

August 29, 2008

BY ELECTRONIC DELIVERY

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

**Re: Medicare Program; Revisions to Payment Policies Under the
Physician Fee Schedule and Other Revisions to Part B for CY 2009;
Proposed Rule [CMS-1403-P]**

Dear Acting Administrator Weems:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to payment policies under the physician fee schedule and other revisions to Part B for calendar year 2009 (the "Proposed Rule").¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we continue to monitor changes to Medicare's reimbursement rates and payment policies for their potential adverse impact on innovation and patient access to drugs and biologicals. BIO appreciates CMS's efforts in implementing the average sales price methodology (ASP)

¹ 73 Fed. Reg. 38502 (July 7, 2008).

consistent with the goals of promoting transparency and predictability for reimbursement of physician administered drugs and biologicals. If Medicare does not compensate physicians appropriately for both the acquisition and administration costs of drugs and biologicals, physicians may not be able to administer these important therapies in their offices, and beneficiary access to them could be curtailed. If physicians and other providers stop providing state-of-the-art therapies to their patients as a result, manufacturers could be discouraged from developing new therapies. BIO urges CMS to protect beneficiary access to important drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. It is with this important goal in mind that our comments:

- Urge CMS not to finalize its proposal to exclude clinical staff time related to quality services from direct inputs in immunization administration codes;
- Urge CMS to continue pre-administration payments for intravenous immune globulin (IVIG);
- Support CMS's use of a volume-weighted average to calculate ASP;
- Urge CMS to instruct its contractors not to apply least costly alternative (LCA) policies to any drug or biological;
- 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 and should continue the five percent threshold;
- Request that CMS implement a materiality standard for ASP restatement;
- Support the expanded definition of physician for purposes of the Competitive Acquisition Program (CAP);
- Encourage CMS to finalize its proposal to allow physicians to transport CAP drugs and biologicals under certain circumstances;
- Urge CMS to permanently exclude CAP units from the calculation of ASP;
- Urge CMS to comply with Congress's intent that there be a positive update to the drug add-on payment in the ESRD setting and to continue using the Producer Price Index (PPI) as the price proxy;
- Encourage the agency to proceed with caution in applying the hospital-acquired conditions payment policy in other settings and to consolidate its proposals into a single rulemaking process;

- Ask CMS to fully implement and study the current gainsharing demonstration programs before proceeding with exceptions to current prohibitions on certain gainsharing arrangements;
- Encourage CMS to finalize quality measurements that are scientifically valid, consensus-based, and minimize physician burden;
- Ask the agency to take the lead on developing and implementing care coordination quality measurements;
- Urge CMS to implement the PQRI-related provisions of the MIPPA in a transparent and public process;
- Encourage reform of the current system of setting payment rates for innovative clinical diagnostic laboratory tests; and
- Ask the agency to change the date of service from the *date of collection* to the *date of performance* for certain novel laboratory-developed tests.

These issues are discussed in depth below.

I. CODING ISSUES

A. BIO urges CMS not to finalize its proposal to exclude clinical staff time related to quality services from direct inputs.

In February 2008, the American Medical Association's (AMA) Resource Value Scale (RVS) Update Committee (RUC) Practice Expense (PE) Subcommittee approved the movement of some of the indirect PE into the pool of direct PE inputs for the immunization administration (IA) codes. During that meeting, the RUC approved moving additional PE inputs into the existing pool of direct PE inputs for the "initial" IA codes of 90465, 90467, 90471 and 90473. The same changes were also approved for the "each additional" codes of 90466, 90468, 90472, and 90474.

In the Proposed Rule, however, CMS states, "*[W]e are in agreement with the RUC (PE) recommendations...except for inclusion of the clinical staff time related to quality activities for the following immunization administration codes: CPT codes 90465-90474. While we allow this time for mammography services due to the specific regulatory requirements required by the Mammography Quality*

*Standards Act (MQSA) of 1992, such MQSA time is not required for immunization services."*²

This means that CMS is proposing to exclude clinical staff time related to quality services when calculating the 2009 PE RVUs for the IA codes. This proposal is in direct conflict with CMS policy goals in other areas of the Medicare program intended to incentivize high-quality care. CMS correctly indicates that MQSA time is not required for immunization services, but there are many federal/state programs that require quality assessment for a variety of immunization services. These requirements and guidelines provide compelling evidence for the RUC-recommended clinical staff times for "quality activities" to be included in the 2009 PE RVUs for the immunization administration codes. BIO urges CMS to reconsider its proposal and accept the RUC PE Subcommittee's recommendations.

