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BY ELECTRONIC DELIVERY

Acting Administrator Charlene Frizzera
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 2010; Proposed Rule
[CMS-1413-P]**

Dear Acting Administrator Frizzera:

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 2010 (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 1,200 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 impact on innovation and patient access to drugs and biologicals. Toward this end, BIO greatly appreciates CMS's efforts in the Proposed Rule to take steps to address the increasingly substantial, negative updates to the conversion factor. Decreasing

¹ 74 Fed. Reg. 33520 (July 13, 2009).

future negative updates to the conversion factor will help ensure that beneficiaries continue to have access to essential treatments and therapies. That said, we are deeply concerned about the 21.5 percent cut projected in 2010. 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.

BIO also is very concerned about the negative effect of CMS's proposed use of data from the American Medical Association's (AMA) Physician Practice Information Survey (PPIS) to establish Practice Expense (PE) Relative Value Units (RVUs) for 2010 for certain specialties, including for hematologists, cardiologists, nuclear medicine and oncologists who administer many of our members' therapies. Such a dramatic change in payment rates from one year to the next has the potential to disrupt patient care and may have serious consequences for patients' health. BIO urges CMS to protect beneficiaries' continued access to appropriate care by delaying the implementation of the PPIS to allow more time for a thorough review, or if the agency decides to proceed in 2010, by phasing-in payment rates using the new survey data and using this period for refinement.

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

- Encourage CMS to finalize quality measurements that are scientifically valid and minimize physician burden;
- Ask the agency to continue to encourage the development of quality measures related to care coordination;
- Request that the agency revise its proposed payment rates for kidney disease education (KDE) services to ensure that they appropriately reflect the time required to deliver them;
- Continue to implement the E-Prescribing Incentive Program as proposed;
- Urge CMS to develop a mechanism to ensure that any changes in approved compendia do not interrupt treatment plans for existing oncology patients;
- Agree that CMS should proceed cautiously and with sufficient public notice before substituting a therapy's widely available market price (WAMP) or average manufacturer price (AMP) for average sales price (ASP) and should continue to use the five percent threshold;
- Request that CMS implement a materiality standard for ASP restatement;

- Encourage CMS to finalize its proposal to discontinue annual competitive acquisition program (CAP) payment amount updates and to implement a quarterly update process;
- Urge CMS to treat similarly all therapies that can be used for treatment of a particular condition when amending the CAP drug list;
- Encourage CMS to finalize its proposal to establish a process for removing drugs from a CAP drug list, including giving affected physicians a choice in how to obtain therapies that have been removed;
- Ask CMS to ensure that as part of a rule that would allow CAP vendors to utilize electronic transactions to supply CAP drugs from vendor-owned stock in physician offices that the existing patient safety requirements are upheld regardless of how therapies are supplied;
- Urge CMS to finalize its proposal to permanently exclude CAP units from the calculation of ASP;
- Urge CMS to finalize its expanded definition of physician for purposes of the CAP;
- Encourage CMS to finalize its proposal to allow physicians to transport CAP drugs and biologicals under certain circumstances;
- Support CMS's decision to continue to reimburse all end-stage renal disease (ESRD) drugs and biologicals at ASP plus six percent;
- Urge CMS to comply with Congress's intent that there not be a negative update to the drug add-on payment in the ESRD setting;
- Encourage reform of the current system of setting payment rates for innovative clinical diagnostic laboratory tests; and
- Ask the agency to change its regulations to provide that the date of service for certain complex diagnostic laboratory tests is the *date of performance* rather than the *date of collection*; and,
- Urge CMS to finalize its proposal to remove physician-administered drugs from the definition of "physician services" for purposes of computing the SGR for future years.

These issues are discussed in depth below.

