Biotechnology Industry Organization

September 4, 2012

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Acting 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; Proposed Rule [CMS-1590-P]

Dear Acting 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) and other revisions to Part B for calendar year (CY) 2013 (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 27 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 2013 and beyond.

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[1] 77 Fed. Reg. 44722 (July 30, 2012).
[2] CMS (Center for Medicare and Medicaid Services). 2012. Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2013. Baltimore, MD: CMS, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/Downloads/sgr2013p.pdf.
[3] 77 Fed. Reg. at 45032.

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

- Urge CMS to ensure that American Medical Association's (AMA) Relative Value Update Committee (RUC) review of certain drug administration codes is carried out carefully and comprehensively, taking account of all time and work expended by physicians, including time spent complying with Risk Evaluation and Mitigation Strategies (REMS) requirements;
- Encourage the agency to analyze the particular nature of the test involved, whether it requires physician work, and how best to ensure adequate and appropriate reimbursement when deciding whether to place each individual molecular pathology laboratory test on the Clinical Laboratory Fee Schedule (CLFS) or the PFS;
- Support the proposed revision to the criteria for substitutions of average manufacturer price (AMP) for average sales price (ASP) and agree that CMS should proceed cautiously and with sufficient public notice before substituting a therapy's widely available market price (WAMP) or AMP for ASP, particularly because the regulation regarding the AMP definition has not been finalized;
- Urge CMS to ensure that each branded prescription drug or biological receives a unique Healthcare Common Procedure Coding System (HCPCS) code, particularly now that manufacturers must report data for each branded prescription drug for purposes of the annual fee on branded prescription drug sales;
- Ask CMS to instruct contractors to publish on their websites their fee schedule or reimbursement methodology for radiopharmaceuticals as a reference for providers;
- Implement the proposed oncology measures group under the Physician Quality Reporting System (PQRS);
- Support CMS's proposal to implement quality measures focused on the treatment of stroke and stroke rehabilitation;
- Support the proposed inclusion of additional quality measures for pneumococcal immunization;
- Support CMS's proposal to adopt a new measure related to anticoagulation therapy and encourage the agency to regularly review and update the PQRS to ensure that measures reflect new evidence and innovations in the provision of healthcare;
- Support CMS's proposal to expand the definition of high or intermediate risk groups eligible for coverage for the Hepatitis B vaccine under Part B;
- Ask CMS to be responsive to new Centers for Disease Control and Prevention (CDC) screening guidelines for Hepatitis C Virus;
- Urge CMS to update Medicare manuals in a timely manner to reflect CDC's Advisory Committee on Immunization Practices (ACIP) recommendations;
- Commend the agency for its deliberate approach and engagement with stakeholders in implementing the value-based payment modifier under the PFS and urge CMS to ensure that the program's measures provide incentives against underuse of appropriate care;

- Support CMS's proposal to create a HCPCS G-code for transition of care services; and
- Urge CMS to provide guidance that clarifies billing practices for for certain Medicare Part B-covered drugs and biologicals provided under the Durable Medical Equipment (DME) benefit is directed specifically to that type of physician-administered drug or biological.

I. POTENTIALLY MISVALUED CODES UNDER THE PFS – BIO urges CMS to ensure that review of drug administration codes is carried out carefully and comprehensively, taking account of all time and work expended by physicians, including time spent complying with REMS requirements.

In the final rule for CY 2012, CMS implemented its proposal to request review by the AMA's RUC of certain high PFS expenditure Current Procedural Terminology (CPT®)[4] codes that CMS identified as potentially misvalued.[5] CMS asked the AMA's RUC to ensure that the physician times, work relative value units (RVUs), and direct practice expense (PE) inputs for these codes are appropriately valued. The codes identified as potentially misvalued include a number of drug administration codes, such as CPT code 96413 for the intravenous infusion of chemotherapy and CPT code 96365 for other therapeutic, prophylactic, or diagnostic intravenous infusions. CMS plans to include any revised valuations in the CY 2013 final rule with comment period.[6]

BIO urges CMS to take all possible steps to ensure that the review of these administration codes is carried out with due regard for the importance of adequate reimbursement for the administration of drugs and biologicals. In addition to reimbursement of the drug or biological product itself, adequate reimbursement for the time and expense of administration is essential to ensuring that patients continue to have access to drug and biological therapies, many of which offer life-saving or disease-altering treatment.