B. CMS should continue payment for preadministration-related services for IVIG.

In the Proposed Rule, CMS proposes to eliminate the payment for IVIG preadministration-related services (G0332).³ BIO urges the agency to continue this payment as this is an essential component of ensuring that Medicare beneficiaries have access to this vital therapy. BIO appreciates that CMS created the preadministration payment policy for CY 2006 in recognition of the challenges that physicians were facing with IVIG.⁴ BIO believes that these challenges still exist warranting a continuation of the preadministration payment policy. Further, the reasons that CMS states for discontinuing the preadministration payment do not support its termination.

In support of terminating the preadministration payment for 2009, CMS relies on a HHS Office of the Inspector General April 2007 study of the IVIG market (OIG Report),⁵ the issuance of new codes for certain therapies, and a slight increase in IVIG utilization. BIO believes that none of these factors, taken

² *Id.* at 38513

³ *Id.* at 38519.

⁴ 70 Fed. Reg. at 70116, 70219-20 (Nov. 21, 2005).

⁵ Office of Inspector General, U.S. Dep't of Health and Human Services, *Intravenous Immune Globulin: Medicare Payment and Availability* (OEI-03-05-00404) (2007).

individually or together, support CMS's conclusion to terminate the preadministration payments. CMS refers to the OIG Report's findings that 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts as support for an improved marketplace.⁶ One would expect this percentage to further decline when taking into account smaller and other regional distributors. BIO does not believe that there is stability in the IVIG marketplace when over 40 percent of the physicians cannot purchase IVIG at or below the Medicare payment rate. Further, CMS states that no other comprehensive studies have been conducted on the IVIG market. BIO, therefore, urges CMS to maintain the preadministration payment until other studies present clearer and more definitive evidence that the IVIG market has stabilized.

Second, CMS states that recent IVIG coding revisions have contributed to increased payments for IVIG and better market conditions. Specifically, CMS created new Healthcare Common Procedure Coding System (HCPCS) codes as of July 2007 to implement a separate payment for each of the liquid formulations of IVIG not included in a billing and payment code as of October 1, 2003. BIO greatly appreciates that CMS created these new codes but does not believe that this action resolved the many IVIG payment issues. While this policy impacts some, but not all, difficulties in the liquid IVIG therapy market, it does not address ongoing concern in the lyophilized IVIG therapy market. A large number of Medicare beneficiaries are treated with lyophilized IVIG. All of the lyophilized IVIG products continue to be bundled in the same HCPCS code.

CMS correctly points out that that the payment rates have increased for the IVIG HCPCS codes. However, to the best of our knowledge, CMS has not taken any specific steps to increase payment rates for IVIG – separate from calculating updated rates based on ASP submissions by the manufacturers of each therapy. Nevertheless, even with the updated payment rates and some brand-specific IVIG codes, there is no evidence that elimination of the preadministration-related services would not adversely impact patient access to IVIG therapy.

Finally, CMS cites the increase in IVIG utilization as evidence to support the elimination of payment for preadministration-related services. BIO does not agree

⁶ 73 Fed. Reg. at 38519.

with this conclusion. In fact, BIO believes that the increase in utilization supports the continuation of the preadministration payment. This payment was created to help compensate physicians for the challenges in locating and administering IVIG. If utilization is increasing, it shows that the payment of preadministration-related services is working as it was originally intended.

BIO urges CMS to continue the preadministration payment for IVIG for calendar year 2009. The preadministration payment improves Medicare beneficiary access to IVIG. Because there have been no findings or reports indicating that the market conditions that led to this policy have substantially improved, BIO believes that it would be inappropriate to discontinue the preadministration payment for 2009.

