BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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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 2011; Proposed Rule [CMS-1503-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) 2011 (the "Proposed Rule").[1] BIO represents more than 1,200 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

[1] 75 Fed. Reg. 40040 (July 13, 2010).

greatly concerned about the increasingly substantial, negative updates to the conversion factor. The net cut of nearly 28 percent in physician payment rates, as a result of the projected 6.1 percent reduction in physician payment rates in 2011 under the sustainable growth rate (SGR) formula combined with the impending 21.2 percent cut that has been thus far delayed by Congress 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 2011 and beyond.

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

- Support the phase-in of the Practice Expense (PE) Relative Value Units (RVUs) calculated using Physician Practice Expense Information Survey (PPIS) data;
- Express concern regarding CMS's proposal to use prices negotiated by the Federal Government to determine updates for "high cost" medical supplies and urge CMS not to implement this proposal;
- Support CMS's proposal to remove all costs related to drug expenses from the Medicare Economic Index (MEI);
- Request that CMS retain the existing monthly capitation payment (MCP) policy for home dialysis services and leave discretion regarding routine check-ups to the provider and his or her patients.
- Support CMS's proposal to create parity between the intranasal/oral and injectable immunization administration codes, but recommend that a modification be made to the crosswalk for one code;
- Support CMS's proposal to add individual and group kidney disease education services as Medicare telehealth services;
- Urge CMS to proceed cautiously in implementing the value-based payment modifier under the PFS and to measure per capita costs and quality of care over a sufficiently long time frame;

- Encourage CMS to finalize the proposed conforming changes to its regulation text to reflect the reimbursement formula set forth in the statute for biosimilar biological products;
- Ask CMS to specify that the patient's personalized prevention plan under section 4103 of the Patient Protection and Affordable Care Act of 2010 (ACA) includes cognitive screening based on the use of a validated screening tool and assessment of cognitive impairment;
- Request 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;
- Ask CMS to clarify that a health risk assessment must be part of the annual wellness visit and that CMS cover and pay for CPT code 99420, "Administration and Interpretation of Health Risk Assessment Instrument (e.g., health hazard appraisal);"
- Support the waiver of the coinsurance and deductible for vaccines and their administration as well as for other preventive services;
- Urge CMS to clarify its proposed carry over methodology for those National Drug Codes (NDCs) for which the manufacturer-reported average sale price (ASP) is not available;
- Ask CMS to clarify its policy for calculating the ASP payment limit for new drugs at 106 percent of wholesale acquisition cost (WAC) and specify a policy for notifying CMS when an NDC or multiple NDCs of a multiple source drug are temporarily not sold by the manufacturer after ASP has begun to be reported;
- 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 ASP, particularly in light of recent statutory changes to the calculation of AMP;
- Ask CMS to specify in the final rule that any new policies relating to ASP issues will apply prospectively only;

- Request that CMS implement a materiality standard for ASP restatements;
- 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;
- Instruct contractors to publish on their websites their fee schedule or reimbursement methodology for radiopharmaceuticals as a reference for providers;
- Support CMS's continued compliance with Congress's intent that there not be a negative update to the drug add-on payment in the end-stage renal disease (ESRD) setting;
- Ask the agency to continue to encourage the development of quality measures related to care coordination and to consider measures to capture whether patients have received preventive vaccinations; and
- Continue to implement the E-Prescribing Incentive Program as proposed.

We discuss these issues in depth below.

I. RESOURCE-BASED PE RVUs – BIO continues to support the phase-in of PE RVUs calculated using PPIS survey data.

BIO appreciates that CMS is phasing in the use of PPIS data to establish PE RVUs over a four-year transition period. As CMS explains in the Proposed Rule, CY 2011 is the second year of the four-year transition to PE RVUs calculated using the PPIS data, and therefore, in general, the CY 2011 PE RVUs are a 50/50 blend of the prior PE RVUs based on the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) and supplemental survey data and the new PE RVUs developed using the PPIS data.[2]

BIO previously expressed concern regarding CMS's proposal to use the PPIS data because of its potentially significant negative impact on payments for physician specialties and the corresponding impact on patient access and care.

[2] Id. at 40049.

BIO continues to believe that phasing in this change will lessen the impact on beneficiaries under the care of specialty physicians and will give patients and physicians time to respond and prepare appropriately for the change in the reimbursement landscape. A phase-in period also gives the agency and interested stakeholders the opportunity to more carefully analyze the new data and its appropriateness in setting PE RVUs as well as gives physician specialty societies the opportunity to collect new and more detailed data where appropriate for refinement. Moreover, it gives the agency the opportunity to evaluate the impact of the change on patient access to determine whether proceeding with full implementation is appropriate.

BIO also supports the continued use of medical oncology supplemental survey data for oncology drug administration services as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

II. POTENTIALLY MISVALUED SERVICES UNDER THE PFS – CMS should not determine updates for "high cost" medical supplies based on the prices negotiated by the Federal Government that do not reflect actual costs to providers.

The Proposed Rule proposes to base future PE updates for "high cost" medical supplies (those priced at $150 or more) on the prices listed for those items on Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) contracts.[3] For supply prices not available on the VA FSS, CMS would extrapolate a price reduction based on the percentage difference between VA FSS prices and the existing PE database prices for similar supplies, currently an average 23 percent reduction.[4]

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[3] Id. at 40082. Although the Proposed Rule refers to the United States General Services Administration (GSA) medical supply schedule, CMS acknowledges that GSA has delegated authority to the VA to procure medical supplies under the VA FSS Program. Id. at 40081. As a result, all references here are to the VA FSS.

[4] Id. at 40082.

BIO believes it is critical for physician payment rates to be derived using data that reflect the prices actually available to providers in the marketplace. For the reasons set forth below, FSS pricing cannot reasonably be considered to represent "typical market prices" for medical supplies and therefore should not be used as a benchmark for the Medicare PFS and other Part B payment policies.