- I. **Resource-Based PE RVUs: BIO urges CMS to protect beneficiary access to specialty care by delaying the implementation of the PPIS to allow more time for a thorough review, or if the agency decides to proceed in 2010, by phasing-in the new payment rates over a refinement period of at least four years.**

In past years, CMS has used data from the AMA's Socioeconomic Monitoring Survey (SMS) and supplemental surveys to derive PE RVUs. In calendar years 2007 and 2008, the AMA conducted a new survey, the PPIS. CMS proposes to use data from the PPIS in place of the SMS survey data and supplemental survey data to update PE RVUs for CY 2010 for specialties that participated in the PPIS.² The effect of this change would be to dramatically reduce payment rates for a number of physician specialties, including for hematologists, cardiologists, nuclear medicine and oncologists who administer many of our members' therapies.³

BIO has concerns regarding CMS's proposal to use the PPIS data because of its potential negative impact on payments for physician specialties and the corresponding impact on patient access and care. Patients who currently are under the care of a specialist may suddenly find that their physicians no longer are willing or able to provide such services because of the significant change in reimbursement, with devastating consequences for patients' health and wellbeing. BIO encourages CMS to consider carefully the comments from physician specialties regarding the proposed use of the PPIS data, and, in particular, their technical and methodological analyses, when considering whether to move forward with this proposal.

CMS has acknowledged in the past the difficulty in appropriately allocating indirect costs to individual services. This is because they are incurred by the physician practice as a whole (e.g. rent, utilities, accounting and legal fees, office staff). For this reason, the agency should proceed cautiously as it considers using the new PPIS data. During the limited time available to analyze these data, several notable issues have been identified.

First, CMS acknowledges the precision levels of PPIS are below the precision requirements for the supplemental survey data. CMS argues that the comprehensiveness, consistency in collection, and contemporaneous nature of the PPIS negates the need for similar precision requirements. However, further analysis seems warranted when specialties like cardiology and medical oncology, who submitted supplemental survey data that met the more stringent previous

² Id. at 33530-31.

³ Id. at 33661.

requirements, now see significant declines in their average practice expenses per hour when the PPIS data are used.

Second, it is not clear whether there has been analysis to determine if there are significant subsets of practice arrangements within a specialty and, if so, whether those subsets adequately represented. For example, there are likely very different practice expenses in hospital-based and office-based practices, and the survey results may be biased if it does not distinguish between these two practice settings. However, it is not clear whether this issue has been explored.

Third, the survey response rates across specialties were low, leading to surprisingly large variability around the estimates. For example, some specialties with \$1 billion or more in annual allowed charges exhibited variability around the mean in excess of plus or minus 20% (with a 10% likelihood the variability was even larger). Given the large payment redistributions that would occur if the PPIS were to be used, this level of variability suggests a need to either collect additional data to reduce the imprecision, or to replace the PPIS with an enhanced survey.

It is notable that when CMS changed to the 'bottom-up' methodology for determining direct practice expense costs beginning in 2007, it first held a Town Hall meeting to discuss the proposal and to allow for public comments. It then published a separate proposed rule in advance of the main proposed rule for 2007. This separate proposed rule allowed additional time to analyze the proposal and submit comments. The changes CMS has proposed for the 2010 practice expense would be even more disruptive than those proposed for 2006. Therefore, the agency should impose a 1-year moratorium on using the PPIS data to fully evaluate questions such as those raised above, and to consider whether it needs to fund and conduct a separate, more comprehensive survey with improved precision power.

If CMS does decide to use the PPIS data to establish PE RVUs starting in 2010, BIO urges CMS to consider doing so through a phase-in with refinement period, spreading full implementation over at least four years. BIO believes that doing so 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 will give the agency and interested stakeholders the opportunity to more carefully analyze the new data and its appropriateness in setting PE RVUs as well as give physician specialty societies the opportunity to collect new and more

detailed data where appropriate for refinement. Moreover, it will give the agency the opportunity to evaluate the impact of the change on patient access to determine whether proceeding with full implementation is appropriate.

II. ISSUES RELATED TO THE MEDICARE IMPROVEMENTS FOR PATIENTS AND PROVIDERS ACT OF 2008 (MIPPA): 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 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,⁴ BIO urges CMS to revise its quality measures regularly to reflect current guidelines in order to promote the provision of the up-to-date care to Medicare beneficiaries.

