patients 6 months or older in the Asthma Measures Group;
- Influenza immunization in patients 18 years and older in the IBD Measures Group; and
- Influenza immunization in patients 6 months or older in the Oncology Measures Group.

B. BIO recommends two ways to help increase uptake of immunizations through the modification and development of quality measures.

With regard to the influenza immunization measures, BIO suggests that CMS consider extending the screening period from August 1 to April 30. Currently, the screening

period is from October 1 to March 31. There are reports of health care providers delaying immunization until October 1 to be in compliance with the influenza measure requirements. However, the CDC recommends that providers begin offering and administering seasonal influenza vaccines as soon as the vaccines are available. In recent years, providers have received their initial shipments of influenza vaccine in August. An end date of April 30 would allow providers more time to administer second doses in children as needed. Thus, revising the influenza immunization measures to include patients who are seen for a visit between August 1 and April 30 should help achieve improved influenza immunization rates.

BIO also recommends that in considering further development and implementation of the value-based payment modifier, CMS develop and include quality measures for all vaccines recommended for adults, as these vaccines have been evaluated by the CDC and the Advisory Committee on Immunization Practices (ACIP) for value as an element of the recommendation process. These recommended vaccines are likely to lead to improved population health outcomes, reduced incidence of vaccine-preventable diseases, and potential cost offsets for Medicare.

C. CMS should finalize its proposal to include the IMM-1 Pneumococcal Immunization Measure in the PQRS for CY 2014 and update the measure to fulfill the goal of aligning measures throughout the reporting programs.

CMS proposes including IMM-1c, Pneumococcal Immunization (PPV23) for High Risk Populations (Age 5 through 64 years), as an individual PQRS measure. BIO strongly supports the inclusion of the IMM-1c measure in the PQRS as well as CMS's effort to align measures throughout payment systems.[21] However, although CMS states in the Proposed Rule that "including this measure from the Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs," the proposed rule for the Inpatient Prospective Payment System (IPPS) for FY 2014 proposed removal of the measure from the IQR Program.[22] BIO opposed removal of the measure, as did the National Vaccine Advisory Committee (NVAC). On June 25, Dr. Howard Koh, Assistant Secretary for Health, transmitted to Administrator Tavenner the NVAC recommendation to retain the IMM-1 measure in IQR as removal of the measure "will drive down pneumococcal immunization rates."

In the IPPS final rule[23], CMS decided to suspend and update the IMM-1 measure rather than remove it altogether from the Hospital IQR Program. BIO commends CMS's decision to not remove the measure, while stressing that it is critical that the updates occur quickly to help align measures across quality reporting programs and ensure patients are appropriately vaccinated against pneumococcal disease, thereby reducing the significant morbidity, mortality, and health care costs associated with the disease. We encourage CMS

[21] *See* 78 Fed. Reg. at 43427.
[22] *See* 78 Fed. Reg. 27486, 27680 (May 10, 2013).
[23] Final Rule Pre-publication (Display) Version: Hospital Inpatient Prospective Payment Systems; Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates, etc. 2013. Available at: https://www.federalregister.gov/articles/2013/08/19/2013-18956/hospital-inpatient-prospective-payment-systems-acute-care-hospitals-and-the-long-term-care-hospital.

to update the measure and propose it for comment in the PFS in one year's time and then re-implement the measure during FY 2015.

The IMM-1c measure included in the PFS proposed rule also needs to be updated, as it specifically cites pneumococcal polysaccharide vaccine (PPV23) even though the ACIP recommends two pneumococcal vaccines, PPV23 and pneumococcal conjugate vaccine (PCV13) for use in adults with immunocompromising conditions. Thus, the measure should be modified to replace any reference to "PPV23" with "pneumococcal vaccine" so that general pneumococcal vaccination status can be assessed. Additionally, the measure is 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 IMM-1c measure should be properly integrated so it is applicable across programs, health care settings, and patient populations.

In summary, considering the importance of pneumococcal immunization in the Medicare population, we urge CMS to: (1) finalize the inclusion of the IMM-1c measure in the PQRS for CY 2014 and modify the measure specifications as needed; and (2) update and re-implement the IMM-1 measure in the Hospital IQR Program in CY 2015.

D. <u>CMS should impose specific requirements on Qualified Clinical Data Registries to ensure they meet the goal of expanding physician reporting and improving the quality of patient care.</u>

CMS proposes a new PQRS reporting mechanism for qualified clinical data registries that would be available for use beginning in CY 2014 for purposes of the CY 2014 PQRS incentive as well as the CY 2016 payment adjustment. The American Taxpayer Relief Act (ATRA) provides that CMS shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Accordingly, CMS proposes that eligible professionals who satisfactorily participate in a qualified clinical data registry for the full calendar year 2014 will be treated as having satisfactorily reported data on quality measures for purposes of the PQRS incentive. "Satisfactory participation" would be defined for the CY 2014 PQRS incentive and the CY 2016 PQRS payment adjustment as reporting at least nine measures available for reporting under the qualified clinical data registry, covering at least three of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's applicable patients, including at least one outcome measure.

BIO expressed its support for CMS's efforts to implement the qualified clinical data registry reporting option in its April 8, 2013, comment letter responding to CMS's Request for Information CMS-3276-NC, and we appreciate CMS's continued efforts to implement this new reporting mechanism through the Proposed Rule.[24] We also stated in our earlier comment letter and continue to believe that it is critical for CMS to require these registries to collect data and quality measures through a scientifically robust, transparent, and validated process. We reiterate here the recommendations included in our previous

[24] 78 Fed. Reg. at 43360-43367, 43476-43477.

comment letter for specific requirements that CMS should impose on qualified clinical data registries 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. BIO urges CMS to require qualified registries to:

- Transparently develop and update data elements and quality measures with stakeholder input by making all review processes open to the public, reviewing and regularly updating data elements and quality measures, and encouraging that all included quality measures are endorsed by a multi-stakeholder process equivalent to that used by the National Quality Forum (NQF);
- Allow for flexibility in data collection methods, including opportunities to collect patient-reported outcomes;
- Capture data longitudinally, not just at a single time interval;
- Employ a transparent, peer-reviewed risk adjustment methodology;
- Supply meaningful feedback to providers to inform their clinical decision-making; and
- Provide for adequate patient protections and consent procedures.

E. <u>CMS should include patient-reported outcomes and measures of patient satisfaction across the PQRS measures groups.</u>

It is vital that quality of care measures be strong enough to give patients confidence in the care they receive, and credible guidance in choosing where to seek care. Various payer, provider, and patient advocacy stakeholders have underscored the need to better capture the patient perspective as the core of quality metrics.

While BIO supports man of the proposed measures, discussed in detail above, we notice that most PRQS measures fail to reflect key patient concerns. These include whether a provider offers the needed skills and experience, access to the best treatments for a particular cancer, low rates of complications along with high rates of good outcomes, and the opportunity to be an active participant in assessing options and decisions about care. BIO urges CMS to add patient-reported outcomes and satisfaction to the quality metrics, and to test early and aggressively methods to gather systematic patient and caregiver feedback as the core of quality measurement, improvement, and public reporting for cancer care. In complement, CMS should develop practice-pattern metrics that address the risks of inappropriate withholding of effective treatments in settings where providers have financial incentives to reduce costs.

X. 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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