
October 10, 2006

***BY ELECTRONIC DELIVERY***

Mark McClellan, Administrator
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, DC 20201

**Re: CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)**

Dear Administrator McClellan:

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 for calendar year 2007 and other changes to payment under Part B (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 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

---

[1] 71 Fed. Reg. 48,982 (Aug. 22, 2006).

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we are greatly concerned about the impact of Medicare's reimbursement on access to drugs and biologicals. If Medicare does not compensate providers appropriately for their acquisition and administration costs, Medicare beneficiaries may be denied access to essential drugs and biologicals. If physicians and hospitals stop providing innovative 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 in this spirit that we offer comments to CMS' proposals regarding the elimination of the deductible for colorectal cancer screening, myriad average sales price (ASP) issues, increasing the clotting factor furnishing fee, placing limits on CMS' substitution of widely available market price (WAMP) or average manufacturer price (AMP) for ASP, clarifying the treatment of drugs and biologicals furnished through durable medical equipment (DME), including resources involved in compounding when pricing compounded drugs, continuing the preadministration-related services for standard and specialty intravenous immune globulin (IVIG), reimbursement for all end-stage renal disease (ESRD) drugs and biologicals at ASP plus six percent, improving the current system of setting payment rates for new outpatient clinical diagnostic laboratory tests, and ensuring adequate reimbursement for drug administration services. These issues are discussed in depth below.

## I. BIO strongly supports CMS' proposal to amend its regulations to exempt colorectal cancer screening from the Part B deductible requirement ["DRA Proposals"].

Colorectal cancer is a particularly grave disease that often exhibits no symptoms until it reaches an advanced stage. It is for this reason that timely screening for colorectal cancer is imperative in order to fight it. Under the provisions of the Deficit Reduction Act of 2005 (DRA), colorectal cancer screening services are no longer subject to the Part B deductible beginning January

1, 2007.[2] In the Proposed Rule, CMS states its intention to conform its regulations to this statutory change, and, accordingly, its regulations now also will except from the Part B deductible colorectal cancer screening services.[3] BIO strongly supports this proposal as it will increase patient access to this important screening service and will help in the fight against this deadly disease.

## II. CMS should continue to provide guidance to providers and patients that the implementation of Part D does not alter coverage for drugs and biologicals under Part B ["ASP Issues"].

In the Proposed Rule, CMS states, "The Medicare Part D program does not change Medicare Part B coverage."[4] BIO agrees with this statement. The Part B benefit design is substantially different from Part D, and patients and providers need to understand the continued availability of coverage for certain provider-administered drugs and biologicals under Part B. We appreciate this and previous CMS statements regarding continuing Part B coverage that help ensure that patients and providers clearly understand that benefits for provider-administered drugs and biologicals remain available. We are concerned, however, by reports of providers asking Medicare beneficiaries to obtain drugs traditionally covered under Part B through Part D pharmacies instead. This "brown bagging" raises several safety concerns, particularly for drugs with special storage and handing requirements. It is opposed by several medical societies and should be opposed by CMS as well. We are further concerned by reports of Medicare Advantage plans denying Part B coverage of drugs traditionally covered under Part B and instead requiring members to obtain these drugs using their Part D coverage, sometimes coupled with a requirement that the drugs be administered at home by a home health agency nurse instead of in a physician office or hospital setting. This raises safety concerns and also increases beneficiaries' out-of-pocket costs since most beneficiaries do not have wraparound coverage for Part D as many do for Part B.

---

2 DRA, § 5113, Pub. L. No. 109-171 (2005).

3 71 Fed. Reg. at 48,999.

4 Id. at 49,000.

## III. BIO urges CMS to use formal rulemaking procedures to provide clear guidance to manufacturers so they are able to submit accurate and consistent ASP data.

Since ASP is intended to serve as and is clearly defined in Federal Statute[5] as a reimbursement mechanism, it is important that CMS carefully consider any changes in the way ASP is calculated. BIO supports predictability and transparency in the ASP calculation, and we therefore have consistently urged CMS to provide clear guidance to manufacturers so that they are able to submit accurate and consistent data.

Although we have been pleased by CMS' efforts to date to work with manufacturers to resolve questions about ASP reporting obligations in the past, we believe that it is critically important that CMS use its annual formal rulemaking procedures to make any changes to the ASP calculation. BIO appreciates the informal guidance CMS has provided on the ASP calculation and the flexibility that it provides, yet we believe it is important that manufacturers and others be given the opportunity to comment on specific proposals prior to further ASP calculation changes. Indeed, to date, CMS has made significant changes and clarifications through Questions and Answers (Q&As) on its website, rather than through formal rulemaking. For example, until this Proposed Rule, the only significant guidance provided by CMS on the proper treatment of service fees in ASP has been through a Q&A.[6] The calculation of ASP is complex, and even a minor change to the way ASP is calculated could have detrimental effects on provider reimbursement and, in turn, patient access. Moreover, stiff penalties are associated with misrepresentations of ASP, making clear guidance even more vital to manufacturers. Unambiguous guidance can be accomplished best through an annual formal rulemaking in which all interested stakeholders are given an opportunity to review and comment on the proposed rule, and CMS is able to consider and respond specifically to the comments made.