In particular, we urge CMS to ensure that the review of drug and biological administration codes takes account of the increased time and effort spent by physicians to comply with the 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 actual drug administration service itself. For example, physicians who choose to prescribe a drug or biological subject to REMS requirements often are required to review a medical guide with each patient or to provide other mandatory patient education each time they administer the treatment. Other 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. Some recent surveys have suggested that

[4] CPT is a trademark of the AMA.
[5] 76 Fed. Reg. 73026, 73066 (Nov. 28, 2011).
[6] Id. at 73065.

physicians are less likely to prescribe products that oblige them to carry out such requirements.[7] As a result, recognizing this additional work and physician time in the reimbursement for administration procedures is vital to maintaining patient access to drug and biological therapies. This additional physician work must also be recognized in the RUC review of the drug administration codes. We urge CMS to ensure this occurs.

II. PAYMENT FOR MOLECULAR PATHOLOGY SERVICES – CMS should decide whether to place each individual laboratory test on the CLFS or the PFS by looking at the particular nature of the test involved, whether the test requires physician interpretation in order to obtain a result, and how best to ensure adequate and appropriate reimbursement.

In the Proposed Rule, CMS requests public comment on whether new AMA Molecular Pathology CPT codes for genetic testing should be assigned for payment under the CLFS or PFS.[8] To ensure adequate and appropriate reimbursement, BIO believes that placement of laboratory tests onto a fee schedule should be driven by the particular nature of each individual test, and whether or not physician interpretation is required in order to obtain a test result. If performance of a test requires physician work via interpretation of the results, the code for the test should be placed onto the PFS. However, if the test is typically performed and interpreted by laboratories and does not require physician work, the code for the test should be placed on the CLFS.

BIO is concerned that CMS's proposal includes an option to move genetic tests to the PFS, because many of these tests are typically read by a Ph.D. geneticist, and do not require a physician. The covered categories of professionals to calculate the work component of payment for these genetic tests do not include Ph.D. geneticists.[9] Accordingly, placement of all of these codes onto the PFS would result in payment amounts that do not take into account the professional component of these services, and will subject these services to co-payments that would otherwise not be required under the CLFS. Similarly, placement of all of these codes onto the CLFS may not appropriately account for physician work required to complete some of these tests.

Treatment of these codes as a group for placement onto fee schedules is not appropriate, and risks inadequate and inappropriate reimbursement for these tests. It is critical that CMS place these codes onto the fee schedule that accounts for all components of the costs of these services. Should CMS move forward with placing all of the codes onto a single fee schedule, there must be a mechanism in place to adjust for adequate and appropriate payment for these

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[7] *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.

[8] 77 Fed. Reg. at 44783.

[9] *See* 42 C.F.R. § 415.130.

codes under that fee schedule. In the absence of adequate and appropriate reimbursement, access to these genetic tests by Medicare beneficiaries may suffer.

III. PART B DRUG PAYMENTS: ASP ISSUES

A. CMS should implement the proposed revision to the criteria for substitutions of AMP for ASP and continue to proceed cautiously and with sufficient public notice on any substitution of WAMP or AMP for ASP, particularly because the regulation regarding the AMP definition has not been finalized.

The Social Security Act (SSA) permits the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[10] The legislative history of this statutory provision clarifies that Congress intended for the Secretary to provide "a number of procedural and substantive safeguards to ensure the reliability and validity of the data" when deciding to substitute WAMP or AMP for ASP.[11] In the PFS final rule for CY 2012, CMS addressed the need for these safeguards by implementing several new criteria for substitutions of AMP for ASP. Under these criteria, substitutions will be made only when:

1. the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter,
2. matching sets of national drug codes (NDCs) are used in the comparison of AMP to ASP, and
3. the value of the AMP-based price substitution is less than the ASP payment limit that is calculated for the quarter in which the substitution is applied.[12]

In light of recent concerns about drug shortages, CMS now proposes to add a new criterion that would "prevent the AMP price substitution policy from taking effect if the drug and dosage form represented by the HCPCS code are reported by the FDA on their Current Drug Shortage list (or other FDA reporting tool that identifies shortages of critical or medically necessary drugs) to be in short supply at the time that ASP payment limits are being finalized for the next quarter."[13] BIO supports this proposal because it recognizes that reducing reimbursement could further harm access to critical or medically necessary drugs in short supply. We ask CMS to implement this new criterion in the final rule.

