

August 30, 2011

BY ELECTRONIC DELIVERY

Donald Berwick, MD
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; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012; Proposed Rule [CMS-1524-P]

Dear Administrator Berwick:

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) 2012 (the "Proposed Rule").¹ BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, 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 about the increasingly substantial, negative updates to the conversion factor. The net cut of 29.5 percent in physician payment rates simply cannot be implemented without dire consequences to patient care. Although we recognize that preventing such a significant cut is largely within Congress's hands, we urge CMS to do anything in its power to mitigate these cuts and ensure that Medicare beneficiaries continue to have access to high quality care in 2012 and beyond.

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

- Urge CMS to ensure that the American Medical Association's (AMA) Relative Value Update Committee (RUC) review of certain drug administration codes is carried out

¹ 76 Fed. Reg. 42772 (July 19, 2011).

- 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;
- Agree that CMS should proceed cautiously and with sufficient public notice before substituting a therapy's widely available market price (WAMP) or average manufacturer price (AMP) for average sales price (ASP), particularly in light of the lack of guidance regarding the AMP definition;
 - Support CMS's proposed revisions to the Addendum A template and appreciate the guidance CMS has provided in the User Manual, but ask CMS to revise the User Manual to reflect the fact that negative values are not valid for ASP, ASP units, and wholesale acquisition costs (WAC);
 - Support CMS's proposal to require reporting on the basis of a specified unit where labeling indicates that the amount of drug or biological product represented by a national drug code (NDC) varies;
 - Ask CMS to ensure that all branded prescription drugs, including biologicals, receive their own Healthcare Common Procedure Coding System (HCPCS) codes, particularly now that data must be reported for purposes of the annual fee on branded pharmaceutical manufacturers;
 - Urge that CMS instruct its contractors to publish on their websites their fee schedule or reimbursement methodology for radiopharmaceuticals as a reference for providers;
 - Ask CMS to proceed cautiously as it implements the 3-day payment window policy and to ensure that Medicare continues to provide appropriate reimbursement for drugs, biologicals, and related administration services furnished by physician practices that are wholly owned or wholly operated by a hospital;
 - Applaud CMS for its proposal to include a health risk assessment (HRA) as part of the Medicare-covered annual wellness visit, but urge the agency to reimburse for it adequately;
 - Request that CMS clarify that the patient's personalized prevention plan under the HRA include *all* recommended vaccines, including those covered under Medicare Part D, and that the definitions of the first annual wellness visit and subsequent annual wellness visit include the option of vaccination by a physician, pharmacist or other healthcare practitioner, as allowed by state law;
 - Request that CMS consider screening guidelines issued by the Centers for Disease Control and Prevention (CDC) in addition to United States Preventive Task Force (USPSTF) and Advisory Committee on Immunization Practices (ACIP) recommendations when determining appropriate screening and preventive services for the Medicare population;
 - Support CMS's proposal to amend Category 2 evaluation criteria for telehealth services and to add smoking cessation to the list of Medicare covered telehealth services;
 - Support CMS's proposal to add smoking cessation counseling as a covered Medicare telehealth service;
 - Support CMS's proposal to revise telehealth consultation codes to include the emergency department site of service;

- Ask the agency to continue to encourage the development of quality measures related to care coordination as well as other evidence-based measures;
- Applaud the inclusion of National Quality Forum (NQF)-endorsed quality measures for influenza, pneumococcal, hepatitis A and hepatitis B vaccination in the appropriate beneficiaries under the physician fee schedule;
- Support CMS's proposal to develop quality measures for diseases and conditions that are prevalent among the Medicare population, such as chronic obstructive pulmonary disease (COPD) and elevated blood pressure, but request that CMS endorse those measures that are transparent and understood by all participants and by the public;
- Support CMS's continued efforts to implement the E-Prescribing (eRx) Incentive Program as proposed;
- Commend CMS for its deliberate approach and engagement with stakeholders in implementing the value-based payment modifier under the PFS and urge CMS to measure per capita costs and quality of care over a sufficiently long time frame; and
- Ask CMS to proceed cautiously as it implements the 3-day payment window policy and to ensure that Medicare continues to provide appropriate reimbursement for drugs, biologicals, and related administration services furnished by physician practices that are wholly owned or wholly operated by a hospital.

I. Potentially Misvalued Services 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 Proposed Rule, CMS notes that it has identified certain high PFS expenditure Current Procedural Terminology (CPT)² codes as potentially misvalued and proposes to request review of these codes by the AMA's RUC to ensure that the physician times, work relative value units (RVUs), and direct practice expense (PE) inputs are appropriately valued.³ 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.

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

² CPT is a trademark of the AMA.

³ 76 Fed. Reg. at 42794.

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 physicians are less likely to prescribe products that oblige them to carry out such requirements.⁴ 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 listed in the Proposed Rule. We urge CMS to ensure this occurs.

In addition, as discussed in section III below, we ask CMS to add CPT code 99420, Administration and interpretation of health risk assessment instrument (e.g., health hazard appraisal), to the list of potentially misvalued services, as it does not contain any RVUs for physician work.

II. Part B Drug Payments: ASP Issues

- A. CMS should continue to proceed cautiously and with sufficient public notice on any substitution of WAMP or AMP for ASP, particularly in light of the lack of guidance regarding the AMP definition.

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.⁵ 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.⁶ As CMS has recognized in the past, and reiterates in the Proposed Rule, “there are complicated operational issues associated with”

⁴ See, e.g., KA Slevin et al., Primary Care Physician Opinion Survey on FDA Opioid Risk Evaluation and Mitigation Strategies, *J Opioid Manage* 2011, 7(2): 109-115; PE Johnson et al., NCCN Oncology Risk Evaluation and Mitigation Strategies White Paper: Recommendations for Stakeholders, *J Natl Comp Canc Netw* 2010, 8: S-7-S-27.