With regard to particular measures, BIO especially commends CMS for retaining the influenza and pneumonia vaccination measures as individual measures in the 2010 PQRI measure set as well as for continuing to include the measures in the preventive care measures group.⁵ 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. BIO also commends CMS for proposing the new measure related to documenting cancer stage. Staging is a critical component of cancer care and can lead to more targeted treatment plans for patients and as a result, better health outcomes.

As part of the evolution of the PQRI program, CMS proposes to further refine the various reporting options available to physicians.⁶ BIO appreciates CMS's acknowledgement of the potential burdens associated with reporting and the agency's attempt to reduce that burden through use of multiple reporting mechanisms and the ability to report on both individual measures and measures

⁴ Section 131(b)(3) of MIPPA will facilitate ongoing participation in PQRI by authorizing incentive payments for quality reporting for 2007 through 2010.

⁵ 74 Fed. Reg. at 33577, 33583.

⁶ *Id.* at 33559-71.

groups. To that end, BIO supports CMS's proposal to also allow physicians to use electronic health records (EHRs) to report certain quality measures in 2010 and the agency's proposals to facilitate group practice reporting.⁷

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, 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.⁸ 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 "Melanoma: Coordination of Care" measure adopted for the 2009 measure set.⁹ 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.

III. MIPPA ISSUES: THE E-PRESCRIBING INCENTIVE PROGRAM

⁷ Id. at 33561, 33569-71.

⁸ 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.

⁹ 74 Fed. Reg. at 33580.

A. CMS should continue to implement the E-Prescribing Incentive Program as proposed.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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 Social Security Act (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 "expected to encourage significant expansion of the use of e-prescribing by authorizing a combination of financial incentives and payment adjustment[s]," particularly because incentive payments are separate from and addition to any PQRI payments.¹⁰ 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.

IV. MIPPA ISSUES: KIDNEY DISEASE PATIENT EDUCATION SERVICES

A. CMS should revise its proposed payment rates for KDE services to ensure that they appropriately reflect the time necessary to deliver them.

Section 152(b) of MIPPA provides coverage of KDE services for patients as a new Medicare-covered benefit under Part B. The Proposed Rule explains, "This new benefit is available for Medicare beneficiaries diagnosed with Stage IV [chronic kidney disease] CKD, who in accordance with accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant."¹¹

BIO believes KDE is a critical new service that has the potential to improve the physical and psychological health of patients with renal disease. We appreciate that CMS has collected – and incorporated – broad stakeholder feedback in its proposal of how to implement this benefit and that the agency is proposing to cover all stage IV patients. In setting its payment rates for KDE services, however,

¹⁰ Id. At 33594.

¹¹ Id. at 33615.

we are concerned that CMS made an error in its calculations that must be fixed to ensure Medicare beneficiaries have access to this valuable benefit. Specifically, CMS crosswalked the proposed payment for KDE to medical nutrition therapy because the two services are similar in the individual and group setting. Unfortunately, CMS did not correctly match up the time for the services – KDE is 60 minutes, and medical nutrition therapy is 15 minutes (30 minutes for a group). Consequently, the 60 minute KDE individual service is proposed to be paid the same as a 15 minute individual medical nutrition therapy service, and the 60 minute KDE group service is proposed to be paid the same as a 30 minute group medical nutrition therapy service. BIO asks CMS to correct this in the final rule such that the 60 minute individual KDE service is paid at four times the rate of a 15 minute individual medical nutrition therapy service and the 60 minute group KDE service is paid at twice the rate of a 30 minute group medical nutrition therapy service.

V. MIPPA ISSUES: REVISION OF DEFINITION OF MEDICALLY-ACCEPTED INDICATIONS FOR DRUGS

A. CMS’s proposal to implement the statutory requirement that compendia have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest is reasonable and should be finalized.