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[10] SSA § 1847A(d)(3)(A).
[11] Medicare Modernization Act Conference Report, H.R. Rep. No. 108-391, at 592 (noting that the safeguards include "notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selection such sources").
[12] 76 Fed. Reg. at 73026, 73289-95.
[13] 77 Fed. Reg. at 44793.

CMS also states that it intends to continue the "cautious approach" it has applied to WAMP and AMP-based price substitutions to date.[14] BIO appreciates CMS's thoughtfulness and restraint in making payment substitutions, and we strongly urge CMS to refrain from any such substitutions until the agency has promulgated and implemented its final rule on the new definitions of AMP. There remains significant ambiguity in the statutory language for the new definition of AMP included in the Patient Protection and Affordable Care Act (ACA) and the alternative definition of AMP for infused, injectable, instilled, implanted or inhaled drugs and biologicals (often referred to as "5i" drugs) not generally dispensed through retail community pharmacies that was enacted in 2010, and many stakeholder questions and comments on the proposed rule, released earlier this year,[15] have yet to be addressed. The final regulations almost certainly will affect the relationship between AMP and ASP, and, accordingly, the appropriateness of price substitution. For example, the final rule will address the standards for determining whether a 5i drug is or is not generally dispensed through retail community pharmacies, and in particular, whether and how manufacturers must periodically evaluate whether a 5i drug satisfies that standard and move the drug between AMP definitions as appropriate. Such standards absolutely will affect how a drug's AMP will relate to its ASP, but until CMS finalizes the AMP rule, manufacturers lack clear instructions for making these determinations. Therefore, we strongly urge CMS to delay implementation of any payment rate substitution until the final rule regarding the AMP definitions has been promulgated and takes effect.

Finally, BIO supports CMS's proposal to continue the applicable threshold for both the AMP and WAMP at 5 percent "until such time that a change in the threshold amount is warranted."[16] BIO also continues to support CMS's policy of providing adequate notice to manufacturers affected by a potential price substitution and urges CMS to work closely with these manufacturers before making any such substitution. It is important that manufacturers have the opportunity to inform CMS of any unique, market-related factors that may affect the relationship between AMP and ASP for a particular quarter. BIO requests that CMS specify in its final rule the process by which manufacturers will be able to provide input prior to any decision regarding a price substitution.

B. CMS should ensure that each branded prescription drug or biological receives a unique HCPCS code, particularly now that manufacturers must report data for each branded prescription drug for purposes of the annual fee on branded prescription drug sales.

Currently, CMS assigns unique HCPCS codes to biological products and single source drugs first sold in the United States after October 1, 2003 to "facilitate separate payment" for

[14] Id. at 44792-93.
[15] 77 Fed. Reg. 5318 (Feb. 2, 2012).
[16] 77 Fed. Reg. at 44792. .

these products, as required by section 1847A of the SSA.[17] Under this policy, the ASP for each newly licensed biological is calculated based on the data reported for that biological, and, consistent with the calculation of a separate payment amount, new biologicals also receive unique HCPCS codes.