⁵ SSA § 1847A(d)(3)(A).

⁶ 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”).

potential payment substitutions.⁷ Therefore, CMS has indicated that it will “proceed cautiously in this area.”⁸

BIO appreciates CMS’s caution in pursuing any potential price substitutions, but strongly urges CMS to postpone indefinitely the implementation of its proposal to begin AMP price substitution in CY 2012.⁹ BIO made the same recommendation last year when CMS first proposed substituting AMP for ASP when the substitution threshold was met.¹⁰ CMS ultimately did not adopt that policy due to the “legislative changes, regulatory changes, and litigation that affected this issue.”¹¹ According to CMS, it is now appropriate to revisit the issue of price substitution. BIO strongly disagrees.

In the Proposed Rule, CMS suggests that the fact that statutory provisions currently do “exist and are currently utilized by manufacturers for the calculation and submission of AMP” is sufficient to justify price substitution.¹² There remains significant ambiguity in the statutory language, however, and CMS still has not provided any guidance to manufacturers on either the new definition of AMP included in the Affordable Care Act (ACA) or 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 last year. In fact, CMS does not even mention the new alternative AMP definition in the Proposed Rule. This oversight is particularly disturbing given that such therapies are more likely to be subject to ASP reporting and that the two alternative AMP definitions include very different categories of sales and discounts, and therefore, could produce significantly different AMP values for the very same drug or biological. CMS cites the November 15, 2010 Medicaid final rule in its discussion of the applicable AMP guidance, but this final rule merely deleted the provisions of the existing regulations that conflicted with the new ACA AMP definition and did not provide any guidance on how that definition should be implemented.

The guidance CMS ultimately provides almost certainly will affect the relationship between AMP and ASP, and accordingly, the appropriateness of price substitution. For example, CMS still must provide guidance regarding how a manufacturer is to determine 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 guidance absolutely will affect how a drug’s AMP will relate to its ASP, but CMS has not yet issued that guidance. Therefore, we strongly urge CMS to delay implementation of any payment rate substitution until it has issued guidance regarding the AMP definitions and given manufacturers the opportunity to implement that guidance.

⁷ 76 Fed. Reg. at 42828.

⁸ Id.

⁹ Id. at 42828-32.

¹⁰ *See* 75 Fed. Reg. 40040, 40156 (July 13, 2010).

¹¹ 76 Fed. Reg. at 42829.

¹² Id.

BIO supports CMS's proposal to continue the applicable threshold for both the AMP and WAMP at 5 percent. For CY 2012, CMS is further proposing that comparison of ASP and AMP only be made when "[t]he ASP for the billing code has exceeded the AMP for the billing code by 5 percent or more in two consecutive quarters, or three of the last 4 quarters immediately preceding the quarter to which the price substitution would be applied."¹³ BIO agrees with CMS that comparison based on a single quarter of ASP and AMP data may reflect only a temporary fluctuation in market prices and not adequately account for underlying market trends.¹⁴ We note, however, that CMS's proposed amendments at section 414.904(d)(3)(iii)(A) may not reflect the three quarter time lag that CMS has identified for substituted prices from the quarter in which the manufacturer sales occurred. This means that the quarters available for purposes of comparing AMP and ASP will not necessarily be those quarters "immediately preceding" the quarter to which the price substitution recommendation would apply. In light of these considerations, we propose the following revisions to CMS's proposed regulatory text at section 414.904(d)(3)(iii)(A):

(A) The ASP for the billing code has exceeded the AMP for the billing code by 5 percent or more in ***the most recent*** two consecutive quarters, or three of the last 4 quarters, preceding the quarter to which the price substitution would be applied ***and for which comparison data are available from the Inspector General.***

We note that these timing considerations also may affect the extent to which CMS can rely on the Office of Inspector General (OIG) analysis as a predictor of savings under CMS's proposal. In support of its proposal, CMS refers to the OIG's "Comparison of Third-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for the First Quarter 2011" that estimates that reimbursement based on 103 percent of AMP would have reduced Medicare expenditures by \$10.3 million in the first quarter of 2011.¹⁵ As set forth in CMS's proposed amended regulation at 42 CFR. § 414.904(d)(3)(i), the payment substitution is applied at the *next* ASP payment amount calculation period after the OIG informs CMS that a drug or biological has exceeded the threshold percentage.¹⁶ The OIG's estimate, in contrast, is based on applying the price substitution to the first quarter 2011 – the same quarter for which the OIG has performed the comparison analysis of the underlying (third quarter 2010) ASP and AMP data – and therefore, may not be an accurate predictor of the actual reduction in expenditure associated with applying the price substitution in accordance with the SSA and CMS regulation to a future quarter. The OIG's estimate also is not based on a substitution of only those ASPs for which the ASP exceeds the AMP in the most recent two consecutive or three out of four quarters, as would be true with CMS's proposal.

BIO also supports CMS's proposal to apply substitution of 103 percent of AMP for 106 percent of ASP only where the AMP and ASP comparisons are based on the same set of NDCs

¹³ *Id.* at 42947 (proposed 42 C.F.R. § 414.904(d)(3)(iii)(A)).

¹⁴ *Id.* at 42829.

¹⁵ *Id.* at 42831.