With over $10 billion in sales, the VA FSS Service acknowledges that it provides access to significantly-reduced "volume discount pricing" for medical supplies due to the massive buying power of the Federal Government.[5] As noted by the Government Accountability Office (GAO), the VA also achieves such "favorable prices . . . by exercising its audit rights and access to contractor data to pursue best prices aggressively for medical supplies and services."[6]

Specifically, companies must disclose to the VA their pricing data and commercial sales practices, including discounts and concessions offered to other customers. The VA uses these data as significant leverage in seeking its pricing goal of obtaining FSS pricing that is equal to or better than the price given to the company's most-favored customer (MFC).[7] In addition to the basic awarded pricing on the FSS, price decreases, discounts, or concessions provided to commercial customers, after the award of an FSS contract can and often do result in similar price reductions to FSS contract pricing. The VA polices these government contract-specific pricing requirements by using its rights to access company records and conduct pre-award and post-award audits.[8]

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[5] U.S. Department of Veterans Affairs, Office of Acquisition and Logistics — National Acquisition Center Federal Supply Schedule (FSS) Service, http://www1.va.gov/oamm/oa/nac/fsss/index.cfm.

[6] U.S. Government Accountability Office, GAO-04-718, Contract Management: Further Efforts Needed to Sustain VA's Progress in Purchasing Medical Products and Services (June 2004), http://www.gao.gov/new.items/d04718.pdf.

[7] General Service Administration Acquisition Manual (GSAM) 538.270, https://www.acquisition.gov/gsam/current/html/Part538.html#wp1858754.

[8] See, e.g., VA Acquisition Regulation (VAAR) Subpart 842.1 – Contract Audit Services (providing for pre-award and post-award audits); VA Contract Clause AS13, Examination of Records by VA (Multiple Award Schedule) (Feb. 1998) (providing for pre-award audits for up to

The FSS solicitation's substantial data disclosure requirements, coupled with the MFC pricing goal and robust audit rights, result in FSS contract pricing that is significantly below typical commercial pricing. As a result, VA FSS prices cannot be considered an accurate or appropriate gauge for tracking the "typical market prices."[9]

Moreover, a number of CMS's assertions in the Proposed Rule regarding the nature of FSS pricing are misleading. CMS states that it understands FSS pricing to be "fair and reasonable," and that it "generally do[es] not include volume and or certain other discounts that may be subsequently negotiated by the buyer. Consequently, we would consider the prices available on the [VA] schedule to represent the 'individual item ceiling' price for a single item purchase, which we believe would be appropriate to estimate the high-cost supply prices for physicians' office purchases."[10] Although BIO acknowledges that Federal buyers can negotiate lower pricing than FSS base prices on a particular order, CMS ignores the substantial leverage, tools, and unparalleled purchasing power the Federal Government wields to arrive at those prices. To equate purchases by the Federal Government—the largest purchaser of goods and services in the world[11]—with those of physician offices simply is inappropriate.

In conclusion, BIO believes CMS should not determine updates for "high cost" medical supplies based on the prices negotiated by the Federal Government that do not reflect actual costs to providers, and CMS should not implement its proposal accordingly.

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two years after contract award); *see also* FAR 52.212-5 (Apr. 2010) (providing for post-award audits for up to three years after payment); FAR 52.215-2 (Mar. 2009) (same).

[9] 75 Fed. Reg. at 40079.

[10] Id. at 40082.

[11] U.S. Small Business Administration, Contracting Opportunities, http://www.sba.gov/contractingopportunities/index.html.

III. PFS UPDATE FOR CY 2011 – BIO supports CMS's proposal to remove all costs related to drug expenses from the MEI.

In the Proposed Rule, CMS states that it is proposing to remove all costs related to drug expenses from the MEI as drugs neither are paid for under the PFS nor are they included in the definition of "physicians' services" for purposes of calculating the physician update via the SGR system.[12] BIO supports the removal of drug expenses from the MEI for consistency with the SGR and recommends that CMS finalize this proposal. In addition, CMS proposes to convene a technical advisory panel later in the year to "review all aspects of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment."[13] BIO supports this proposal but encourages CMS to update the MEI as proposed rather than wait until the technical advisory panel is convened. It is important that the increasing relative costliness of physician practice expenses, as evidenced by CMS's analysis, be reflected in Medicare payments.

IV. ESRD RELATED SERVICES FOR HOME DIALYSIS (Current Procedural Terminology (CPT) CODES 90963, 90964, 90965, and 90966) – BIO requests that CMS retain the existing MCP policy for home dialysis services and leave discretion regarding routine check-ups to the provider and his or her patients.

In the Proposed Rule, CMS proposes to require that the physician or practitioner furnish at least one in-person patient visit per month for home dialysis patients in order to receive the MCP amount.[14] We support CMS's intention to ensure that Medicare beneficiaries receive appropriate, high quality medical care for the treatment of ESRD. However, we are concerned that this proposed requirement might affect patient choice and ultimately affect physician-patient shared decision-making regarding visit frequency, a hallmark of the flexibility afforded to patients receiving dialysis care at home.

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[12] 75 Fed. Reg. at 40088.
[13] Id. at 40095.
[14] Id. at 40101.

CMS has acknowledged the importance of patient choice for home dialysis patients. Specifically, 42 C.F.R. § 494.90(b)(4) regarding Conditions for Coverage (CfC) requires that "[t]he dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing the ESRD care at least monthly." However, in a Frequently Asked Question (FAQ) concerning the CfC published by CMS on September 4, 2009, the agency addressed the disparity between the CfC requirement that all dialysis patients see a physician monthly and the lack of frequency for the home dialysis MCP by stating:

> The CfC require equivalent care among facility-based and home patients. Equivalent care means that home patients are expected to be provided physician/APRN/PA contact monthly, as is expected for in-center patients. This contact could occur in the dialysis facility, at the physician's office, or in the patient's home.[15]

In this same document, CMS addressed a question regarding acceptable reasons for a home patient not to be seen by a physician every month, stating that "[i]f a home patient chooses not to be seen by a physician every month, this is an 'acceptable reason' because patient choice is a hallmark of these ESRD regulations."[16]

BIO requests that CMS continue to leave discretion regarding routine check-ups to the provider and his or her patients and that CMS clarify in the final rule that the existing MCP policy for home dialysis services will remain in place.

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[15] CMS, ESRD Basic Technical Surveyor Training, ESRD FAQs Version 1.1, 34, https://www.cms.gov/GuidanceforLawsAndRegulations/Downloads/faqsep2009.pdf.
[16] Id.

V. INTRANASAL/ORAL IMMUNIZATION CODES (CPT) CODES 90467, 90468, 90473, AND 90474) – BIO supports CMS's proposal to create parity between the intranasal/oral and injectable immunization administration codes, but recommends that a modification be made to the crosswalk for one code.