As we have said in our comments on prior proposed rules, unique codes also will be needed to separately track sales of branded prescription drugs for purposes of the annual fee on branded pharmaceutical manufacturers under section 9008 of ACA. For purposes of this fee, "branded prescription drug" includes any prescription drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act and any biological product licensed under section 351(a) of the Public Health Service Act.[18] The Secretary of Health and Human Services is required to report the per-unit ASP and the number of units of the branded prescription drug paid for under Medicare Part B. Furthermore, CMS is required to "establish a process for determining the units and allocated price . . . for those branded prescription drugs that are not separately payable or for which National Drug Codes are not reported."[19] In its guidance implementing section 9008, the Internal Revenue Service (IRS) has proposed to estimate the amount of sales attributable to each manufacturer in a multiple-product HCPCS code using ASP sales data as a proxy for Part B sales.[20] Such estimates, which risk inaccurate calculation of each manufacturer's share of the annual branded prescription drug fee, can be avoided if each branded prescription drug and each biological product receives its own HCPCS code. We therefore urge CMS to take all available steps to ensure that each drug or biological is given a unique HCPCS code.

C. CMS should instruct contractors to publish on their websites their fee schedule or reimbursement methodology for radiopharmaceuticals as a reference for providers.

Medicare's reimbursement rates for drugs and biologicals are clearly presented in the quarterly update to the ASP file published on CMS's website, but there is no similar source of information about reimbursement for radiopharmaceuticals. Although the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established ASP-based reimbursement for drugs and biologicals, section 303(h) of that law clarified that the amendments to the statute did not change the payment methodology for radiopharmaceuticals "including the use by carriers of invoice pricing methodology." Contractors currently reimburse radiopharmaceuticals at either 95 percent of average wholesale price (AWP) or use invoice pricing. Many contractors do not publish information about the methodology they use or provide the current reimbursement rates for radiopharmaceuticals, however, making it difficult for providers to understand how much they will be paid for administering a particular product and to verify that they are being paid the correct amount under the contractor's methodology. BIO asks

[17] Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics, May 18, 2007. Available at: http://www.cms.gov/MedHCPCSGenInfo/downloads/051807_coding_annoucement.pdf.
[18] ACA § 9008(e)(2).
[19] ACA § 9008(g)(2).
[20] Internal Revenue Service, Notice 2011-9, at 7 (Jan. 14, 2011).

CMS to instruct its contractors to publish on their websites their reimbursement rates for radiopharmaceuticals or the methodology used by that contractor.

IV. QUALITY REPORTING INITIATIVES

A. CMS should implement the proposed measures groups for oncology care.

Beginning in 2013, CMS proposes to use an oncology measures group under the PQRS.[21] This measures group addresses care for breast and colorectal cancer and includes several measures generally applicable to the treatment of patients with cancer.[22] We share CMS's belief that it is important to measure quality in cancer care,[23] and we encourage CMS to work with stakeholders from the cancer treatment community to continue to develop and refine appropriate measures for breast, colorectal, and other cancers.

B. BIO supports CMS's proposal to implement quality measures focused on the treatment of stroke and stroke rehabilitation.

BIO supports CMS's proposal to further the goals of HHS's Million Hearts initiative to improve heart and stroke care, and further supports CMS in adopting paired quality measures related to Tissue Plasminogen Activator (t-PA), [24] currently the only FDA-approved therapy for acute ischemic stroke. Approximately 3-8 percent of patients who present with acute ischemic stroke currently receive t-PA. Excluding patients who are contraindicated and arrive beyond the 4.5 hour time-window, only one-third of potentially eligible patients currently are being treated. Ultimately, the choice to treat is between the physician and patient; such a decision is complicated, multi-factorial, and holds substantial gravity. However, irrespective of the final decision, consideration to treat with t-PA is not an unreasonable mandate for health care providers who are faced with limited options in a short time frame for patients who present with a significantly disabling event. Therefore, we support the inclusion of this paired measure to improve stroke care and stroke rehabilitation.

C. BIO supports the inclusion of an additional pneumococcal immunization quality measure.

The CDC's ACIP recommends that all persons aged 65 years and older and persons under 65 years with certain risk factors receive a pneumococcal vaccine. CMS has implemented more comprehensive pneumococcal immunization measures in the hospital setting through the Inpatient Quality Reporting System (IQR) that apply to most populations included in the ACIP's current recommendations. However, the agency does not propose to include comprehensive pneumococcal immunization measures in ambulatory settings through the PQRS. Instead, CMS

[21] 77 Fed. Reg. at 44964.
[22] Id. at 44976-77.
[23] Id. at 44964.
[24] Id. at 44831.