¹⁶ *Id.* at 42947.

for the billing code, as we agree that “incomplete” AMP data may not adequately account for market-related drug price changes.¹⁷ We recommend that CMS also specify in its final rule that the AMP and ASP must be calculated using the same ASP volumes for the quarter to avoid comparison of inconsistent or inappropriate volume-weighted prices.

Finally, BIO agrees with CMS that any price substitution only should last for a single quarter. BIO also continues to support CMS’s policy of providing adequate notice to manufacturers impacted by a potential price substitution and urges CMS to work closely with affected 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. BIO supports CMS’s proposed revisions to the Addendum A template and appreciates the guidance CMS has provided in the User Manual, but asks CMS to revise the User Manual to reflect the fact that negative values are not valid for ASP, ASP units, and WAC.

CMS is proposing to revise the Addendum A template to (1) split the NDC column into three separate reporting fields, corresponding to the three segments of an NDC; (2) add a new field to collect an Alternate ID for products without an NDC; and (3) expand the current FDA approval number column to account for multiple entries and supplemental numbers.¹⁸ CMS also has added a macro to the Addendum A template that allows manufacturers to validate the format of their data prior to submission. BIO supports CMS’s proposed revisions, and we agree that they will facilitate more accurate and consistent ASP data reporting, thereby reducing the administrative burden associated with manufacturers’ price reporting obligations. We appreciate CMS’s efforts to review, and, as necessary, revise, its data collection tools.

We also appreciate that CMS has released a User Manual to assist manufacturers in completing Addendum A.¹⁹ We believe that this provides helpful guidance and will aid manufacturers in completing their ASP submissions. We note, however, that with regard to the entry of ASP, number of ASP units, and WAC in Addendum A, the User Manual indicates that “valid values” are “[a]ny positive or negative numbers including zero.”²⁰ We do not think that negative numbers are valid for these fields and urge CMS to revise the Manual to indicate that negative values are not “valid” for ASP, ASP units, and WAC in Addendum A. We request that the Manual instead instruct manufacturers who have negative values to report “0.000,” as manufacturers are instructed to do when they have no ASP, ASP units or WAC to report.

¹⁷ Id. at 42830.

¹⁸ Id. at 42832.

¹⁹ ASP Data Collection Template/Data Validation Macro User Manual, Version 1.4, available at: https://www.cms.gov/McrPartBDrugAvgSalesPrice/01a11_CY2012_Changes_to_Reporting.asp
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²⁰ Id. at 6.

- C. BIO supports CMS's proposal to require reporting on the basis of a specified unit where labeling indicates that the amount of drug or biological product represented by an NDC varies.

Manufacturers are required to report ASP price and volume data at the NDC level.²¹ There are, however, a limited number of drug and biological products, as defined by an NDC, that contain a variable amount of active ingredient such that vials with the same NDC but different volumes might be sold during the same ASP reporting period. CMS explains that this proposal would apply to only a few plasma-derived products, such as clotting factors and a treatment for antitrypsin deficiency. BIO recognizes that, for these products, the variability could affect the accuracy of pricing calculations. In order to avoid inaccuracies, BIO supports CMS's proposal to maintain a list of HCPCS codes for which manufacturers report ASPs for NDCs on the basis of specified unit. CMS is proposing to update this list through program instructions or other subregulatory guidance.²² BIO urges CMS to ensure that manufacturers are given adequate notice of any changes to this list so that they have sufficient time to provide the alternative reporting that CMS requires.

- D. 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 these products, as required by section 1847A of the SSA.²³ 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 said in our comments to last year's proposed rule, 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.²⁴ 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

²¹ 42 C.F.R. § 414.804(a)(1).

²² 76 Fed. Reg. at 42833.

²³ 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.

²⁴ ACA § 9008(e)(2).

and allocated price . . . for those branded prescription drugs that are not separately payable or for which NDCs are not reported.”²⁵ 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.²⁶ 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.

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

III. Incorporation of HRA Into Annual Wellness Visit

- A. BIO applauds CMS for its proposal to include a HRA as part of the Medicare covered annual wellness visit, but we urge the agency to reimburse for it adequately.

BIO applauds CMS’s proposal to include a HRA as a part of the annual wellness visit covered under Part B through section 4103 of the ACA.²⁷ We believe that the addition of the HRA to the list of services provided in the annual wellness visit under 42 C.F.R. § 410.15 will both promote the health of Medicare beneficiaries and help control Medicare costs.

BIO recommends that CMS consider incorporating prevention-related services into the definition of what the HRA entails. The proposed form of the HRA evaluation tool explicitly collects information on family history, body-mass index, and history of tobacco use, all of which

²⁵ ACA § 9008(g)(2).

²⁶ Internal Revenue Service. Notice 2011-9, at 7 (Jan. 14, 2011).

²⁷ 76 Fed. Reg. at 42837.

contribute to wellness. In addition, BIO suggests that the HRA collect information specifically related to preventive services. This would include history of appropriate vaccinations (e.g. pneumonia and influenza) as well as tobacco screening and cessation counseling.

BIO remains concerned, however, that payment for the HRA is not adequately included in the proposed payment for the annual wellness visit under HCPCS codes G0438 (Annual wellness visit; includes a personalized prevention plan of service [PPPS], first visit) and G0439 (Annual wellness visit; includes a PPPS, subsequent visit). In addition to inadequately paying for this valuable service, BIO is concerned that this payment policy establishes a negative precedent for future preventative services that may be implemented through the coverage process. Section 101(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) permits CMS to add coverage of additional preventative services under certain conditions. Specifically, if CMS determines through the national coverage determination process that the service is recommended with a grade A or B rating by the USPSTF and meets certain other requirements, the service can be covered.²⁸ Should CMS not adequately pay for the HRA, or include the appropriate services within the HRA, the payment rate for all future preventative services could also be inadequate due to this precedent.