Section 1861(t)(2)(B) of the Social Security Act (SSA) requires that “[o]n and after January 1, 2010, no compendia may be included on the list of compendia [used to determine medically-accepted indications of drugs and biologicals used off-label in anticancer chemotherapeutic regimens] unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.” CMS proposes to implement this statutory requirement by amending the current definition of compendia in 42 C.F.R. § 414.930(a) to include the requirement.¹² The agency further proposes that a compendium could meet this requirement by publishing the evidence considered and the review of the evidence leading to the development of compendium’s recommendations on its web site, including the names of the individuals who have substantively participated in the development of the recommendations.¹³ CMS also proposes that a compendium have a process for disclosing by publication on its web site information regarding

¹² Id. at 33621-23.

¹³ Id. at 33621-22.

potential financial and non-financial conflicts of interest associated with the individuals who are responsible for the compendium's recommendations as well as their immediate family members.¹⁴

BIO believes CMS's proposal is a reasonable way to implement the statutory requirement that compendia have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest. The requirement that compendia make the evidence and evaluation of the evidence used to make recommendations publicly available on their web sites is not overly burdensome and will increase transparency by allowing for independent review by interested parties. The proposed process for disclosure of potential conflicts of interest should further increase transparency. It also is unlikely to be overly burdensome because, as CMS notes, publishers of the four currently-recognized compendia have conflict of interest disclosure policies similar to those that are proposed.¹⁵ BIO therefore encourages CMS to finalize its proposal to implement the new statutory requirement for a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.

We ask CMS to include in its requirements for a "publicly transparent process for evaluating therapies" a requirement that the compendia disclose the timeframe in which it will reply to, and act upon, any submissions it has solicited from outside entities. This requirement would be addressed in a new subsection (v) under the definition of "publicly transparent process for evaluating therapies" at 42 C.F.R. § 414.930:

(v) The timeframe in which it will reply to, and act upon, any submissions it has solicited from outside entities.

We also ask CMS to include in the final rule a statement recognizing the importance of the compendia in helping patients, physicians, and other practitioners identify the most appropriate treatment options for each patient's condition. The compendia are particularly important in cancer care, where a large number of treatment regimens involve the use of FDA-approved therapies for indications other than those on their labels. In addition, similar to the Medicare statute, many state laws rely on the compendia to identify medically accepted uses of drugs that must be covered by health insurance.

¹⁴ Id. at 33622.

¹⁵ Id.

B. BIO urges CMS to establish a grandfathering provision to ensure that existing oncology patients' treatment plans are not affected by the removal of any compendium from the list of recognized compendia.

CMS notes that “[a]ll currently listed compendia will be required to comply with [the new] provisions, as of January 1, 2010, to remain on the list of recognized compendia,” and “urge[s] currently listed compendia publishers to submit evidence demonstrating compliance with the MIPPA provisions . . . no later than December 31, 2009.”¹⁶ BIO is concerned about the impact on a patient that is being treated with an off-label anticancer chemotherapeutic regimen that has been determined to be medically-accepted by a currently-recognized compendium if that compendium fails to meet the new provisions and is removed from the list of recognized compendia as of January 1, 2010.

For example, CMS recognizes that not all of the currently-recognized compendia provide conflict of interest disclosure information for family members of individuals who participate substantively in development of the compendia recommendations.¹⁷ If a compendium did not submit evidence demonstrating compliance with this requirement by December 31, 2009, it would be removed from the list of recognized compendia the next day under CMS’s proposal. This could result in a beneficiary’s losing coverage overnight for an initiated course of treatment that previously had been covered. The only options for a patient in this situation are either to continue the treatment at the patient’s own expense, that may be financially devastating, or to suspend the treatment, potentially having a detrimental impact on the patient’s health.

To avoid this problem, BIO urges CMS to adopt a grandfathering provision that would allow patients that begin prior to December 31, 2009 an off-label anticancer chemotherapeutic regimen that has been deemed medically-accepted by a recognized compendia to continue to have the course of treatment covered even if the compendia is removed from the list of recognized compendia after that date for non-compliance with the new provisions. This will ensure that the new provisions apply prospectively only and do not adversely affect patients already undergoing treatment.