In the Proposed Rule, CMS proposes to crosswalk the PE values for the intranasal/oral and injectable immunization CPT codes to ensure that the PE RVUs are consistent between those intranasal/oral and injectable immunization administration codes that describe services utilizing similar PE resources.[17] BIO is supportive of CMS's proposal to create parity between the intranasal/oral and injectable immunization codes. However, the proposed crosswalk for CPT code 90468 does not achieve the intended parity. CMS's proposal crosswalks the PE RVUs associated with the additional administration injectable code for adults and children older than eight years old (CPT code 90472) to the additional administration intranasal code for children under the age of eight years (CPT code 90468). The more appropriate PE RVU crosswalk for CPT code 90468 is the additional administration injectable code for children under the age of eight years (CPT code 90466), which reflects the additional clinical time and other practice expenses expended to provide immunizations to young children. To ensure that the PE RVUs are consistent, we recommend that CMS finalize its proposal with one modification - change the proposed crosswalk for CPT code 90468 to CPT code 90466.

Further, we understand that two new immunization administration codes that will not differentiate between the route of administration will be effective January 2011, and that these two new codes will replace existing CPT codes 90466 through CPT codes 90468. We recommend that CMS assign at least the same level of proposed PE RVUs for the immunization administration codes for children under the age of eight years set forth in the Proposed Rule, as modified above, to these new codes.

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[17] 75 Fed. Reg. at 40104.

VI. SUBMITTED REQUESTS FOR ADDITION TO THE LIST OF TELEHEALTH SERVICES FOR CY 2011 – BIO supports CMS's proposal to add individual and group kidney disease education services as Medicare telehealth services.

CMS proposes to include both individual and group kidney disease education as covered Medicare telehealth services.[18] BIO supports CMS's decision to include kidney disease education as a covered Medicare telehealth service because we believe that it will provide patients at-risk for developing chronic kidney disease and ESRD with access to education services that may help in controlling the progression of disease. Additionally, we believe that providing Medicare beneficiaries with access to kidney disease education telehealth services will furnish them with information that could enable better disease management and improved clinical outcomes. BIO encourages CMS to adopt its proposal to include both individual and group kidney disease education as covered Medicare telehealth services in the final rule.

VII. SECTION 3003: IMPROVEMENTS TO THE PHYSICIAN FEEDBACK PROGRAM AND SECTION 3007: VALUE-BASED PAYMENT MODIFIER UNDER THE PFS – BIO urges CMS to proceed cautiously in implementing the value-based payment modifier under the PFS and to measure per capita costs and quality of care over a sufficiently long time frame.

As CMS explains in the preamble to the Proposed Rule, there are two sections of ACA that are relevant to the Physician Resource Use Measurement & Reporting (RUR) Program that provides confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 3003 continues the confidential feedback program to physicians on resource measures began under Phase I of the Program and requires, beginning in 2012, reports that compare patterns of resource use of individual physicians to

[18] Id. at 40108-09.

other physicians.[19] Until a Medicare-specific episode grouping software is developed, CMS explains that it plans "to provide overall per capita cost information, as well as per capita cost information for beneficiaries with five common chronic diseases: (1) Diabetes, (2) congestive heart failure, (3) coronary artery disease, (4) chronic obstructive pulmonary disease, and (5) prostate cancer."[20] Section 3007 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 groups of physicians based on the relative quality and cost of care of their Medicare beneficiaries.[21] This payment modifier will be phased in beginning January 1, 2015 through January 1, 2017.

BIO appreciates that CMS recognizes the need to engage stakeholders as it transitions towards implementation of the payment modifier under section 3007. We believe that 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 five chronic diseases identified by CMS 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 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.

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[19] Id. at 40114.
[20] Id.
[21] Id.

VIII. SECTION 3139: PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS – CMS should finalize the proposed conforming changes to its regulation text to reflect the reimbursement formula set forth in the statute for biosimilar biological products.

Under ACA, the Food and Drug Administration (FDA) is authorized to license biological products as biosimilar or interchangeable biological products.[22] ACA also amends section 1847A of the Social Security Act (SSA) to establish a reimbursement methodology for these products, effective the first day of the second calendar quarter following enactment of ACA.[23] Section 1847A, as amended, applies to both biosimilars and interchangeable biological products that would be approved under an abbreviated Biologics License Application (BLA), based upon the approval of a full BLA for a "reference biological product." Section 1847A, as amended, would require CMS to reimburse these products at the ASP for the biosimilar or interchangeable biological product plus six percent of the ASP for the reference biological product.[24] In the Proposed Rule, CMS includes conforming changes to its regulation text to reflect the reimbursement formula set forth in the statute.[25] BIO supports these changes to the regulatory text, and CMS should finalize them.

IX. SECTION 4103: MEDICARE COVERAGE OF ANNUAL WELLNESS VISIT PROVIDING A PERSONALIZED PREVENTION PLAN

A. BIO applauds the expansion of preventive services coverage under section 4103 of ACA and asks that CMS specify that the cognitive screening include the use of a validated screening tool and assessment of cognitive impairment.

Effective January 1, 2011, Medicare Part B will cover an annual wellness visit provided by a health professional without any cost-sharing or coinsurance

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[22] Pub. L. No. 111-148, § 7002 (2010).
[23] Id. § 3139.
[24] SSA § 1847A(b)(8), as added by ACA § 3139.
[25] 75 Fed. Reg. at 40122, 40258-59.

from an eligible beneficiary. As required by the statute, the initial annual wellness visit includes the development of a personalized prevention plan for the beneficiary, with updates to the plan in subsequent annual wellness visits. One of the elements to be included in both the first and subsequent annual wellness visits providing personalized prevention plan services, as defined in proposed 42 C.F.R. § 410.15, is "detection of any cognitive impairment that the individual may have."[26] CMS has proposed to define "[d]etection of cognitive impairment" for purposes of this section to mean "assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers or others."[27]

BIO applauds CMS's recognition that wellness visits should include detection of cognitive impairments as well as the agency's preliminary definition of this term. We also believe that appropriate cognitive screening additionally requires administration of a validated objective screening tool, such as but not limited to the Mini-Cog, AD8, or MoCA. (We also recommend that this approach be used for function and depression assessments as well. That is, the use of a validated screening tool.) These tools will likely improve the identification of early dementia or mild cognitive impairment (MCI). The use of a tool will establish a baseline and permit longitudinal tracking of cognitive health. The use of a screening tool can be appropriately applied by any outpatient healthcare provider (e.g., physicians, nurse practitioners, and physician assistants) and support staff. The benefits of such screening will increase further as treatment options are developed for MCI and as simpler screening tools are developed and validated.