In the CY 2011 final rule, CMS stated that it would reevaluate payment for the annual wellness visit once the HRA was incorporated.²⁹ In the CY 2012 Proposed Rule, however, CMS refers back to its conclusion in the CY 2011 final rule that because “the services described by CPT codes 99204 and 99214 already include ‘preventive assessment’ forms,” those codes continue to be the most appropriate crosswalk for reimbursement of the annual wellness visit, even now that it contains the HRA.³⁰ In order to ensure that physicians are adequately compensated for providing wellness visits and other preventive services, as a means to promote prevention, BIO encourages CMS to revisit the coding and reimbursement for annual wellness visits to ensure that physicians are appropriately reimbursed for time and resources involved. Insufficient payment will discourage physicians from providing these visits and future preventive services, which in turn decreases the likelihood that they will furnish these valuable services. . Neither CPT code 99204 (Level 4 new patient office or other outpatient visit) nor CPT code 99214 (Level 4 established patient office or other outpatient visit) includes a requirement for an HRA, however, and BIO continues to believe that reimbursement for the annual wellness visit under a crosswalk to those codes is inadequate in light of the increased work and resources spent by physicians and health care professionals in administering and interpreting the HRA. Accordingly, BIO urges CMS to incorporate the RVUs for existing CPT code 99420, Administration and interpretation of health risk assessment instrument (e.g., health hazard

²⁸ For example, CMS recently initiated a few National Coverage Analyses in light of this authority, which include (1) Intensive Behavioral Therapy for Obesity; (2) Intensive Behavioral Therapy for Cardiovascular Disease; (3) Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse; and, (4) Screening for STIs and HIBC for the prevention of STIs. (<http://www.cms.gov/medicare-coverage-database/indexes/nca-open-and-closed-index.aspx?bc=BAAAAAAAAAAAAA&#Open>)

²⁹ See 75 Fed. Reg. 73369, 73411 (Nov. 29, 2010).

³⁰ 76 Fed. Reg. at 42839.

appraisal), into G0438 and G0439 to recognize the additional resources necessary to appropriately perform a HRA. In addition, the current physician work RVU for CPT code 99420 is zero. We urge CMS to refer this code to the AMA's RUC to survey physician specialties to determine an appropriate physician work RVU for this code.

- B. BIO requests that CMS clarify that the patient's personalized prevention plan should include *all* recommended vaccines, including those covered under Medicare Part D, and that the definitions of the first annual wellness visit and subsequent annual wellness visit include the option of vaccination by a physician, pharmacist or other healthcare practitioner, as allowed by state law.

BIO believes that the new annual wellness visit that provides a personalized prevention plan for all Medicare Part B beneficiaries will help to ensure that America's seniors receive important preventive services such as immunizations. We hope that the addition of this annual visit will lead to increased immunization rates and therefore a decrease in the illness, hospitalizations and deaths they are meant to prevent. To meet this important goal, we urge CMS to:

1. Ensure that all types of healthcare providers understand the need to include immunizations in the preventive services plan;
2. Ensure that the full set of vaccines recommended by the ACIP are included in the healthcare providers' planning, regardless of whether the vaccine is covered by Medicare Part B or Part D; and
3. Include in the definitions of the first and subsequent annual wellness visits providing personalized prevention plan services, the option of seeking such services through a physician, pharmacist or other healthcare practitioner, as appropriate, to implement the patient's screening and immunization schedule.

Section 4103 of ACA includes within the list of elements that may be contained within a patient's personalized prevention plan the establishment of "[a] screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the USPSTF and ACIP, and the individual's health status, screening history, and age-appropriate preventive services covered under this title." We ask that CMS revise its proposed regulatory definition of a "First annual wellness visit providing personalized prevention plan services" at 42 CFR § 410.15 to include establishment of "[a] written screening *and immunization* schedule for the individual" to underscore the inclusion of those immunizations recommended by ACIP as part of this personalized prevention plan. BIO further requests that CMS make this same change to the proposed definition of "Subsequent annual wellness visit providing personalized prevention plan services" in section 410.15 to include an update to "[t]he written screening *and immunization* schedule for the individual"

BIO also urges CMS to make clear that the immunization portion of the annual prevention services plan should incorporate *all* of the recommended vaccines for the individual patient based on his or her age and specific health needs. ACIP's adult immunization schedule, which includes recommendations by age and by underlying medical conditions, includes approximately nine vaccines that might be appropriate for Medicare beneficiaries. Due to the

structure of the Medicare program, however, at present only three of these ACIP-recommended vaccines are included in Part B: influenza, pneumococcal and hepatitis B vaccines. All of the other vaccines recommended for seniors currently are covered under Medicare Part D. BIO is concerned that without this clarification, health care providers will not include key immunizations recommended by the ACIP in the patient's immunization schedule because they are covered only by Medicare Part D. We ask CMS to add the following sentence to its proposed description of the written screening schedule at 42 CFR § 410.15: "This written screening and immunization schedule shall include all vaccines recommended by the Advisory Committee on Immunization Practices for an individual based on age, risk status or underlying medical condition, as set forth in the Recommended Adult Immunization Schedule, regardless of whether those vaccines are covered under Medicare Part B or Part D."