¹⁶ Id. at 33621.

¹⁷ Id. at 33622.

VI. ASP ISSUES

A. 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.

The SSA allows the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.¹⁸ 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.¹⁹ BIO appreciates that CMS recognizes “that there are complicated operational issues associated with potential payment substitutions.”²⁰ Further, CMS states that it will proceed cautiously in implementing WAMP and provide manufacturers with adequate notice before substituting WAMP or AMP for ASP.²¹ 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.

B. 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 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

¹⁸ See SSA § 1847A(d)(3)(A).

¹⁹ 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”).

²⁰ 74 Fed. Reg. at 33623.

²¹ Id.

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 National Drug Code (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.

VII. CAP ISSUES

A. CMS should finalize its proposal to discontinue annual CAP payment amount updates and to implement a quarterly update process using reasonable net acquisition cost (RNAC).

CMS proposes to discontinue annual CAP payment updates and to implement a quarterly update process using RNAC.²² BIO agrees with CMS that such a change will ensure that CAP payment amounts will be better able to keep up with unanticipated drug cost changes, thereby lowering potential vendor risk and likely attracting vendors to the program. Therefore, BIO supports this proposal.

²² *Id.* at 33624-25.

BIO believes, however, that it is important for CMS to finalize its proposal to limit payment amounts under the new update process to ASP plus six percent to maintain a level of parity between the two systems and prevent a situation in which significant payment differentials “might skew incentives and choices.”²³

B. BIO urges CMS to treat similarly all therapies that can be used for treatment of a particular condition when amending the CAP drug list.

CMS proposes to narrow the CAP drug list to higher cost items used by specialties that most frequently prescribe drugs under the CAP.²⁴ CMS proposes to “fill in” other therapies that have reasonably high utilization in Medicare that are “related to drugs already in the CAP.”²⁵ The stated purpose of the fill-in process is to ensure that certain categories of drugs used under the CAP are more fully represented, although CMS has yet to determine how it will determine which drugs should be filled in.²⁶

BIO supports CMS’s proposal to narrow the CAP drug list because it will ease the accounting, tracking, and claims submission burden related to the CAP. However, we believe that instead of focusing solely on costs, CMS should focus on those products that are commonly administered by physicians, as well as other products whose exclusion from the program would create an undue burden on participating physicians. BIO urges CMS to consider carefully the comments of individual BIO members regarding specific drugs and biologicals that should be included in the CAP drug list. In general, BIO believes that it is important that the CAP drug list not be used—intentionally or otherwise—to create financial incentives that would result in a preference for certain therapies over others when those drugs or biologicals are used for the same treatment purpose. That is, in determining how to narrow the CAP drug list, and in selecting “fill in” drugs and biologicals, CMS should ensure that all therapies that can be used to treat a particular condition are treated similarly, by including all of them in the CAP drug list, or excluding all of them, as is appropriate. This will help ensure that the CAP drug list is not used inappropriately to advantage or disadvantage particular therapies.

²³ Id. at 33624.

²⁴ Id. at 33626.

²⁵ Id.

²⁶ Id.

C. CMS should finalize its proposal to establish a process for removing therapies from a CAP drug list, including giving affected physicians a choice in how to obtain therapies that have been removed.

CMS proposes to create a process to allow an approved CAP vendor to request the permanent removal from its CAP drug list of a Healthcare Common Procedure Coding System (HCPCS) code for which no NDCs are available.²⁷ According to CMS, the process would be available to respond to “sudden, long-term changes in drug supply that are beyond the control of the approved CAP vendor,” and is “not intended to be used frequently” or to “manag[e] short-term unavailability.”²⁸ Under the proposal, physicians served by an affected vendor could switch to ASP reimbursement for any removed drugs or biologicals or switch CAP vendors.²⁹

BIO supports the proposal to create a process to remove drugs and biologicals from the CAP list to mitigate the effects that interruptions in availability can have on an approved CAP vendor’s ability to supply CAP drugs during the course of the contract. However, removing drugs and biologicals from the CAP list should only occur in situations where there are long-term supply issues beyond the vendor’s control. BIO appreciates CMS’s proposal to give physicians participating in the CAP who are affected by the deletion of a HCPCS code from an approved CAP vendor’s drug list options for obtaining the drug that has been deleted to ensure that the physician can proceed after such a disruption in the manner most sensible for the beneficiary’s continued access to necessary drugs and biologicals.