Mild Cognitive Impairment is often a leading clinical indicator of the early stages of Alzheimer's Disease and a cognitive screening tool will allow identification of patients who should be referred for additional diagnostic testing. This will become of ever increasing importance as new drug therapies become available in the coming years that modify the underlying course of disease. Additionally, the Alzheimer's scientific community's view is that drug treatment

[26] Id. at 40247.
[27] Id. at 40246.

may be most effective if started at a much earlier stage of disease, before the emergence of full blown dementia, and drug therapies are being studied in Alzheimer's Disease patients at the MCI / Predementia stage of disease. If it can be shown that treatments are more effective if administered at this early stage of disease, then the ability to identify patients early (starting with screening) will be essential.

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 Advisory Committee on Immunization Practices (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 United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 410.15 the option of vaccination by a physician, pharmacist or other healthcare practitioner, as allowed by state law.

C. BIO asks CMS to clarify that a health risk assessment must be part of the annual wellness visit and that CMS cover and pay for CPT code 99420, "Administration and Interpretation of Health Risk Assessment Instrument (eg, health hazard appraisal)."

Although CMS acknowledges that section 4103 of ACA requires that a health risk assessment (HRA) must be included in the annual wellness visit beginning January 1, 2011, it does not propose to include this as a requirement for the visit.[28] CMS proposed that it would revise the regulations to include the HRA in the definition of the annual visit when the HRA guidelines and the model HRA tool are available. The guidelines (including standards for interactive telephonic or web-based programs) are required to be developed within 1 year of enactment of ACA (March 23, 2010 was the date of enactment), and the model HRA tool is required to be developed and made available within 18 months following enactment.

We are concerned that by not requiring the HRA as part of the annual wellness visit beginning January 1, 2011, CMS would unnecessarily delay the

[28] Id. at 40126.

opportunity to begin to improve beneficiaries' health and to control Medicare costs as a result. As outlined further below, we believe CMS should include the HRA as a required element of the wellness visit beginning January 1, 2011.

We recommend that, effective January 1, 2011, CMS add a requirement to the regulations at sections 410.15(a) and (b) that an HRA accredited by the National Committee for Quality Assurance (NCQA) must be included as part of the first and subsequent annual wellness visits in order to be eligible for payment. NCQA accreditation means that health plans that undergo NCQA Accreditation surveys will receive automatic credit for using the accredited HRA. As part of the accreditation process, NCQA surveyors access the tool and review the supporting documentation. The certification designation is valid for two years, and as part of the evaluation, NCQA assesses whether the HRA vendor has a process in place to review and update the HRA at least every two years based on current or new evidence.

This approach of relying on NCQA accreditation would enable CMS to move forward with the HRA as a required element of the benefit prior to developing additional guidelines, while maintaining a minimum existing standard. Alternatively, CMS should require the HRA effective January 1, 2011, and implement the applicable HRA guidelines through separate rulemaking.

In the Proposed Rule, CMS states the first wellness visit is similar to the Welcome to Medicare Initial Preventive Physical Exam (IPPE), and that the physician work and practice expense for both services are very similar. Therefore, for CY 2011, CMS proposes to provide the same payment amount for the first wellness visit and the IPPE (equivalent to payment for CPT 99204: Level 4 new patient office or other outpatient visit). For a subsequent wellness visit, CMS proposed to pay an amount equivalent a Level 4 established patient office or other outpatient visit (CPT code 99214).[29]

[29] Id. at 40128-29.

However, because neither the IPPE, CPT code 99204, nor CPT code 99214, include a requirement for an HRA, there is no payment for the HRA included in the proposed payment for the annual wellness visit. Therefore, in order to recognize the additional costs of the physician or health professional to administer and interpret the HRA, an additional payment for that purpose is necessary. There is an existing CPT code 99420, "Administration and Interpretation of Health Risk Assessment Instrument (eg, health hazard appraisal)), but it is currently treated as a noncovered service by CMS (valued at $10.19 in the Proposed Rule, with a status indicator 'N' for Noncovered). Because ACA section 4103 establishes the HRA as a central component of this new, covered, wellness visit, CMS should change the status indicator for CPT code 99420 to allow payment for this service.

In addition, the current physician work RVU for CPT code 99420 is zero. We urge CMS to refer this code to the CPT RVU Update Committee to survey physician specialties to determine an appropriate physician work RVU for this code.

X. SECTION 4104: REMOVAL OF BARRIERS TO PREVENTIVE SERVICES IN MEDICARE – BIO supports CMS's proposal to waive the coinsurance and deductible for vaccines and their administration as well as for other preventive services.

In the Proposed Rule, CMS states that vaccines and their administration meet the statutory requirements for waiver of the deductible and coinsurance under Medicare as required by section 4104 of ACA.[30] BIO believes this is consistent with Congressional intent to preserve beneficiary access to preventive services and strongly supports this proposal. Waiving the coinsurance and deductible for vaccines and their administration will encourage Medicare beneficiaries to receive appropriate immunizations. Vaccines are a simple, safe, and cost-effective method of preventing negative health outcomes and mitigating the need for hospitalizations or other more costly treatments. We also support this waiver applying to all settings where these immunization services could be furnished. As discussed

[30] Id. at 40130.

above, pharmacists, particularly retail pharmacists, have played a critical role in providing seniors with convenient access to needed vaccinations. BIO also applauds the waiver of the coinsurance and deductible for other **preventive** services, including bone mass measurement tests and certain screening tests for colorectal and breast cancer. These are important changes that likely will improve beneficiaries' health outcomes.

BIO is concerned, however, that by limiting the waiver to only those vaccines covered under Medicare Part B that are recommended by the United States Preventive Services Task Force (USPSTF), a significant obstacle to proper immunization of at-risk seniors remains. As CMS notes, the USPSTF ceased to make recommendations with regard to vaccines and vaccine administration after 1996, to avoid conflicting with ACIP.[31] Those ACIP-recommended vaccines that are covered under Medicare Part D and not subject to the waiver will continue to present cost barriers for beneficiaries. Several of these vaccines are designed to prevent diseases that are particularly onerous for seniors, such as shingles (herpes zoster). Others are significant for those with certain underlying illnesses, such as hepatitis A for those with chronic liver disease. Recognizing these potential obstacles, in section 4204(e) of ACA, Congress obligated the GAO to conduct a study on the ability of Medicare beneficiaries to access routinely recommended vaccines that are covered under Medicare Part D, including "any barriers" to such access. BIO is very concerned that failing to provide a mechanism to reduce beneficiaries' financial barriers to access for the rest of the ACIP-recommended vaccines means that many will not take advantage of those preventive services even when they are included as part of the patient's personalized prevention services plan. We ask CMS to work with us and Congress to ensure Medicare beneficiaries have access to these important, cost-effective vaccines.