Finally, BIO emphasizes that pharmacists, especially in the retail sector, are pivotal to the full implementation of influenza and pneumococcal vaccination programs across the nation. Information from the American Pharmacists Association for 2009 showed that U.S. pharmacists delivered over 16 million doses of vaccine across all age groups. The convenience and accessibility of pharmacists' locations has been very important for seniors, and we believe these factors will continue to be important in implementing the patient's immunization schedule set forth in the personalized prevention plan. For these reasons, BIO asks CMS to also include in the proposed regulatory definitions of "First annual wellness visit providing personalized prevention plan services" and "Subsequent annual wellness visit providing personalized prevention plan services" at 42 CFR § 410.15 the option of vaccination by a physician, pharmacist or other healthcare practitioner, as allowed by state law.

C. BIO requests that CMS consider screening guidelines issued by the CDC in addition to USPSTF and ACIP recommendations when determining appropriate screening and preventive services for the Medicare population.

In establishing guidelines for the annual wellness visit, the Secretary has included a requirement for "a written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on the recommendations of the USPSTF, the ACIP, and the individual's health status, screening history, and age-appropriate preventive services covered by Medicare."³¹

We commend this initiative to improve the health of Medicare beneficiaries and support the use of evidence-based guidelines. However, we also recognize that there are certain areas, such as screening for hepatitis C, where the USPSTF recommendations are inconsistent with other existing guidelines, such as those issued by the CDC. As such, we would urge the Secretary to amend the regulations to include consideration of the evidence-based CDC guidelines in addition to USPSTF and ACIP recommendations when determining appropriate screening and preventive services for the Medicare population.

³¹ Id. at 42836.

MIPPA authorized CMS to cover and reimburse for preventive services given an "A" or "B" rating by the U.S. Preventive Services Task Force (USPSTF). Similarly, the ACA provides statutory authority for Medicare beneficiaries to receive a personalized prevention plan that incorporates ACIP-recommended vaccines. However, discrepancy between what is recommended by authoritative sources and what is covered by Medicare continues to be problematic, especially as more preventive services are proven to be effective. While we acknowledge that CMS lacks the authority to determine coverage for preventive services in Medicare, it is important that the agency encourage providers to rely on preventive evidence base guidelines, including those outside of ACIP and USPSTF.

In the United States, 2.7–3.9 million people are chronically infected with the hepatitis C virus.³² However, approximately 75 percent of those infected are unaware of their status.³³ Given the asymptomatic nature of hepatitis C, some patients may not know they have the disease until they experience symptoms of more severe liver disease, which can take decades to emerge. Left untreated, hepatitis C can lead to serious chronic conditions, including liver failure, cirrhosis and liver cancer. In addition, hepatitis C-related liver disease is a leading reason for liver transplants.³⁴

Baby boomers account for two out of every three cases of HCV infection,³⁵ which means the impact to Medicare may be significant if their disease goes unrecognized and untreated. As the population ages, one study estimates that Medicare's share of chronic HCV-infected patients could increase from 12 percent in 2009 to 39 percent in 2028.³⁶ Over the next 20 years, total annual Medicare costs associated with treating hepatitis C infection are projected to increase substantially, from \$5 billion to \$30 billion, unless changes are made to the way these patients are identified and managed.³⁷

We commend the Secretary for addressing this public health crisis and releasing a national "Action Plan for the Prevention, Care and Treatment of Viral Hepatitis"³⁸ that underscores the importance of identifying persons infected with viral hepatitis early in the course of their disease. However, despite the risks associated with not diagnosing this disease, as well

³² Heather M. Colvin and Abigail E. Mitchell, eds. "Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C." Committee on the Prevention and Control of Viral Hepatitis Infections; Institute of Medicine, pg. 21 (2010). Available at <http://www.nap.edu/catalog/12793.html>.

³³ *Id.* at pg. 26.

³⁴ Pyenson, B. et al. "Consequences of Hepatitis C Virus – Costs of a Baby Boomer Epidemic of Liver Disease." Milliman, Inc., pg. 10 (Report commissioned by Vertex Pharma. Inc.). May 2009.

³⁵ Pyenson, *supra* note 9 at pg. 4.

³⁶ *Id.* at pg.13.

³⁷ *Id.* at pg. 3.

³⁸ U.S. Department of Health and Human Services. "Action Plan for the Prevention, Care and Treatment of Viral Hepatitis." May 2011. Available at: http://www.hhs.gov/ash/initiatives/hepatitis/actionplan_viralhepatitis2011.pdf

as the potentially high cost burden if left untreated, USPSTF has recommended against the practice of screening the general population who are not at increased risk for hepatitis C virus and has found insufficient evidence to recommend for or against routine screening for hepatitis C in adults at high risk for infection. This is inconsistent with the CDC guidelines, which recommend that people at high risk for hepatitis C be screened. It is also our understanding that the CDC intends to update its screening guidelines in 2012 to recommend one-time hepatitis C screening for all adults born between the years of 1946 to 1965 who have a higher prevalence of hepatitis C than the general population and typically do not know they are infected. The Secretary has indicated in the action plan that Health and Human Services (HHS) will initiate actions to support USPSTF efforts to update its guidelines and, to the extent possible, coordinate across agencies to ensure that guidelines for hepatitis testing, care and treatment are aligned. However, until progress is made with these initiatives to improve and promote early identification of infected individuals, we urge the Secretary to consider updating existing regulations to include screening recommendations consistent with the CDC guidelines.

IV. Quality Reporting Initiatives

A. CMS should continue to encourage the development of quality measures relating to care coordination as well as other evidence-based measures.

BIO commends CMS for its continued leadership in developing care coordination measures that will improve care and efficiency in our fragmented health care system. As patients are transferred from one care setting to another, such as between departments in the hospital, from the emergency room to the hospital, or from the hospital to the patient's home or a skilled nursing facility, communication is vital to continuity of care and desirable health outcomes. Unfortunately, patients and their families often bear the burden of initiating and coordinating follow-up care despite the fact that they lack the necessary clinical knowledge.