II. ASP ISSUES

A. BIO supports CMS's use of a volume-weighted average to calculate ASP.

On April 1, 2008, CMS changed the way it calculates the ASP for each HCPCS code. This change was mandated by the enactment of the Medicare, Medicaid, and SCHIP Extension Act of 2007⁷ (MMSEA) that requires CMS to calculate ASP based on a volume-weighted average of the total number of HCPCS billing units sold. Prior to the statutory change, CMS weighed smaller and larger package sizes equally. The ASP for one vial was equally weighted with the ASP for a box of five vials. As a result, CMS did not determine a weighted-average ASP for each billing code, but rather a weighted-average ASP per National Drug Code (NDC) unit. BIO believes that this was an inappropriate number to use for CMS's rate-setting purposes for most therapies.

CMS proposes to continue calculating ASP consistent with the volume-weighted average detailed in the MMSEA.⁸ BIO believes that using this methodology results in a more accurate reflection of the average price of all the units of the drug or biological sold. Accordingly, BIO urges CMS to finalize this proposal and use the volume-weighted average of the total number of billing units when computing the ASP for a HCPCS code that includes multiple NDCs.

⁷ Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. No. 110-173, 121 Stat. 2492.

⁸ *Id.* at § 112(a). 73 Fed. Reg. at 38521.

B. Consistent with legal requirements, CMS should instruct its contractors not to apply LCA to any drug or biological.

The MMSEA also established a special payment rule for certain inhalation drugs furnished through an item of durable medical equipment (DME).⁹ Specifically, the MMSEA requires CMS to reimburse the two drugs that this provision applies to the lower of the blended ASP (brand and generic) or each drug's ASP. Similarly, BIO believes that the payment rules for most drugs and biologicals are clearly stated in Section 1847A of the Social Security Act (SSA). Under this section, reimbursement for drugs and biologicals is set at 106 percent of the drug or biological's ASP or, for new drugs without established ASPs, is based on wholesale acquisition cost (WAC).

Despite these clear statutory mandates, CMS's contractors continued to apply LCA policies to the drugs identified by the MMSEA and some covered by Section 1847A of the SSA. Recently, Medicare contractors were applying LCA to the class of drugs identified in the MMSEA such that they were reimbursing the brand therapy based on the generic's ASP and not the lower of the blend of the brand and generic therapy's ASP or the brand therapy's ASP. Additionally, contractors continue to apply LCA to other drugs and biologicals that are clearly governed by Section 1847A of the SSA.

In June of this year, CMS instructed its contractors to withdraw the LCA policies for the inhalation drugs and to take no further action before December 31, 2008. BIO believes that the statutory payment provisions of the MMSEA and 1847A are clear. Accordingly, we urge CMS to finalize its contractor instructions regarding inhalation drugs and to further instruct its contractors to not apply LCA to any drug or biological.

C. CMS should proceed cautiously and with sufficient public notice on any substitution of WAMP or AMP for ASP and should continue the five percent threshold.

⁹ MMSEA at § 112(b).

The Medicare statute allows the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.¹⁰ The legislative history of this statutory provision clarifies that Congress intended for the Secretary to provide “a number of procedural and substantive safeguards to ensure the reliability and validity of the data” when deciding to substitute WAMP or AMP for ASP.¹¹ BIO appreciates that CMS recognizes “that there are complicated operational issues associated with potential payment substitutions.”¹² Further, CMS states that it will proceed cautiously in implementing WAMP and provide manufacturers with adequate notice before substituting the WAMP or the AMP for the ASP. BIO agrees with this approach and urges the agency to work closely with affected manufacturers before making any payment substitution. Finally, BIO supports CMS’s proposal to continue the applicable threshold for both the WAMP and AMP at five percent.

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

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 quarter impacted is too far in the past for any revision of the reimbursement rate to have any impact. BIO believes that establishing a materiality or *de minimis* threshold for restatement of ASPs, in combination with a requirement to notify CMS of the error and the methodology used to estimate its impact, will reduce this administrative burden while at the same time protecting manufacturers from the risk of penalty.

¹⁰ See Social Security Act (SSA) § 1847A(d)(3)(A).

¹¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 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”).

¹² 73 Fed. Reg. at 38521-22.