[31] Id.

XI. PART B DRUG PAYMENT: ASP ISSUES

A. CMS should clarify its proposed carry over methodology for those NDCs for which the manufacturer-reported ASP is not available.

CMS is proposing a new methodology that would carry over the most recently reported ASP for an NDC for purposes of calculating the Medicare payment rate when the reported ASP for that NDC is unavailable. Specifically, CMS proposes to carry over the previously reported ASP when (i) missing manufacturer ASP and/or WAC data could cause significant changes or fluctuations in ASP payment limits, defined as a ten percent or greater change in the ASP payment limit as compared to the previous quarter, and (ii) efforts by the agency to obtain a manufacturer reported ASP before the publication deadlines for the Medicare ASP payments limits are unsuccessful.[32] This proposed process raises a number of questions that are not addressed by either CMS's proposed regulatory text or its preamble discussion. BIO urges CMS to provide clarity on these issues, each of which is discussed in detail below.

1. CMS should specify the criteria for application of the carry over methodology in regulation.

CMS states in the preamble that the carry over methodology only will apply where the missing data result in a ten percent or greater change in the ASP payment limit as compared with the previous quarter *and* the agency's efforts to obtain the reported ASP prior to the publication deadline for the quarterly payment rate have not been successful. BIO supports this two-part test but is concerned that the test is not reflected in CMS's proposed regulatory text at 42 C.F.R. § 414.904(i). The proposed regulation states only that "[i]f manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits," the payment rate will be calculated by carrying over the most recently available reported ASP from a previous quarter, as adjusted.[33] BIO urges CMS to revise this

[32] Id. at 40153.
[33] Id. at 40259 (proposed 42 C.F.R. § 414.904(i)).

proposed regulation text to specifically include the two criteria set forth in the preamble, as follows:

> (i) . . . the payment limit is calculated by carrying over the most recent available manufacturer ASP price from a previous quarter for an NDC, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported during both the most recently available quarter and the current quarter***, at such times when:***
>
> ***(A) Efforts by CMS to obtain manufacturer ASP data before the publication deadline for quarterly payment limits are not successful; and***
>
> ***(B) Such data would result in a 10 percent or greater change in the ASP payment limit compared to the previous quarter***.

2. CMS should provide greater specificity regarding what its efforts will be to obtain manufacturer data before the publication deadline.

CMS states that it will pursue the carry over methodology when efforts by the agency to obtain the manufacturer reported ASP before the payment limit publication deadlines have not been successful, but the Proposed Rule does not provide any detail regarding what those efforts might entail. BIO recommends that CMS expressly state in the final rule that it will contact the person identified on the manufacturer's ASP Addendum B for the most recently reported quarter. In addition, we encourage CMS to accept information available from or supplied by third party sources that may explain the failure to report the ASP data. We also request that CMS specify the exact publication deadline for each quarter that CMS will use for determining whether use of carry over ASP data is necessary.

3. CMS should finalize its proposal to exclude products with zero sales from the carry over methodology, but also should provide additional specificity on how it will make this determination.

CMS states that NDCs that have zero sales or are no longer being manufactured will not be subject to this proposed carry over process.[34] BIO agrees with this approach, because only ASPs for those products with sales in the quarter should be included in the calculated payment rate. We request, however, that CMS specify in the final rule how it will confirm and document that a particular NDC did not have any sales in the relevant quarter for this purpose. Moreover, as discussed in section B. 2. below, BIO strongly believes that the published reimbursement rate for a given quarter must accurately reflect only the prices of those drugs that are actively sold by manufacturers during that quarter. If the manufacturer fails to report ASP, it may be because the manufacturer no longer sells the product. For example, in the case where a multiple source drug launches "at risk" and faces the potential for a court decision or voluntary determination that such a product violates the patent of the related single source drug, the manufacturer may be under a legal obligation to cease sales of the drug launched at risk. In this case, CMS should not carry over the ASP because including drugs not sold by manufacturers could limit the ability of physicians and beneficiaries to access needed therapies within that payment code.

4. CMS should adjust the carried over ASP by the weighted average change in ASP for that manufacturer's other drugs in the same payment code, if any, or otherwise based on the weighted average change in ASP for all drugs in the payment code.

CMS has proposed to adjust any ASPs that are carried over by the "weighted average of the change in the manufacturer ASP for the NDCs that were reported during both the most recently available quarter and the current quarter."[35] We support this approach, as we believe it promotes CMS's goal of minimizing non-

[34] Id. at 40153.
[35] Id.

market related price fluctuations in Medicare payment rates, but request that CMS modify the methodology. Specifically, we request that CMS specify in the final rule that to the extent the manufacturer of the NDC to which the carried over ASP applies has reported the ASP for other NDCs in the same code, this weighted average will be calculated based only on the change in that manufacturer's reported ASPs, as the prices of that manufacturer's other drugs are the most likely to move in concert with the drug that was not reported. The change in reported ASPs for the products of other manufacturers in that same code may have no relationship to the potential change in ASP for the products not reported. Only if that manufacturer does not have other reported ASPs in the same payment code should the weighted average be calculated across all products in the code. In this latter case only, if CMS is missing ASP data for a multiple source drug within a payment code, the weighted average should be calculated based on the reported ASPs for all other NDCs within the code, including any single source products.

5. CMS should limit the duration of the application of the carried over ASP.

BIO urges CMS to specify in its final regulation that a previously reported NDC may be carried over no more than one quarter following the quarter in which it was initially reported. By the time a carried over ASP is used in the calculation of the payment rate, it will reflect sales data for a quarter that is at least three quarters prior to the quarter for which the payment rate is being calculated. An ASP that is any more than one quarter old may not accurately represent current prices in the marketplace for purposes of calculating the payment limit for the current quarter and thus could skew Medicare reimbursement rates.

We further recommend that this methodology only apply where a drug has been reported for at least four quarters, and where the manufacturer is obligated to report ASP. Some period of ASP reporting history is necessary to support any conclusion that the absence of such ASP data would cause a significant fluctuation in payment rates, and BIO believes a full calendar year of reporting provides an appropriate baseline for such determination. In addition, BIO believes the carry over methodology should not apply to manufacturers that do not have a Medicaid

rebate agreement in effect for the applicable quarter because such manufacturers are not required to report ASP data.