D. CMS should finalize its proposal to allow CAP vendors to use electronic transactions to supply CAP drugs from vendor-owned stock in physician offices and make clear in the final rule that patient safety requirements continue to apply to all CAP vendors regardless of how drugs are supplied.

CMS has in the past prohibited participating CAP physicians from maintaining a stock of an approved CAP vendor’s drug in his or her inventory because of reservations about potential program integrity and drug diversion.³⁰

²⁷ Id. at 33627-28.

²⁸ Id.

²⁹ Id. at 33628.

³⁰ See id.

Noting that “concerns over program integrity and drug diversion have not come to pass,”³¹ CMS proposes to allow approved CAP vendors to use electronic transactions to furnish CAP drugs from nominal quantities of approved CAP vendor-owned stock located at the physician’s office.³² The stated purpose of the proposal is to increase flexibility in the program by allowing vendors who are able to supply drugs and biologicals in this manner to participate in the CAP bidding process.³³ CMS proposes to continue to prohibit physicians from taking title to or paying for CAP drugs and states that the proposal does not affect the requirements for information that must be submitted with a prescription order, the applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to such data, and state licensing requirements.³⁴ Finally, CMS proposes that CAP emergency delivery and restocking still would be required.³⁵

BIO agrees that providing alternative approaches bidders may use to supply drugs under the CAP may attract potential vendors and help make the program viable, thereby providing greater beneficiary access to necessary drugs and biologicals. Accordingly, BIO supports the proposal, but recommends that CMS permit CAP vendors to institute monthly inventory management cycles to allow for reconciliation between the CAP vendor and physician offices. Under the current system, many physicians face short inventory management cycles, which require significant coordination between the physician office and vendor. A monthly reconciliation cycle will further reduce operational and administrative burdens for physician offices and may help attract more physicians to participate in the CAP program. Further, BIO believes that the continued applicability of prescription order information submission requirements, state licensing requirements, and emergency delivery and restocking requirements are crucial for patient safety and urges CMS to make clear in the Final Rule that these requirements continue to apply to all CAP vendors.

E. CMS should finalize its proposal 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

³¹ Id.

³² Id. at 33628-29.

³³ Id. at 33629.

³⁴ Id.

³⁵ Id.

give manufacturers an incentive to provide discounts to approved CAP vendors that will, in turn, result in lower prices under the CAP.”³⁶ The November 2005 rule amended the definition of “unit” in 42 CFR § 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.³⁷ 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.³⁸ 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.³⁹ CMS has concluded that “operational experience has not indicated a reason for changing [the] policy of excluding CAP units sold to approved CAP vendors for use under the CAP from ASP calculations.”⁴⁰

BIO has long supported the exclusion of CAP units from the ASP calculation to achieve CMS’s stated policy goal of ensuring that payment amounts under the ASP methodology are not affected by the CAP. We agree with CMS that such exclusion will continue to promote the separation and independence of the two drug payment models. Accordingly, we are pleased to support CMS’s proposal to permanently exclude drugs supplied under the CAP from ASP calculations by changing the definition of “unit” at 42 C.F.R. § 414.802.

F. 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 Specialists (CNSs), Physician Assistants (PAs), and other providers who can legally prescribe drugs administered incident to a physician’s office visit.⁴¹ The stated goal of the proposal is to afford other providers the opportunity to participate in the CAP.⁴² CMS expects that most

³⁶ Medicare Program, Exclusion of Vendor Purchases Made Under the CAP for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the ASP; Interim Final Rule, 70 Fed. Reg. 70478, 70480 (Nov. 21, 2005).