BIO urges CMS to apply a materiality 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. 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 change 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 reported for a quarter that is more than [six] quarters prior to the quarter in which the manufacturer discovers the error.

(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.

III. CAP ISSUES

A. CMS should finalize its expanded definition of physician for purposes of the CAP.

CMS proposes to expand the definition of physician for purposes of the CAP to include Nurse Practitioners (NPs), Clinical Nurse Specialist (CNSs), Physician Assistants (PAs), and other providers who can legally prescribe drugs administered incident to a physician's office visit.¹³ The stated goal of this proposal is to afford other providers the opportunity to participate in the CAP. In doing so, the agency anticipates, if finalized, an increase of no more than one percent of CAP participants.

¹³ *Id.* at 38523.

BIO believes that the expanded definition of physician could provide greater treatment options for Medicare beneficiaries, especially those who live in rural or underserved areas. As a result, Medicare beneficiaries may be able to access critical drug and biological therapies in a more convenient and preferable setting. As such, BIO asks that CMS finalize this proposal.

B. CMS should finalize its proposal to allow physicians to transport CAP drugs and biologicals under certain circumstances

CMS proposes to permit the transport of CAP drugs between a participating CAP physician's practice locations subject to voluntary agreements between the approved CAP vendor and the participating physician.¹⁴ CMS states that it believes that allowing CAP physicians to transport CAP drugs will make the CAP more flexible and therefore more appealing to physicians. BIO continues to believe that the CAP could provide greater Medicare beneficiary access to important drug and biological therapies. BIO therefore supports CMS's efforts to provide CAP physicians with greater flexibility, however, we share the agency's concerns regarding diversion and product integrity.

To address these concerns, CMS states that any voluntary agreement between a CAP vendor and a participating CAP physician to transport a CAP drug must include requirements that the drug or biologicals are not subjected to conditions that will jeopardize their integrity, stability, or sterility while being transported. Consistent with BIO's concerns, CMS further states that it is concerned about the possibility that spoilage or breakage could occur as physician's transport CAP drugs. BIO members invest millions of dollars in order to comply with the many state and federal laws relating to product integrity. This investment helps to ensure that each Medicare beneficiary receives the drug or biological in its approved and most effective form. BIO urges CMS to ensure that it is the responsibility of each CAP vendor to take appropriate steps to warn each participating physician of any necessary handling or storage requirements that have not already been communicated to the physician for any drug or biological. Further, BIO asks that the agency carefully monitor these agreements such that all CAP drugs retain their integrity and stability throughout the distribution chain.

¹⁴ *Id.* at 38523-24.

Finally, CMS states that any arrangement between a CAP vendor and a participating CAP physician must protect against fraudulent diversion of CAP drugs as well as comply with all applicable state and federal fraud and abuse laws. BIO agrees and urges CMS to finalize this requirement and its other proposals requiring the CAP physician to ensure the integrity and stability of CAP drugs.

C. CMS should permanently exclude CAP units from the calculation of ASP.

CMS has defined the term “unit” in section 414.802 of the ASP regulations to exclude units of CAP drugs sold to an approved CAP vendor for use under the CAP during the first three years of the CAP.¹⁵ The initial three-year contract period for the CAP will expire at the end of this year, and CMS has not addressed whether this exclusion will continue for the next CAP contract cycle. BIO strongly recommends that CMS revise section 414.802 to permanently exclude CAP units from the calculation of ASP.

As CMS explained when it established the CAP exclusion in a November 2005 interim final rule, “excluding CAP drug units from the ASP calculation will give manufacturers an incentive to provide discounts to approved CAP vendors that will, in turn, result in lower prices under the CAP.”¹⁶ The November 2005 rule amended the definition of “unit” in section 414.802 to exclude units of CAP drugs “administered to a beneficiary by a participating CAP physician” during the first three years of the program.¹⁷ CMS revised this regulatory exclusion in August 2006 to specify that manufacturers should exclude units of CAP drugs “sold to an approved CAP vendor” to address manufacturer concerns about being able to identify units administered to a beneficiary by a CAP physician.¹⁸ CMS said it would evaluate the impact of excluding CAP units from ASP after the initial three-year period of the program to determine whether CMS should continue the exclusion.¹⁹

¹⁵ 42 C.F.R. § 414.802.