6. CMS should clarify that the carry over ASP will not affect manufacturer restatements.

BIO requests that CMS clarify that to the extent CMS has carried over the ASP for a particular quarter, this carry over will not preclude a manufacturer from restating the ASP for that quarter in the future, once the problem that resulted in failure to report ASP and need for the carry over ASP has been remedied. We ask that CMS include this clarification in its final rule.

B. Regarding partial quarter ASP data for new drugs or biologicals, CMS should clarify its policy for calculating the ASP payment limit for new drugs and specify a policy for notifying CMS of the withdrawal of a multiple source drug after ASP has begun to be reported.

BIO appreciates that CMS has taken the opportunity to describe its policy for calculating the ASP payment limits during the first quarter of sales for single source drugs and multiple source drugs, but it requests that CMS provide additional clarity on these policies, as discussed below.

1. CMS should clarify its policy for calculating the ASP payment limit for new single source drugs at 106 percent of WAC.

BIO is concerned that CMS's description of its policy for calculating the ASP payment limit during the first quarter of sales for single source drugs could be viewed as inconsistent with the policy articulated in CMS's final rule regarding payment policies under the PFS for the calendar year 2005[36] (the "2005 PFS Rule"), which makes clear that this policy may apply to more than just the first quarter of sales. We recommend that CMS incorporate this policy into its

[36] 69 Fed. Reg. 66236, 66302 (Nov. 15, 2004).

regulation at 42 C.F.R. § 414.904(e)(4) regarding the payment limit for drugs during an initial period for which ASP data are not sufficiently available.

The preamble of the Proposed Rule states that "it has been our policy to price new single source drugs at WAC *for the first quarter* (unless the date of first sale is on the first day of the quarter)."[37] The preamble to the 2005 PFS Rule, however, states that "during an initial period (not to exceed a full calendar quarter) where data on prices for sales for a drug are not sufficiently available from the manufacturer to compute an ASP," CMS will pay based on WAC or the methodologies in effect on November 1, 2003 "for a limited period."[38] This time period "*will start on the date that sales of the drug begin and end at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales*.[39] That is, for a single source drug that is not launched on the first day of the quarter, the payment rate may be based on WAC not just for the first, partial quarter of sales, but also for at least two subsequent quarters. For example, if a single source product is launched on January 15, 2010, the payment rate for the four quarters in the year will be determined as follows:

- First Quarter 2010 – Partial Quarter of Sales: Payment is based on 106 percent of WAC.
- Second Quarter 2010 – First Full Quarter of Sales: Payment is again based on 106 percent of WAC. The first ASP is reported during the second quarter, thirty days after the end of the launch quarter.
- Third Quarter 2010 – Second Full Quarter of Sales: Payment is again based on 106 percent of WAC, because the ASP reported for the first quarter of sales (the first quarter 2010) does not reflect a full quarter of sales.
- Fourth Quarter 2010 – Third Full Quarter of Sales: Payment is based on 106 percent of the ASP reported for the second quarter 2010, the first full quarter of sales.

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[37] 75 Fed. Reg. at 40154 (emphasis added).
[38] 72 Fed. Reg. at 66302.
[39] Id. (emphasis added).

We recommend that CMS amend section 414.904(e)(4) to make it consistent with CMS's policy as set forth in the 2005 PFS Rule. We also recommend that CMS make clear in regulation that it applies 106 percent of the WAC during this initial period, consistent with its past practice:

> (4) Payment limit in a case where the average sales price during the first quarter of sales is unavailable. In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on ***106 percent of*** the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003 ***for a limited period. This limited period will start on the date that sales of the drug begin and end at the beginning of the quarter after CMS receives information from the manufacturer regarding ASP for the first full quarter of sales.***

Finally, we also ask CMS to clarify that payment for new drugs and biologicals during the initial period before an ASP is computed shall be based on 106 percent of the WAC or 95 percent of average wholesale price (AWP), the methodology in effect as of November 1, 2003, as required by the statute.[40] We have learned that some contractors are reimbursing new drugs and biologicals during this initial period based on invoice prices, not WAC or AWP. The use of invoice prices instead of the published WAC to establish payment for these products is contrary to the statute and CMS's guidance to contractors. SSA § 1847A(c)(4) requires payment during the initial period in which an ASP is not available to be based on the WAC or the methodologies in effect under Part B on November 1, 2003, to determine payment amounts for drugs and biologicals. On November 1, 2003, the methodology in effect was described in SSA § 1842(o)(1), which set payment to physicians, suppliers, and other persons for drugs and

[40] SSA §§ 1842(o)(1)(C), 1847A(c)(4).

biologicals not paid on a cost or prospective payment basis "equal to 95 percent of the average wholesale price."[41] In addition, CMS's own manual instructions in effect on November 1, 2003, did not include use of invoice prices. The 2003 version of the Medicare Carriers Manual said,

> Drugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that are paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anti-cancer drugs, and blood clotting factors.[42]

Because neither the statute nor CMS's manual instructions established the use of invoice pricing as one of Medicare's payment methodologies as of November 1, 2003, Medicare should not use invoice prices now when a published WAC is available.

Moreover, Medicare's current guidance to contractors requires payment to be based on 106 percent of WAC when a WAC is available. This guidance states,

> "The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP."[43]

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[41] SSA § 1842(o)(1) (2003).
[42] Medicare Carriers Manual, Part 3, § 5202 (2003).
[43] Medicare Claims Processing Manual, ch. 17, § 20.1.3.

This guidance correctly describes the requirements for payment based on WAC for new drugs and biologicals, although it is incorrect with regard to use of invoice prices. To ensure that new drugs and biologicals are reimbursed appropriately and in accordance with the statute before an ASP is available, BIO asks CMS to clarify in the final rule and in its guidance that contactors must establish payment for these products at 106 percent of the published WAC, and if a WAC is not available, at 95 percent of AWP, rather than invoice prices.

2. CMS should calculate the ASP payment limit for new multiple source drugs and product line expansions of single source drugs using WAC and also specify a process for notifying CMS when an NDC or multiple NDCs of a multiple source drug is temporarily not sold by the manufacturer after ASP has begun to be reported for that drug so that these NDCs can be excluded from the calculation of the Medicare payment limit.