proposes to limit 2013 PQRS reporting to National Quality Forum (NQF) endorsed measure #0043, which applies only to individuals aged 65 years and older.[25] Therefore, BIO supports the inclusion of NQF #0617, entitled "High Risk for Pneumococcal Disease – Pneumococcal Vaccination,"[26] in the PQRS as a substitute or complement to NQF #0043, as this measure more appropriately captures the populations under age 65 that ACIP recommends receive a pneumococcal vaccine in addition to including the population aged 65 years and older. The use of comprehensive quality measures for adult immunizations will help to ensure that healthcare providers routinely discuss and offer vaccines to their patients, resulting in higher vaccine uptake among adults, better health outcomes, and reduced health expenditures for vaccine preventable diseases.

D. BIO supports CMS's proposal to adopt a new measure related to anticoagulation therapy, and we encourage the agency to regularly review and update the PQRS to ensure that measures reflect new evidence and innovations in the provision of healthcare.

BIO supports CMS's proposal to adopt a new measure entitled, "Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy," which is intended to replace an outdated anticoagulation therapy measure.[27] BIO applauds CMS for recognizing the need to remove an outdated measure and to replace it with a measure that reflects innovation in care. We believe CMS's decision in this instance illustrates the importance of regularly reviewing and updating quality measures under the PQRS. BIO believes it is crucial that CMS identify and then implement quality measure updates that reflect new treatments and evidence consistent with the latest, evolving standard of care. We encourage CMS to establish a process for updating and removing out-of-date measures in a timely manner.

V. Coverage of Preventive Services

A. BIO supports CMS's expansion of Part B coverage eligibility for Hepatitis B vaccines to persons with diabetes.

BIO supports CMS's proposal to include persons with diabetes among the high risk groups eligible for Part B coverage of the Hepatitis B vaccines. The Hepatitis Vaccines Work Group of the CDC's ACIP evaluated the risk of contracting Hepatitis B among diabetes patients to be intermediate and/or high based on the highly infectious and environmentally stable nature of the disease as well as its ability to be transmitted as a direct result of diabetes monitoring and treatment equipment. ACIP found that not only have breaches of infection control been found to lead to Hepatitis B in various hospital and outpatient settings (including long-term care

[25] National Quality Forum. Measure Number 0043, Pneumonia vaccination status for older adults. Available at: http://www.qualityforum.org/QPS/0043.
[26] National Quality Forum. Measure Number 0617, High Risk for Pneumococcal Disease – Pneumococcal Vaccination. Available at: http://www.qualityforum.org/QPS/0617.
[27] 77 Fed. Reg. at 44834-5, 44955.

facilities, private offices, and community health centers), but diabetic persons over the age of 60 years were at an increased risk of contracting Hepatitis B compared to similar non-diabetic persons.[28] Due to the increased risk and seriousness of contracting the virus in this population, BIO supports CMS's designation of persons with diabetes as eligible under Part B coverage to receive the Hepatitis B vaccines.

B. CMS Should Be Responsive to New CDC Screening Guidelines for Hepatitis C Virus.

CMS should consider policies that support CDC's final guidance recommending that all those born during 1945 through 1965 receive a one-time blood test for hepatitis C virus (HCV).[29] These guidelines are critically important to public health, as screening and earlier identification of infected persons will help to mitigate the projected burden of HCV-related chronic disease and its consequences.

Given the prevalence of HCV in the "baby boomer" population, which is or will soon become eligible for Medicare, there are recognized benefits to proactively screening this population. 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[30] and a reduced risk of mortality among persons diagnosed with HCV infection by 50 percent.[31]

In addition, two recent studies have found birth-cohort screening interventions to be cost-effective. In a cost-effectiveness simulation conducted by the CDC and published in the *Annals of Internal Medicine*, when compared with risk-based screening, birth-cohort screening in the primary care setting would identify 808,580 additional cases of chronic HCV infection and, if followed by treatment, could reduce the number of deaths by 121,000.[32] A similar study in *Hepatology* found that compared to the current strategy of risk-based screening, a birth-cohort screening of all Americans born between 1946 and 1970, followed by treatment, would reduce deaths by 78,000. The study also found that birth cohort screening of this population would