¹⁶ Medicare Program, Exclusion of Vendor Purchases Made Under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales Price (ASP); Interim Final Rule, 70 Fed. Reg. 70478, 70480 (Nov. 21, 2005).

¹⁷ *Id.* at 70481.

¹⁸ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, Final Rules and Interim Final Rule, 71 Fed. Reg. 47870, 48132 (Aug. 18, 2006).

¹⁹ *Id.*

BIO believes that CMS should continue the exclusion of CAP units from the ASP calculation. Making this exclusion permanent is critical to achieving CMS's stated policy goal of ensuring that payment amounts under the ASP methodology are not affected by the CAP. We urge CMS to implement this change by amending the definition of "unit" in section 414.802 to remove the three-year limitation on the exclusion of CAP units from ASP.

IV. ESRD PROVISIONS

A. BIO urges CMS to comply with Congress's intent that there be a positive update to the drug add-on payment in the ESRD setting and to continue using PPI as a price proxy.

CMS proposes to apply a zero update to the drug add-on payment in ESRD facilities for calendar year 2009.²⁰ BIO believes that this proposal is inconsistent with Congressional intent. The statute states, "The Secretary shall annually increase the basic case-mix adjusted payment amounts."²¹ Congress enacted this provision because it envisioned annual increases to the drug add-on payment. Had Congress intended a zero or negative update it would have used the word "adjustment" consistent with other provisions in this section of the statute. For 2006, Congress instructed the Secretary to make certain adjustments to the payment rate for separately payable drugs and biologicals.²² By choosing the word "increase" as opposed to "adjustment," Congress signals to the Secretary that it anticipates an increase to the drug add-on. BIO, therefore, believes that CMS is ignoring Congressional intent with its proposal for a zero update to the drug add-on. Accordingly, BIO urges CMS to provide an annual increase to the drug add-on payment consistent with Congressional intent.

Further, CMS proposes to use ASP as the price proxy for the separately payable ESRD drugs instead of using the PPI for prescription drugs.²³ As a result of using ASP data for separately paid ESRD drugs for the previous ten quarters, CMS projects a negative update to the drug add-on payment. BIO believes that

²⁰ *Id.* at 38529.

²¹ SSA § 1881(b)(12)(F).

²² SSA § 1881(b)(12)(B)(ii).

²³ 73 Fed. Reg. at 38529.

using ASP as a price proxy as opposed to PPI is inconsistent with previous practice and leads to a conclusion that runs counter to Congressional intent. BIO urges CMS to continue to use the PPI as the price proxy.

B. CMS should proceed with caution in applying the hospital-acquired conditions payment policy in other settings and should consolidate its proposals into a single rulemaking process.

In the Proposed Rule, CMS discusses the possibility of, but does not propose, expanding the broad principle of “Medicare not paying for healthcare-associated conditions” beyond the Inpatient Hospital setting into other areas such as physician practices and hospital outpatient departments.²⁴

BIO urges CMS to exercise caution in expanding its payment policy regarding hospital-acquired conditions (HACs) from the inpatient hospital setting to other provider settings. The Hospital Inpatient Prospective Payment System (IPPS) HAC payment provision, authorized under section 1886(d)(4)(D) of the Social Security Act (SSA), requires the selection of at least two HACs that (1) are high cost and/or high volume; (2) result in assignment to a higher paying Medicare Severity-Diagnosis Related Group (MS-DRG) when present as a secondary diagnosis; and (3) are reasonably preventable through the application of evidence-based guidelines. For selected conditions, after October 1, 2008, Medicare will only assign a discharge to the higher MS-DRG if the selected HAC condition was not present upon admission.²⁵

Although BIO recognizes the importance of harmonizing incentives and payment mechanisms across different care settings, we strongly believe that CMS should gain greater experience with the payment mechanism in the inpatient setting prior to applying the approach to additional providers. When CMS first developed its quality initiatives, the agency began with hospitals and built on knowledge gained in that arena in order to develop subsequent initiatives for physicians and other settings. BIO suggests CMS employ this same incremental expansion approach with regard to the implementation of the HAC payment mechanism.