CMS has proposed to add NDCs for new multiple source drugs and product line expansions of single source drugs to the ASP-based payment rate calculation for a quarter as soon as these products are reported. BIO believes that CMS should instead apply the same policy set forth above with respect to single source drugs; that is, where the new multiple source drug or product line expansion of a single source drug is not launched on the first day of the quarter. The WAC for the new NDCs should be used for the first, partial quarter of sales and at least two subsequent quarters in the calculation of the ASP plus six percent allowance. We believe this approach will promote stability in payment rates.

BIO believes that this approach also should include a process for notifying CMS when an NDC or multiple NDCs of a multiple source drug is temporarily not sold by the manufacturer after the ASP has begun to be reported for that drug, so that the NDC(s) can be excluded from the calculation of the Medicare payment limit. For example, because of a prolonged raw materials shortage, a multiple source drug may temporarily no longer be sold by the manufacturer. This nonetheless could affect the Medicare reimbursement rate for all drugs within the code if it is included in the payment rate calculation. BIO strongly believes that

the published reimbursement rate for a given quarter must accurately reflect only the prices of those drugs that are actively sold by manufacturers during that quarter. Including drugs no longer sold by manufacturers could limit the ability of physicians and beneficiaries to access needed therapies within that payment code. We ask that CMS specify in the final rule that such drugs are excluded from the payment rate calculation as soon as they cease to be sold by the manufacturer, and that CMS will retain discretion to revise payment rates currently in effect to exclude ASPs relating to products only recently determined to be unavailable.

C. CMS should continue to proceed cautiously and with sufficient public notice on any substitution of WAMP or AMP for ASP, particularly in light of recent statutory changes to the calculation of AMP.

The SSA permits the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[44] 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.[45] CMS recognizes in the Proposed Rule "that there are complicated operational issues associated with" potential payment substitutions and states that it will continue to proceed cautiously in this area.[46] CMS states further that it remains committed to providing manufacturers with adequate notice before substituting WAMP or AMP for ASP.[47]

BIO appreciates CMS's caution in pursuing any potential price substitutions, but strongly urges CMS to postpone indefinitely implementation of its proposal until it can consider the effects of the upcoming changes to the calculation of AMP

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[44] See SSA § 1847A(d)(3)(A).
[45] MMA 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 selecting such sources").
[46] 75 Fed. Reg. at 40156.
[47] Id.

effective the fourth quarter 2010 pursuant to ACA, as well as recently enacted legislation creating an alternative definition of AMP for infused, injectable, instilled, implanted, and inhaled drugs. CMS has yet to issue guidance to manufacturers regarding how to implement the new statutory definition of AMP under ACA, or the just-enacted alternative AMP. All of these pending changes may impact the relationship between AMP and ASP, as already noted by the Office of Inspector General (OIG).[48] We urge CMS to delay implementation of any payment rate substitution until manufacturers have implemented the changes to the AMP methodology under ACA and recently enacted legislation and CMS itself has developed experience with these new AMP data.

BIO supports CMS's proposal to continue the applicable threshold for both the WAMP and AMP at 5 percent. For calendar year 2011, CMS is further proposing that comparisons of ASP to AMP will 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 four quarters; immediately preceding the quarter to which the price substitution recommendation would apply."[49] BIO agrees with CMS that comparisons 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. 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.[50] This means that those quarters available for purposes of comparing the 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

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[48] See OIG, Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010 4, n.10 (OEI-03-10-00150) (Apr. 26, 2010) ("Effective October 2010, [ACA] changes the definition of AMP in a way that is not relevant for the purposes of this report. However, it may impact pricing comparisons between ASPs and AMPs for the fourth quarter of 2010 and beyond.").
[49] 75 Fed. Reg. at 40259 (proposed 42 C.F.R. § 414.904(d)(3)(iii)(A)).
[50] See Id.

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 four quarters, preceding the quarter to which the price substitution recommendation would apply ***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 OIG's analysis as a predictor of savings under CMS's proposal. In support of its proposal, CMS cites to OIG's Comparison of Third-Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010 that estimates that reimbursement based on 103 percent of AMP would have reduced Medicare expenditures by over half a million dollars in the first quarter of 2010. As set forth in CMS's proposed amended regulation at section 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. The OIG's estimate, in contrast, is based on applying the price substitution to the first quarter 2010 – the same quarter for which the OIG has performed the comparison analysis of the underlying (third quarter 2009) ASP and AMP data – and therefore may not be an accurate predictor of the actual reduction in expenditures 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 for the billing code, as we agree that "incomplete" AMP data may not adequately account for market-related drug price changes. 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 comparisons 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 effect the relationship between AMP and ASP for 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.

D. CMS should specify that any new policies relating to ASP issues will apply prospectively only.

CMS proposes several new policies with regard to ASP issues, including carry over ASPs, intentional overfill, and substitution of AMP-based payment for ASP.[51] CMS states an effective date for the AMP substitution provisions only,[52] leaving uncertain the effective date of the other proposed changes. As we have previously commented with regard to ASP issues,[53] changes to methodologies should be applied prospectively only. Prospective application is essential to ensuring compliance with new methodologies and policies. As such, if CMS finalizes any of these new proposals we ask the agency to state in the final rule that the revised regulation applies prospectively to ASPs calculated for the first quarter of 2011 and used to set payment rates for the third quarter of 2011, and does not apply to claims or submissions of data prior to January 1, 2011.

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[51] Id. at 40153.
[52] Id. at 40259.
[53] See, e.g., Letter from J. Slotnik, BIO, to M. McClellan, CMS, regarding BIO comments on the CY 2007 Physician Fee Schedule Proposed Rule, October 10, 2006, at 15-16.

E. CMS should implement a materiality standard for ASP restatements.

BIO requests that CMS clarify in the final rule that a manufacturer may restate previously reported ASP data where it identifies an error in such data. We further request that CMS provide guidance to manufacturers regarding such restatements, including implementing a materiality standard for restating ASP data. When a manufacturer identifies errors in previously-submitted ASP data, the lack of a clear threshold for reporting errors leads manufacturers to restate those ASP data even where the change from the originally reported ASP is immaterial, or where the error is discovered many quarters after the quarter in which the ASP was used for reimbursement. Recalculating and resubmitting the ASPs affected by the error creates a significant administrative burden for both the manufacturer and for CMS. At the same time, reporting the change may have little or no practical effect, given the immateriality of the change or the fact that the quarter impacted is too far in the past for any revision of the reimbursement rate to have any impact. BIO believes that establishing a threshold for restatement of ASP that includes both materiality and a time component, in combination with a requirement to notify CMS of such errors and the methodology used to estimate its impact, will reduce unnecessary administrative burden for CMS and manufacturers, while at the same time protecting manufacturers from the risk of penalty.