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[28] CDC. 2011 (December 2011) Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report 60(50); 1709-1711, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm.
[29] 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.
[30] Id. at 10.
[31] Id. at 5.
[32] Rein, D. B., et al. 2012. The Cost-Effectiveness of Birth-Cohort Screening for Hepatitis C Antibody in U.S. Primary Care Settings. *Annals of Internal Medicine* 156(4):263-270.

result in 84,000 fewer cases of cirrhosis, 46,000 fewer cases of liver cancer, and 10,000 fewer liver transplants.[33]

For these reasons, BIO strongly supports the CDC's recommendation that adults born from 1945 through 1965 should receive one-time testing for HCV and urges CMS to adopt any policies supportive of these guidelines.

C. CMS should update the Medicare manuals in a timely manner to be consistent with the recommendations of the CDC's ACIP.

CMS should update the Medicare benefit manuals to reflect the ACIP immunization recommendations in a timely manner. As an authoritative, and often sole, source of Medicare policy, the benefit manuals should accurately reflect the ACIP recommendations, which represent the most recent, medically relevant standard for use of vaccines to control disease. To do this, CMS should adopt a routine process for tracking ACIP recommendations and incorporating them in the Medicare benefit manuals in a defined, predictable amount of time.

VI. PHYSICIAN VALUE-BASED PAYMENT MODIFIER AND THE PHYSICIAN FEEDBACK REPORTING PROGRAM – BIO commends CMS for its deliberate approach and engagement with stakeholders in implementing the value-based payment modifier under the PFS and urges CMS to ensure that the program's measures provide incentives against underuse of appropriate care.

In the Proposed Rule, CMS presents additional proposals to implement the Value-Based Payment Modifier required by section 3007 of ACA. This separate budget-neutral payment modifier will be applied to the fee-for-service PFS payment formula to provide differential payment to a physician or groups of physicians based upon the quality of care furnished to Medicare beneficiaries compared to cost during a performance period.[34] This payment modifier will be phased in from January 1, 2015, through January 1, 2017. CMS proposes to begin phasing-in the modifier with groups of physicians with 25 or more eligible professionals.[35] CMS would divide those groups into two categories: (1) groups that have met the proposed criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentive or the proposed criteria for satisfactory reporting using the administrative claims-based reporting mechanism, applicable to the 2015 and 2016 PQRS payment adjustment; and (2) groups that have not met those reporting criteria.[36] Groups in the first category would have the option of having their value-based payment modifier calculated based on a quality-tiering approach that could result in positive or negative payment adjustments.[37] Groups in the second category would

[33] McGarry, L. J., et. Al. 2012 Economic Model of a Birth Cohort Screening Program for Hepatitis C Virus. *Hepatology* 55(5):1344-1355.
[34] 77 Fed. Reg. at 44991.
[35] Id. at 44995.
[36] Id. at 44995-96.
[37] Id. at 44996.

receive a negative 1.0 percent payment adjustment.[38] CMS also proposes to "align the value-based payment modifier with the PQRS and utilize Medicare claims data in order to reduce administrative burden on groups of physicians."[39] To this end, CMS proposes to include all measures in the PQRS Group Practice Reporting Option (GPRO) web-interface, claims, registries, and EHR reporting mechanisms for 2013 and beyond.[40] A composite score for each group would be calculated based on its performance on the quality measures and measures of total per capita cost and per capita cost for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes).[41]

CMS recognizes that "physician quality measurement is still evolving and that [its] methodologies are still developing."[42] BIO recognizes the complex issues associated with implementing the value-based modifier, particularly as quality measurement continues to evolve. We commend CMS's efforts to implement the modifier in a transparent manner with input from stakeholders, and we encourage CMS to continue to actively engage stakeholders as implementation progresses. It is critical for the agency to involve clinicians, treatment guideline developers, and clinical experts from manufacturers in the discussion as they are likely to have the cost data and clinical information necessary when considering how to implement the modifier. As CMS acknowledges, such a payment modifier has the potential to impact the delivery of care to Medicare beneficiaries, and therefore it is important that it be based on fair and actionable measures of patient costs and quality of care. BIO firmly believes that the manner in which this modifier is implemented will have a significant impact on clinical decision making.