²⁴ Id. at 38533.

²⁵ Id. at 38533.

In addition, BIO would appreciate the opportunity to comment on the HAC proposals as a whole through a single rulemaking process. In a number of rules, CMS proposes to expand HACs to various settings. By consolidating the proposals into a single rule, CMS would afford commenters such as BIO the opportunity to compare the approach across different settings, facilitating the provision of more holistic feedback. Again, we believe such rulemaking should only take place after CMS has first gained experience with this policy in the inpatient hospital setting.

V. PHYSICIAN SELF-REFERRAL AND ANTI-MARKUP ISSUES

A. CMS should fully implement and study the current gainsharing demonstration programs before proceeding with exceptions to current prohibitions on certain gainsharing arrangements.

CMS solicits comments on its proposed exception to certain fraud and abuse laws to permit incentive payments or shared saving payments between hospitals and physicians.²⁶ These payments would result from the implementation of shared savings programs that CMS defines broadly to include pay for performance (P4P) and gainsharing programs. These programs seek to align physician economic incentives with those of hospitals by providing physicians with a share of the hospitals' cost savings resulting from physicians' efforts to control costs. In the Proposed Rule, CMS describes some of its ongoing and upcoming shared savings demonstration programs. The agency specifically describes three demonstration programs that have not yet been implemented,²⁷ and emphasizes that patient quality care improvement is a priority and a goal for shared saving programs. BIO agrees with CMS's goals; however, we urge CMS to implement all of its pending demonstration programs and study their results before moving forward with this proposal.

The agency cites section 1877(b)(4) of the SSA as its authority to create regulatory exceptions for financial relationships that it determines do not pose a risk of program or patient abuse. CMS then proposes a detailed regulatory exception to allow shared saving programs. BIO believes that this proposal is

²⁶ Id. at 38549-58.

²⁷ Id. at 38550.

premature. Section 1877(b)(4) provides that the Secretary exercise his authority after he determines that there is no risk of program or patient abuse. Because the demonstration programs that CMS detailed have not even started, the Secretary could not have determined that shared saving programs do not pose a risk of program or patient abuse. Further, the Secretary cannot be assured that shared saving programs CMS's stated goal of improved patient quality of care until these demonstration programs are complete. Accordingly, BIO urges the agency to fully implement the pending demonstration programs and study their outcomes to assure that these arrangements do not pose a risk of program or patient abuse and promote patient care before adopting this exception proposal.

BIO further notes that, in addition to the physician self-referral law, shared savings arrangements must not violate the anti-kickback and civil money penalty (CMP) statutes. While the OIG, not CMS, has authority over these statutes, the preamble discussion does not indicate how the regulatory exception can be implemented without a determination by the OIG that the individual shared savings arrangement will not subject providers to sanctions under the anti-kickback and/or CMP laws. Although the OIG has issued favorable advisory opinions for several shared savings arrangements, the OIG has done so only on a case-by-case basis and has required many safeguards within those arrangements. And, even in those favorable advisory opinions, the OIG has stated that the arrangements constituted "an improper payment to induce reduction or limitation of services" in violation of the CMP statute and, potentially, the anti-kickback statute. Therefore, any shared savings arrangement may run afoul of the anti-kickback and CMP laws and may pose an undue risk to providers.

VI. PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI)

A. BIO appreciates CMS's continued efforts to expand the PQRI quality measure set with measures that are scientifically valid and that minimize physician burden.

CMS continues to expand quality reporting in the physician office setting in ways that BIO believes will improve patient care and facilitate better physician decision-making while imposing minimal administrative burdens. As the PQRI

program matures,²⁸ BIO urges CMS to regularly revise its quality measures to reflect current guidelines in order to promote the provision of the up-to-date care to Medicare patients.

As part of the evolution of the PQRI program, CMS proposes to further refine the various reporting options available to physicians. CMS permits claims-based reporting for individual measures and allows both claims-based and registry-based reporting for select groups of measures.²⁹ BIO appreciates CMS's acknowledgement of the potential burdens associated with reporting and the agency's attempt to reduce that burden through use of registries and measures groups reporting. BIO especially commends CMS for retaining the influenza and pneumonia vaccination measures as individual measures in the 2009 PQRI measure set as well as for continuing to include the measures in the preventive care measures group.³⁰ As mentioned in previous comments, BIO strongly supports aggressive immunization strategies for both diseases and believes that inclusion of these measures will contribute to higher immunization rates among vulnerable populations.