³⁷ Id. at 70481.

³⁸ 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).

³⁹ Id.

⁴⁰ 74 Fed. Reg. at 33630.

⁴¹ Id. at 33631-32.

⁴² Id.

non-physician practitioners would bill under specific physician provider numbers, but does not want to exclude practitioners who are able to bill independently for drugs associated with services that are covered when provided by a physician from participating in the CAP.⁴³

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 more convenient and preferable settings. As such, BIO asks that CMS finalize this proposal.

G. 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.⁴⁴ 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.⁴⁵ As BIO previously commented, we support CMS's efforts to provide CAP physicians with greater flexibility; however, we also 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.⁴⁶ Consistent with BIO's concerns, CMS further states that it is concerned about the appropriate storage and handling of drugs during a physician's transport.⁴⁷ 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

⁴³ Id.

⁴⁴ Id. at 33632-33.

⁴⁵ Id. at 33632.

⁴⁶ Id.

⁴⁷ Id.

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.

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.⁴⁸ 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.

VIII. ESRD PROVISIONS

A. BIO supports CMS's decision to continue to reimburse all ESRD drugs and biologicals at ASP plus six percent.

In the Proposed Rule, CMS does not propose any changes to reimbursement for separately billable ESRD drugs and biologicals, which remains at ASP plus six percent.⁴⁹ BIO continues to support using the ASP plus six percent methodology for separately billable drugs when billed by freestanding or hospital-based ESRD facilities. ASP-based reimbursement is the best option available under the statute, and it is more accurate and easier to administer than updating a prior year's acquisition cost data.

B. BIO urges CMS to comply with Congress's intent that there not be a negative update to the drug add-on payment in the ESRD setting.

CMS proposes to use trend analysis from ASP data to update the drug add-on amount for the separately payable ESRD drugs for calendar year 2010.⁵⁰ Using this analysis, CMS calculates the average annual change in drug expenditures to be negative 2.2 percent.⁵¹ CMS also estimates the growth in enrollment to be 1.3 percent.⁵² Combining these two figures produces a projected 3.5 percent decrease

⁴⁸ Id.

⁴⁹ See id. at 33635.

⁵⁰ Id. at 33636.

⁵¹ Id.

⁵² Id.

in the per patient growth of drug expenditures.⁵³ Instead of implementing a reduction to the drug add-on, however, CMS proposes to implement a zero update for 2010.⁵⁴

The statute states, “The Secretary shall annually increase the basic case-mix adjusted payment amounts.”⁵⁵ 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.”⁵⁶ BIO agrees with the interpretation of the statute and urges CMS to implement it in the final rule.

IX. CLINICAL LABORATORY FEE SCHEDULE ISSUES

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

Many of the newer clinical lab tests, and even more of those in 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 both lives and money. However, certain diagnostic tests do not fit into the current reimbursement model because of the complex testing that must be done on the patient’s blood or tissue specimen. Furthermore, 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 to a current code

⁵³ Id. at 33637.

⁵⁴ Id.

⁵⁵ SSA § 1881(b)(12)(F).

⁵⁶ 74 Fed. Reg. at 33637.

or creating a new code for the test and allowing the contractors to “gap fill” or establish their own payment rates 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 has expressed its interest in 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 true value of these tests, and reiterates that interest here.

Developing and bringing to market this new generation of diagnostic tests typically is far more costly and complex than a traditional lab test. Even with regards to CMS’s gap filling methodology, aimed at new tests for which there is no comparable, existing test, BIO is concerned that payment variation 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 data is available will lead to inappropriate reimbursement and little opportunity for adjustment even if the payment rate 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 rate established by the carrier serving that lab becomes a *de facto* national rate, 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 continues to urge the agency to provide greater detail and clarity regarding the cross-walking decision-making process.

BIO again 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, improved clinical outcomes, and increases in 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 establishing payment rates for these novel lab tests. Ensuring an appropriate reimbursement system which recognizes novel technology, such as molecular diagnostic tests, will

further facilitate continued investment and development of these diagnostics. This will go a long way toward realizing the promise of personalized medicine.