BIO is concerned, in particular, that the cost and quality measurements may not fully capture the benefits of appropriate use of drugs and biologicals, or take into consideration that some specialists only provide care to beneficiaries for specific conditions and diseases for which quality measures may not be available. After considering the challenges of implementing value-based payment systems that succeed at improving quality and controlling costs, the Working Group on Optimizing Medication Therapy in Value-Based Healthcare (Working Group), composed of representatives of seven provider organizations, Premier, the American Medical Group Association, and the National Pharmaceutical Council developed a framework and recommendations for integrating pharmaceuticals into value-based purchasing systems. The Working Group recognized that it is critical to "proactively consider medications an essential part of the full spectrum of condition management, and not just an expense or care silo."[43] The group recommended that "in each circumstance where there are condition-specific incentives for

[38] Id.
[39] Id. at 44992.
[40] Id. at 44998.
[41] Id. at 45007.
[42] Id. at 44992.
[43] *See* DuBois, R. W., et al. 2012. Role of Pharmaceuticals in Value-Based Healthcare: A Framework for Success. *American Journal of Managed Care* 1;18(7):e, http://www.ajmc.com/articles/Role-of-Pharmaceuticals-in-Value-Based-Healthcare-A-Framework-for-Success.

achieving cost savings, there should also be a quality metric to detect underuse."[44] In addition, "the role, impact, and characteristics of medication therapy management will vary by condition, and a 'one size fits all' approach will not yield optimal clinical or economic outcomes."[45] We agree with these recommendations and we urge CMS to consider them as it moves forward with implementation of the Value-Based Payment Modifier. We also urge CMS to consider the long-term savings, such as reductions in hospitalizations and other patient costs, that may be achieved by appropriate use of drug and biological therapies that may be more costly in the shorter term yet yield substantial savings over time. We ask that as CMS proceeds with implementing the payment modifier, it seek to measure both per capita cost and quality of care over several years.

VII. PRIMARY CARE AND CARE COORDINATION – BIO supports CMS's proposal to create a HCPCS G-code for transition of care services.

BIO supports CMS's proposal to create a HCPCS G-code to describe transition of care services furnished by a treating physician to a beneficiary during a hospital or other institutional stay to care furnished by the beneficiary's primary physician in the community. Specifically, the code would describe "all non-face-to-face services related to the transitional care management furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services; and a partial hospitalization program at a CMHC to community-based care."[46]

BIO believes CMS's approach engenders coordinated, seamless care for Medicare beneficiaries at a crucial time in their treatment course, which often does not end with the conclusion of an inpatient stay. Robust care coordination has the potential to improve patient outcomes through increased medication management and decreased medical and medication errors. Assigning a G-code to capture the services related to transition of patient care provides a better assessment of this critical function.

VIII. OTHER ISSUES:CMS should clarify that its guidance on physician billing practices for certain Medicare Part B-covered drugs and biologicals provided under the DME benefit is directed specifically to that type of physician-administered drug or biological.

The Proposed Rule includes a clarification on how injectable drugs and biologicals used in conjunction with one particular type of DME should be billed to Medicare. In response to concerns raised regarding its 2010 and 2011 change requests (CRs 7109 and 7397), CMS uses this proposed rule to clarify the billing procedure for injectables used to refill intrathecal pumps,

[44] Id.
[45] Id.
[46] 77 Fed. Reg. at 44777.

a procedure performed in a physician's office because the subcutaneous location of the pump increases the risk and complexity of refilling it (compared to that of external DME).[47] In this case, CMS states that physicians must buy the injectable drugs and bill Part B directly. To avoid confusion by Medicare providers, BIO asks CMS to clarify that the applicability of this guidance is limited to drugs used to refill an implantable intrathecal pump covered under the Part B DME benefit.

IX. 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 these comments or need any additional information. Thank you for your attention to these very important matters.

Respectfully submitted,

/s/

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[47] Id. at 44793.