B. CMS should continue to encourage the development of quality measures relating to care coordination.

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. Unfortunately, often patients and their families bear the burden of initiating follow-up care despite their insufficient knowledge about the condition.

A number of studies have found that insufficient care coordination, medication errors, and miscommunication may contribute to increased costs and

²⁸ Section 131(b)(3) of the Medicare Improvements for Patients and Providers Act of 2008 will facilitate ongoing participation in PQRI by authorizing incentive payments for quality reporting for 2007 through 2010.

²⁹ 73 Fed. Reg. at 38560-64.

³⁰ *Id.* at 38569, 38572.

suboptimal care outcomes.³¹ 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, such as the proposed "Melanoma: Coordination of Care" measure under consideration for the 2009 measure set.³² Inclusion of this and other care coordination measures will improve patient care and lead to more efficient use of limited healthcare resources.

C. BIO urges CMS to implement the provisions of Medicare Improvements for Patients and Providers Act of 2008 through a transparent, public process.

CMS is required to implement a number of new PQRI-related provisions in 2009 as a result of the recent Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). BIO urges CMS to establish a predictable and timely process for implementing the new MIPPA requirements. Such a process should include input from providers and other interested stakeholders to ensure the new provisions will minimize changes to current PQRI billing practices and allow providers to implement any new requirements in an efficient and timely manner. BIO looks forward to working with CMS to ensure the successful implementation of these new requirements.

VII. EXPIRING PROVISIONS/CLINICAL LABORATORY FEE SCHEDULE

A. The current reimbursement methodology for diagnostic laboratory tests is antiquated and should be reformed.

In order to realize the promise of personalized medicine, targeted diagnostics must be seen as the entryway and must be valued and reimbursed differently from traditional tests. Many of the newer clinical lab tests, and even more of those in

³¹ 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.

³² 73 Fed. Reg. at 38571.

development, represent an entirely new generation of diagnostics that can predict who is likely to develop certain cancers and other diseases, whether and how they will respond to particular therapeutics, what dosage of a particular drug is optimum for the individual, how combinations of drugs will be metabolized by people with particular genetic traits, the likelihood of recurrence of certain diseases, and the possibility of organ rejection. Furthermore, many other novel molecular diagnostics are being developed for disease sub-typing, disease prognosis, and treatment side-effects. These diagnostics will facilitate treatment that is far more tailored to individual characteristics and could save lives and money. Finally, certain diagnostic tests do not fit into a current reimbursement model because of the comprehensive testing that must be done on the patient's blood or tissue specimen. Often these tests are not performed in the same location as where the collection of the specimen occurred. This changing paradigm requires a new approach and new thinking towards coverage and reimbursement in order to fully stimulate and reward development of sophisticated diagnostic tests.

BIO firmly believes that maintaining the current reimbursement system will not provide sufficient incentives to encourage these innovations. Currently, diagnostic tests are reimbursed by either "crosswalking" the test into a current code or creating a new code for the test and allowing the carriers to "gap fill" or establish their own prices for the new code for a period of time until a national rate is calculated. Neither methodology is market-based, and the pace of innovation is slowed accordingly. BIO looks forward to working with CMS to reform the crosswalking and gapfilling methodologies to create a transparent and predictable market-based system that will stimulate and reward innovation, and reflect the value of these tests.

Developing and bringing to market this new generation of diagnostic tests typically is far more costly and complex than a traditional lab test. And even under CMS's gapfilling methodology, aimed at new tests for which there is no comparable, existing test, BIO is concerned that pricing variations among contractors may be so great, and so unpredictable, that innovation will be stifled and beneficiary access to these tests impeded. We also are concerned that setting a national payment amount when the market for the tests is not yet well-established and little claims experience is available will lead to inappropriate reimbursement and little opportunity for adjustment even if the pricing later is acknowledged to

have been set too low. In addition, because many of these new tests are proprietary and may be offered and performed by only one lab in the country, the gapfilled price established by the carrier serving that lab becomes a de facto national price, and if it is insufficient, it may not be economically feasible for the lab to offer the test at all. Additionally, BIO believes that the cross-walking process lacks transparency and predictability. CMS does not clearly state its decision making process when determining reimbursement amounts via the cross-walking process. BIO urges the agency to provide greater detail and clarity regarding the cross-walking decision-making process.