A number of studies have found that insufficient care coordination, medication errors, and miscommunication may contribute to increased costs and suboptimal care outcomes.³⁹ Although all patients experience transitions of care that necessitate some level of coordination between providers, the lack of care coordination particularly can affect patients with chronic conditions. Given the broad need for care coordination, CMS should continue to encourage consensus organizations to develop appropriate measures and such measure updates should be physician-led, such as the proposed "Melanoma: Coordination of Care" measure.⁴⁰ Inclusion of this and other care coordination measures will improve patient care and lead to improved outcomes as well as more efficient use of limited healthcare resources.

³⁹ Institute of Medicine. "Crossing the Quality Chasm: A New Health System for the 21st Century." Washington, DC: National Academy Press, 2001; EA Coleman et al. "Posthospital Care Transitions: Patterns, Complications, and Risk Identification." *Health Serv Res.* 2004 October; 39(5): 1449–1466; AJ Forster et al. "The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital." *Ann Internal Med* 2003, 138(3): 161-67.

⁴⁰ 76 Fed. Reg. at 42867.

- B. BIO applauds the inclusion of NQF-endorsed quality measures for influenza, pneumococcal, hepatitis A, and hepatitis B vaccination in the appropriate beneficiaries under the physician fee schedule.

BIO supports the development and use of appropriate, evidence-based quality measures throughout the healthcare system, and we believe that adult immunizations should be included at every level of the healthcare system. Performance measures are currently in place for all vaccines in the pediatric and adolescent series and these measures have had a positive impact on utilization and prevention. A similar level of success has not been reached in adults. Only 26 to 65 percent of adults receive ACIP-recommended vaccines, depending on the vaccine and target population.⁴¹ As a result of low vaccination coverage, 40,000 to 50,000 adults die annually from vaccine-preventable diseases in the United States.⁴² The direct annual cost of vaccine-preventable disease in adults in the United States is approximately \$10 billion.⁴³ Using 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 cost savings.

The health and economic benefits of adult immunization measures are evident following the introduction of performance measures for influenza and pneumococcal vaccinations in the Veterans Health Administration (VHA) in 1995. Among eligible adults, influenza vaccination rates increased from 27 to 70 percent, and pneumococcal vaccination rates rose from 28 to 85 percent, with limited variability in performance between networks. Pneumonia related hospitalization rates decreased by 50 percent and it is estimated that the VHA saved \$117 for each vaccine administered.⁴⁴

- C. BIO applauds CMS's proposal to develop quality measures for diseases and conditions that are prevalent among the Medicare population, such as chronic obstructive pulmonary disease (COPD) and elevated blood pressure, but we request that CMS endorse those measures that are transparent and understood by all participants and by the public.

BIO supports CMS in its efforts to expand the physician quality reporting system (PQRS) and we continue to encourage CMS to expand quality reporting in the physician office setting in ways that will improve patient care and facilitate better physician decision-making. BIO urges CMS to regularly revise its quality measures to reflect current guidelines in order to promote the provision of up-to-date care to Medicare patients. At the same time, we urge CMS to remain

⁴¹ Id.

⁴² Infectious Diseases Society of America and the Robert Wood Johnson Foundation. "Trust for America's Health. Adult Immunization: Shots to Save Lives." February 2010. Available at: <http://healthyamericans.org/report/73/adult-immunization-2010>.

⁴³ Id.

⁴⁴ Jha A, Wright S, and J. Perlin. "Performance measures, vaccinations, and pneumonia rates among high-risk patients in Veterans Administration Health Care." *Am J Public Health*. 2007; 97(12):2167-2172.

focused on supporting those quality measures that are reliable, valid, and transparent. Quality measurement is meaningful only to the extent that the measures proposed and finalized are comparable across all providers and understood by participants, stakeholders and the public.

BIO is concerned that some of the measures CMS is proposing for CY 2012 are not endorsed by the NQF or other consensus-based measure development entities. For example, while BIO supports CMS in its proposal to incorporate quality measures related to elevated blood pressure into the PQRS, we are concerned that some of the measures within this category are not easily identifiable. For all of the measures listed in this category, the developer is listed as the American Board of Internal Medicine (ABIM). Yet, for three of the proposed measures within this category, "Complete Lipid Profile," "Counseling for Diet and Physical Activity," and "Patient Self-Care and Support," we were unable to locate an ABIM measure that uniquely corresponded with the measure proposed by CMS. For example, several measures appeared to have some relationship to the titles proposed by CMS, but it was not clear which, if any, CMS is proposing to include in the PQRS.

In order for BIO and other stakeholders to provide meaningful comments on quality measures proposed for CY 2012 as well as future reporting cycles, CMS must continue to provide transparency into the process, including the methodologies, algorithms, and the data on which proposed measures are based. Therefore, while BIO supports CMS in expanding the PQRS program in addition to its commitment to increasing provider participation, we urge the agency to continue to do so in a transparent manner.

D. CMS should establish a process for updating measures and removing out-of-date measures, in a timely manner.

BIO appreciates CMS's continued commitment to developing and proposing new quality measures under the PQRS. CMS does not, however, specifically indicate how it will update measures based on changes instituted by the organization endorsing the measures or based on other clinical considerations. Nor does CMS address removal of outdated measures. BIO believes that it is crucial for CMS to provide guidance in this regard given the important role that quality performance plays in the PQRS. If out-of-date or inappropriate measures are left in place, physicians will nonetheless be compelled to meet the specifications in order to be eligible for incentive payments. This could result in suboptimal patient care.