As it has done previously, BIO urges CMS to apply a threshold to restatements of ASP. We propose that where a manufacturer identifies an error in its ASP submission for a prior quarter, the manufacturer will not be required to restate the affected ASP where, for an individual NDC-11 or, where the manufacturer reports ASP for all NDCs in a given billing and payment code, for an individual billing and payment code: (1) correction of the error would result in a change that is less than the lower of one cent or one percent of the originally reported ASP, in the case of an individual NDC, or the weighted average ASP at the billing unit level, in the case of a billing and payment code; or (2) the error relates to an ASP submitted for a quarter that is more than six quarters prior to the quarter in which the manufacturer discovers the error. In each scenario, the manufacturer also would have to disclose to CMS the cause of the error and its

methodology for estimating the impact of correcting the error within 90 days of discovery.

This narrow exception to the obligation to restate ASPs can be implemented by amending 42 CFR § 414.806 and making a conforming change to 42 CFR § 414.804, as follows:

Section 414.806 is amended by—

A. Redesignating the current paragraph as paragraph (a).
B. Adding new paragraph (b). The addition reads as follows:

§ 414.806 Penalties associated with the failure to submit timely and accurate ASP data.

* * * * *

(b) (1) Notwithstanding the foregoing, the Secretary will not consider a misrepresentation to have occurred in relation to an NDC where a manufacturer identifies an error in the reporting of the ASP for the NDC and the following two conditions are met:

(i) For the individual NDC—

(A) The manufacturer estimates using reasonable methods that correction of the error would result in a change in the reported ASP that is less than or equal to the lower of $0.01 or one percent; or

(B) The error relates to an ASP submitted for a quarter that is more than six quarters prior to the quarter in which the manufacturer discovers the error, i.e., if the affected ASP is reported for the fourth quarter 2007 and the error is discovered by the manufacturer in the third quarter 2009, it would fall within this provision, because the fourth quarter 2007 is more than six quarters prior to the third quarter 2009.

(ii) The manufacturer discloses in writing to CMS within 90 days of discovery of the error the nature of the error, the corrective action taken to address the error on a prospective basis, and the manufacturer's methodology for estimating the impact to the previously reported ASP of correcting the error.

(2) Where the manufacturer is responsible for reporting ASP data for all NDCs within a billing and payment code, the conditions described in paragraph (b)(1)(i)(A) of this section may be satisfied where the correction of the error as to all affected NDCs within the billing and payment code results in a change to the ASP for the billing and payment code, as calculated in accordance with 42 C.F.R. § 414.904, that meets the condition in paragraph (b)(1)(i)(A) of this section.

* * * * *

Section 414.804 is amended by adding new paragraph (a)(7). The addition reads as follows:

§ 414.804 Basis of payment.
* * * * *
(a) * * *
(7) The certification in paragraph (a)(6) of this section will be deemed true as to any ASP subject to a disclosure in compliance with § 414.806(b).

This proposal accomplishes the goals of both protecting manufacturers from penalty where there is a *de minimis* impact on the original ASP and providing CMS with notice of the error. BIO urges CMS to adopt this proposal in its final rule.

F. CMS should ensure that all branded prescription drugs, including biologicals, receive their own HCPCS codes, particularly now that data must be reported for purposes of the annual fee on branded pharmaceutical manufacturers.

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 Social Security Act (SSA).[54] 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.

Unique codes also will be needed to separately track use 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

[54] Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics, May 18, 2007, http://www.cms.gov/MedHCPCSGenInfo/downloads/051807_coding_annoucement.pdf.

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.[55] 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."[56] BIO believes that the best process would be for CMS to ensure that all branded prescription drugs, including biologicals, receive their own HCPCS codes.

G. 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 for information about reimbursement for radiopharmaceuticals. Although the 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.

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[55] ACA § 9008(e)(2).
[56] ACA § 9008(g)(2).

XII. PROVISIONS RELATED TO PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED BY ESRD FACILITIES – CMS should continue to comply with Congress's intent that there not be a negative update to the drug add-on payment in the ESRD setting.

CMS projects that the combined growth in per patient utilization and pricing for CY 2011 would result in a negative update to the ESRD drug add-on amount equal to 0.2 percent.[57] Instead of implementing a reduction to the drug add-on, however, CMS proposes to implement a zero update for 2011.[58] The statute states, "The Secretary shall annually increase the basic case-mix adjusted payment amounts."[59] In the Proposed Rule, CMS states, "Our understanding of the statute contemplates 'annually increase' to mean a positive or zero update to the drug add-on."[60] BIO agrees with the interpretation of the statute and believes CMS should to implement its proposed zero update in the final rule.

XIII. ISSUES RELATED TO THE MEDICARE IMPROVENTS FOR PATIENTS AND PROVIDERS ACT OF 2008 (MIPPA)

A. PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI) – CMS should continue to encourage the development of quality measures relating to care coordination and consider measures to capture whether patients have received preventive vaccinations.

BIO believes CMS's leadership remains vital to the development of 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.

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[57] 75 Fed. Reg. at 40166.
[58] Id.
[59] SSA § 1881(b)(12)(F).
[60] 75 Fed. Reg. at 40166.

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.[61] The lack of care coordination particularly can affect patients with chronic conditions, although all patients experience transitions of care that necessitate some level of coordination between providers. 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.[62] 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. BIO also supports the expansion of the measures groups to include important chronic conditions such as asthma.

We also commend CMS on its inclusion of quality measures that ascertain whether or not patients have received preventive vaccinations such as the influenza and pneumococcal vaccines. However, in an effort to ensure that patients who respond "no" to these questions receive appropriate follow-up care, we recommend that measures be tested and considered for future inclusion that capture this information. For example, a future measure might state: "For patients who respond that they have not received a pneumococcal vaccination, was the vaccination given or was the patient directed to a pharmacy or other facility for vaccination (yes, no)."

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[61] 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 at al., The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital, Ann Internal Med 2003, 138(3): 161-67.
[62] 75 Fed. Reg. at 40191.

B. INCENTIVES FOR ELECTRONIC PRESCRIBING (eRx) – CMS should continue to implement the E-Prescribing 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 and addition to any PQRI payments.[63] We agree with 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.

XIV. 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/

Laurel L. Todd
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[63] Id. at 40202.