BIO asks for CMS to engage in discussions, both internally and with external stakeholders, to explore the research, therapeutic, and economic environments in which these next generation diagnostic tests are developed and to ensure that Medicare's payment policies take into consideration the investment of human and capital resources that go into these diagnostics, as well as the tremendous potential benefits, in terms of cost savings, clinical outcomes, and quality of life for Medicare beneficiaries. In the short term, we also ask that CMS seek input from interested parties in this arena regarding the appropriate guidance and criteria to provide to contractors that are pricing these novel lab tests. By ensuring appropriate value recognition of molecular diagnostic tests, the agency will create financial stability and attractiveness for the industry further facilitating continued investment and development of these diagnostics. This will go a long way toward realizing the promise of personalized medicine.

B. CMS should change the date of service from the *date of collection* to the *date of performance* for certain novel laboratory-developed tests.

Medicare's Laboratory Date of Service for Specimens regulations³³ establish the date of service for laboratory tests to be the date on which the specimen was collected. While the regulations provide exceptions for tests performed on stored specimens, the exceptions only apply to specimens stored for at least 14 days following the date the patient was discharged from the hospital. As a result, for tests performed on specimens obtained during hospital procedures, any test furnished within the 14-day window is deemed to have been provided on the date the specimen was collected.

³³ 42 C.F.R. § 414.510

In addition, Medicare's bundling rules³⁴ result in an unintended effect of the dates of service regulation when applied to certain novel laboratory-developed tests. In cases where the date of service for the laboratory test coincides with the date on which the patient was a hospital patient, Medicare's bundling rules treat the service as if it were furnished by the hospital even though the hospital may have nothing to do with the ordering or use of the test.

In order for laboratory tests that are technically furnished "during a hospital stay or encounter" to be covered, the hospital providing the treatment must bill for the laboratory service and assume professional responsibility for the test quality. Hospitals are reluctant to assume responsibility for the following reasons:

- The test is completely unrelated to the patient's hospital stay and is not used in the management of the patient during the hospital stay;
- Hospitals are reluctant to assume professional responsibility for tests that are not offered by the hospital and which are offered by laboratories that are unaffiliated and unfamiliar to the hospital;
- In instances where the test was furnished to a patient who was a hospital inpatient at the time the specimen was obtained, the payment made under the inpatient PPS is only payment available to the hospital, and hospitals are therefore reluctant to share with the laboratory a Medicare payment that does not reflect the cost of the laboratory service; and,
- In instances where the patient was a hospital outpatient when the specimen was obtained, Medicare will make a separate payment for the test under the Clinical Laboratory Fee Schedule, but the hospitals must assume the financial risk that the service is covered and that Medicare will reimburse as the hospital is obligated to pay the laboratory.

For these reasons, hospitals are delaying orders to avoid the responsibility required if the date of service relates the tests back to the hospital stay or encounter and are therefore cancelling orders.

BIO urges CMS to change the date of service from the date of collection to the date of performance for tests with the following criteria: the test is a genetics,

³⁴ 42 C.F.R. § § 411.15 and 410.42

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genomic, proteomic or cancer chemosensitivity assay; it is developed in-house; it is performed after the patient discharge or encounter; and the results are not used to manage the patient during the stay or encounter.

VIII. CONCLUSION

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We also applaud CMS's efforts to promote quality care for Medicare beneficiaries and believe that adequate reimbursement is an imperative part of this process. As discussed, it is imperative that Medicare compensate providers adequately for the costs associated with acquiring and administering these therapies in order to ensure that Medicare beneficiaries are not denied access to vital drugs and biologicals administered in physician offices. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel Todd
Director of Reimbursement
& Economic Policy