One example of this is CMS's proposed measure on warfarin therapy (CMS measure #200; NQF measure #0084).⁴⁵ According to the NQF, this measure would assess the percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.⁴⁶ This measure is already outdated. There are more advanced therapeutic options available for these patients today as well as

⁴⁵ 76 Fed. Reg. at 42869.

⁴⁶ National Quality Forum. Measure Number 0084, Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation. Available at: <http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=385#k=0084>

additional therapies in development. Leaving the measure in place may force physicians to use a therapy that is no longer the only clinically-appropriate, or even recommended, choice.

Based on this example, BIO asks CMS to institute a process for reviewing the existing measures and for updating or removing measures that are outdated on a timely basis, and in no event later than six months after the date at which the measure becomes obsolete. CMS may also consider creating an exception process for providers who follow new guidelines or measures so as to not hinder patient care when quality measures lag behind changes in treatment.

V. Incentives and Payment Adjustments for Electronic Prescribing – CMS should continue to implement the eRx Incentive Program as proposed.

The MMA promoted the use of e-prescribing by requiring the adoption of uniform standards for the Part D e-prescribing program. Section 1848(m) of the SSA, as amended by section 132 of MIPPA further promotes the use of e-prescribing by authorizing incentive payments to eligible professionals or group practices who are “successful electronic prescribers.” BIO agrees with CMS that this program is intended “to continue to encourage significant expansion of the use of electronic prescribing by authorizing a combination of financial incentives and payment adjustments,” particularly because incentive payments are separate from an addition to any PQRI payments.⁴⁷ We continue to support the specific proposals CMS makes with respect to the criteria for determining successful e-prescribers and successful reporting, how measures are reported, and the required functionalities for a qualified e-prescribing system and ask CMS to finalize them.

VI. Proposals Related to Telehealth Services for CY 2012

A. BIO supports CMS's proposal to amend criteria for Category 2 evaluation of covered telehealth services.

In the Proposed Rule, CMS proposes to refine its criteria for adding Category 2 codes to the list of Medicare telehealth services starting in CY 2013. Current Category criteria require requestors to “submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the requested service.”⁴⁸ For CY 2013, CMS is proposing to modify its current requirement to demonstrate clinical comparability (i.e. similar diagnostic findings or therapeutic interventions) to the same service when provided face-to-face and to instead require only a demonstration of clinical benefit without any direct comparison. As the proposed Category 2 criteria state, “Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.”⁴⁹

⁴⁷ 76 Fed. Reg. 42885.

⁴⁸ *Id.* at 42822-42823.

⁴⁹ *Id.* at 42827.

Since the Category 2 criteria were proposed in 2003, no applicant has been able to demonstrate clinical comparability of a proposed telehealth service with the same service when provided face-to-face. Therefore, no proposed telehealth services have been added based on the current Category 2 criteria. In our view, the clinical comparability standard is too high of a threshold and may be preventing Medicare beneficiaries from receiving needed services. The promise of telemedicine extends beyond services that are similar to office visits; and in some cases, for example, physical and occupational therapy, the alternative to care via telehealth may be no care or service at all. As such, BIO supports CMS's proposal to modify the criteria used to evaluate Category 2 telehealth requests and replace the existing comparability standard with a demonstrated clinical benefit standard.

BIO applauds CMS for recognizing this limitation and supports its proposal to revise the Category 2 criteria to make it more likely for these services to be added to the list of telehealth services. The proposed standard is appropriately rigorous and will allow for additional services to be added to the list of telehealth services and expand access for patients without introducing risk of harm to beneficiaries.

B. BIO supports CMS's proposal to add smoking cessation counseling as covered Medicare telehealth service.

CMS proposes to include smoking cessation counseling as a covered Medicare telehealth service.⁵⁰ Smoking is a risk factor for several chronic diseases such as emphysema, chronic bronchitis, coronary artery disease, atherosclerosis, stroke, heart disease, diabetes, hypertension and cancer. BIO supports CMS's decision to include smoking cessation counseling as a covered Medicare telehealth service because we believe that it will provide patients at-risk for developing chronic conditions access to education services that may help in controlling the progression of disease. We believe that providing Medicare beneficiaries with access to smoking cessation telehealth services, especially those that reside in rural areas with limited access to health care, will furnish them with information that could enable better disease prevention and health promotion. BIO therefore encourages CMS to adopt its proposal to include smoking cessation as a covered telehealth benefit.

C. BIO supports CMS's proposal to revise telehealth consultation codes to include the emergency department site of service.

BIO supports CMS's proposal to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. As discussed in the Proposed Rule, with the 2010 elimination of consultation codes, and the resulting guidance provided for inpatient telehealth consultations, there was no clear path for billing a telehealth consultation in the emergency department.

Telehealth, including telemedicine, is playing an increasingly important role in improving patient access to quality health care in the emergency department. For example, stroke, a leading

⁵⁰ Id. at 42823.

cause of disability, is a complex disease that requires rapid diagnosis and specialized care. Many patients with stroke present in the emergency department and require immediate diagnosis in order to begin disease-altering therapy such as tissue plasminogen activator. A variety of conditions can mimic acute stroke and the ability to rapidly and accurately differentiate among these can be challenging for physicians without neurological expertise.⁵¹ However, access to neurologists across the United States is limited, especially in rural areas, because there are approximately 4 neurologists per 100,000 persons.⁵² The use of telemedicine for diagnosis and treatment of stroke has been critical in linking patients with timely, expert care, which in turn may improve care through the initiation of treatment more rapidly. Therefore, BIO supports CMS's proposal to revise the telehealth consultation code descriptors to explicitly allow them to be used in the emergency department.