B. CMS should change its regulations to provide that the date of service for certain complex diagnostic laboratory tests is the *date of performance* rather than the *date of collection*.

Current Medicare regulations (42 C.F.R. § 414.510) establish the date of service for laboratory tests as the date on which the specimen was collected (*e.g.*, when the biopsy was performed that harvested the tissue specimen), unless the test is performed on a specimen stored for at least 14 days following the date the patient was discharged from the hospital. Consequently, any test performed on specimens obtained during hospital procedures within 14 days of discharge is deemed to have been provided on the date the specimen was collected, *i.e.*, the date on which the patient was a hospital patient. Under other Medicare rules (42 C.F.R. §§ 411.15(m) and 410.42), when the date of service for the laboratory test coincides with the date on which the patient was a hospital patient, the laboratory service is treated as if it was furnished by the hospital, even though the hospital may have nothing to do with the ordering or use of the test.

With respect to a narrow class of advanced diagnostics, the combination of these rules are creating a host of financial and administrative disincentives for hospitals, which in turn create obstacles for physicians and their patients, and genuine barriers to access to these specialized tests.

In light of these problems, BIO urges CMS to change 42 C.F.R. § 414.510 such that the date of service for certain advanced diagnostics would be the *date of performance* rather than the *date of collection*. This revised treatment should apply only to advanced diagnostic tests that meet the following criteria:

- The test is an analysis of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, or gene expression or similar method, or is a cancer chemotherapy sensitivity assay or similar method, but not including methods principally consisting of routine chemistry or routine immunology;
- The specimen was collected while the patient was undergoing a hospital procedure;

- The test was performed after the period during which the individual was a patient of the hospital and the specimen was collected;
- The results of the test do not guide the treatment provided during the hospital stay or encounter when the specimen was collected;
- The test was reasonable and medically necessary for the treatment of an illness;
- The test is developed and performed by a laboratory that is independent of the hospital in which the specimen was collected; and
- The test is not furnished by the hospital where the specimen was collected to a patient of such hospital, directly or under an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients.

X. PFS UPDATE FOR CY 2010: BIO supports CMS's efforts to bring stability to the Medicare Program and preserve patient access to necessary care by changing the sustainable growth rate (SGR) calculation methodology to reduce future negative updates to the conversion factor, but continues to be deeply concerned about the 21.5 percent cut projected in 2010.

Under the SGR system, as a result of a consistent increase in the volume and intensity of physician services over time and legislative intervention in prior years, CMS has had to propose significant reductions in PFS rates. Each year the proposed reduction threatens to limit patient access to necessary treatments and therapies by reducing reimbursement rates. This year's estimated 21.5 percent reduction⁵⁷ in particular would seriously challenge the ability of providers to continue to participate in the Medicare Program and, correspondingly, have severe consequences for patient access. The annual proposed reductions also cause instability in the Medicare Program generally because year-to-year reimbursement rates are subject to substantial variation. As a result, BIO agrees with CMS that the current physician payment system needs to be reformed.

CMS recognizes there are a "breadth of options" available to facilitate reform of the physician payment system.⁵⁸ In the Proposed Rule, the only mechanism proposed is to remove physician-administered drugs from the definition of "physician services" for purposes of computing the SGR for future years and to make the change retrospective to the base year of 1996.⁵⁹ Because the

⁵⁷Id. at 33649-50.

⁵⁸Id. at 33650.

⁵⁹Id. at 33650-51.

effect of this proposal will be to reduce the number of years in which physicians are projected to experience a negative update, thereby bringing greater stability to the Medicare Program and ensuring continued patient access to necessary services and therapies, BIO supports the proposal, and asks CMS to finalize it.

BIO also is deeply concerned about the 21.5 percent cut projected in 2010. 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.

XI. 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. Accordingly, as discussed in these comments, we support CMS's proposal to modify the SGR calculation methodology and urge the agency to proceed cautiously and incrementally in using PPIS data to update PE RVUs. 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/

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