VII. Improvements to the Physician Feedback Program and Establishment of the Value-Based Payment Modifier (Effect of Sections 3003 and 3007 of the ACA on the 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 measure per capita costs and quality of care over a sufficiently long time frame.

CMS explains in the preamble to the Proposed Rule that it is continuing to implement changes made by the ACA to the Physician Feedback Program, a program that provides confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. In 2011, CMS will pursue Phase III of the Program, expanding the number of physicians who receive feedback reports, with the expectation of expanding dissemination of reports to cover 100,000 physicians nationally in CY 2012.⁵³ CMS also explains that its Medicare-specific episode grouper, required by section 3003 of ACA to be developed by January 1, 2012, requires further testing and development but that aspects of the episode grouper could be applied on a limited basis in feedback reports in 2012 or 2013.⁵⁴ The agency anticipates that the episode grouper will determine episode-based costs for a subset of high cost, high volume conditions, including six of the following nine conditions: hip fracture/hip replacement; pneumonia; heart attack; coronary artery disease; asthma; COPD; stroke; diabetes; and heart failure.⁵⁵

In addition, section 3007 of ACA requires the Secretary to apply a separate budget-neutral payment modifier to the fee-for-service PFS payment formula that will provide for differential payment to a physician or group of physicians based on the relative quality and cost

⁵¹ Schwamm, Lee et al. "Recommendations for the Implementation of Telemedicine Within Stroke Systems of Care: A Policy Statement From the American Heart Association," *Stroke*, *Journal of the American Heart Association*, pg. 2639 (May 7, 2009).

⁵² *Id.* at 2638.

⁵³ 76 Fed. Reg. at 42907.

⁵⁴ *Id.*

⁵⁵ *Id.*

of care of their Medicare beneficiaries.⁵⁶ This payment modifier will be phased in beginning January 1, 2015 through January 1, 2017. In the Proposed Rule, CMS recognizes the need to move deliberately in implementing differential payment and to engage stakeholders in an extensive dialogue on implementation. The Proposed Rule begins to lay out specific measures on which a payment modifier would be based and proposes specific quality of care measures for physicians.⁵⁷

As CMS continues to evaluate and propose new measures under the value-based payment modifier, we urge the agency to establish a process for updating measures and removing out-of-date measures, in a timely manner. In the Proposed Rule, CMS recommends under the payment modifier quality measure entitled "Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation."⁵⁸ As stated in Section IV of this comment letter in our discussion of quality measures under the PQRS, BIO is concerned that if physicians are required to comply with out of date performance measures, patient care could be compromised. BIO therefore asks CMS to institute a process for reviewing the existing measures and for updating or removing measures that are outdated on a timely basis, and in no event later than six months after the date at which the measure becomes obsolete.

With respect to cost-related measures for the value based payment modifier, BIO urges CMS to ensure that patient care is not being compromised in efforts to reduce costs. BIO recommends that continued efforts to develop and deploy measures should be focused on performance rather than service volume (e.g., resource use measures). BIO advises CMS to assure that all measures for reporting adequately assess quality, without inappropriately incentivizing cost reductions. Additionally, we encourage CMS to ensure these measures are harmonized with other programs, so physicians are not overburdened in tracking additional measures.

BIO commends CMS for holding listening sessions to seek input on implementation of the payment modifier under section 3007, 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 per capita cost information for those beneficiaries with the nine conditions identified by CMS for possible inclusion in the episode grouper may not reflect the long-term reduction in hospitalizations and other patient costs that are achieved by prescribing drug and biological therapies that may be more costly in the shorter term and yet yield substantial savings over time. We urge CMS to consider the long-term

⁵⁶ Id. at 42908.

⁵⁷ Id. at 42909-11.

⁵⁸ Id. at 42869.

savings that may be achieved by such treatments and 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.

VIII. 3-Day Payment Window Policy – BIO asks CMS to proceed cautiously as it implements the 3-day payment window policy and to ensure that Medicare continues to provide appropriate reimbursement for drugs, biologicals, and related administration services furnished by physician practices that are wholly owned or wholly operated by a hospital.

CMS proposes to require physician practices owned or operated by hospitals to apply a modifier to preadmission non-diagnostic services related to the admission and all diagnostic services provided during the 3-day payment window.⁵⁹ The hospital would be required to notify the physician about the admission so the physician can apply the modifier.⁶⁰ If the patient is admitted to the hospital, the physician would be paid only for the professional component or the facility setting rate for the non-diagnostic service provided.⁶¹

BIO is concerned about the potential impact of this proposal on access to drug and biological therapies and related administration services. Under the proposal, if the patient is admitted to the hospital for a clinically related inpatient stay, the physician would not be paid for his or her drug administration services because there is no facility PFS reimbursement for those services. CMS does not address payment for drugs in the Proposed Rule, leaving unclear whether the physician would be reimbursed for the drugs and biologicals purchased by the physician and furnished to the patient. The proposal also could lead to increased administrative burdens and delays in payment because affected physicians would have to hold all claims for three days until they learn whether the patient has been admitted to the hospital for a reason related to the treatment provided in the office. We ask CMS to proceed cautiously as it implements the 3-day payment window policy and to ensure that Medicare continues to provide appropriate reimbursement for drugs, biologicals, and related administration services furnished by physician practices that are wholly owned or wholly operated by a hospital.

⁵⁹ 76 Fed. Reg. at 42915.

⁶⁰ Id.

⁶¹ Id.

Donald Berwick, Administrator

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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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