### A. CMS should define the term purchaser.

---

5 Social Security Act SSA § 1847(A).

6 See Q&A #3318, located at http://questions.cms.hhs.gov.

In the Proposed Rule, CMS attempts to revise its guidance on the proper treatment of administrative and service fees in the ASP calculation. This amended guidance provides that fees paid by manufacturers to an entity, whether or not that entity takes title to the product, must be considered price concessions for purposes of the ASP calculation unless the fees meet the Proposed Rule's definition of a bona fide service fee.[7] The preamble to the Proposed Rule clarifies that this standard is applicable to service fees paid to group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).[8] BIO strongly opposes the application of the bona fide service fee standard to entities, such as GPOs, that do not take title to product. Even if CMS were to conclude that such entities are included in the ASP calculation, BIO urges CMS to exclude from the ASP calculation fees paid to non-purchasers where such fees are otherwise protected by safe harbors under the Anti-Kickback Act. .

ASP is defined by statute as the measure of "the manufacturer's sales to all purchasers . . ."[9] The Medicare Modernization Act does not define the term purchaser, and BIO urges CMS to define this crucial term so as to provide clarity regarding the types of entities that are statutorily eligible for the ASP calculation. ASP is intended measure the acquisition costs of those entities whose reimbursement will be based on ASP. Accordingly, BIO believes it is appropriate to define a purchaser as an entity that takes title to and possession of a product. It is only entities that take title to and possession of product, such as hospitals, clinics, physicians, and pharmacies, which are reimbursed based on ASP, and therefore only transactions involving such entities should be included when measuring this important reimbursement metric. The inclusion of non-purchaser transactions in the ASP calculation that do not impact provider acquisition cost necessarily will have the effect of decreasing the accuracy of ASP as a measurement of provider acquisition costs, potentially having a drastic impact on provider reimbursement and, therefore, patient access.

### B. CMS should clarify that fees paid to non-purchasers are not price concessions.

---

7 71 Fed. Reg. at 49,001.

8 Id.

9 Social Security Act (SSA) § 1847A(c)(1) (emphasis added).

With the term "purchaser" defined in this way, BIO urges CMS to revise the Proposed Rule to clarify that GPOs are not purchasers and, for that reason, fees paid to GPOs need not be evaluated for inclusion in the ASP calculation. GPOs are entities that negotiate contracts with vendor manufacturers on behalf of their members that are health care providers, such as hospitals, clinics, nursing homes, and physician practices. GPOs do not themselves purchase drugs and biologicals, but instead negotiate contracts that providers use in making their own purchases. GPOs allow health care providers to band together for the purpose of negotiating with manufacturers, but GPOs in general never themselves purchase product. Given that GPOs are not purchasers, any fees paid by a manufacturer to a GPO should not be considered a price concession that is eligible for the ASP calculation.

The Office of Inspector General has studied GPOs and their relationships with their members and found that there are situations in which a GPO may share some portion of the fee paid by a manufacturer with its members, who are purchasers.[10] Manufacturers have no control over these arrangements and typically are unaware of the contractual terms between the GPO and its members.[11] Accordingly, even when the GPO shares some portion of a manufacturer fee with its members, the exact amount is not known by the manufacturer and therefore, those fees should not be considered discounts provided by the manufacturer to a purchaser.

A requirement to treat GPO administrative fees as a discount in the above situations also would face a significant practical hurdle. Specifically, manufacturers would have no basis for determining the amount of the fee that is

---

[10] The Office of Inspector General (OIG) found in an audit conducted of three large GPOs that the GPOs retained a significant amount of the administrative fees and that their practices regarding passing on administrative fees to members differed. See Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

[11] BIO recognizes, however, that where the contract between the manufacturer and the GPO directs the GPO to pass on service fees to the GPO's members, the manufacturer indirectly would be paying fees to a purchaser, and, therefore, the bona fide service fee standard should be applied to the portion of the fee passed on to the members.

shared with the member purchasers or to which product the fee should be attributed as a price concession. Without this information, manufacturers have no basis for including these fees in the ASP calculation.

The Proposed Rule also purports to clarify that the bona fide service fee standard applies not only to GPOs, but also to PBMs.[12] BIO asks that CMS explain the basis for the proposed application of the bona fide service fee definition to fees paid to PBMs. Specifically, we ask CMS to explain whether it considers PBMs to be a purchaser, as defined above, such that fees paid to PBMs are subject to evaluation under the bona fide service fee definition. If that is the basis for CMS' position, BIO asks that CMS clarify whether this position is applicable to fees paid to PBMs that are not associated with product purchased by the PBM, e.g. product that is purchased by a pharmacy other than by a mail order pharmacy that is owned by the PBM. As discussed above, if the basis for the Proposed Rule's application to PBMs is that the bona fide service fee standard is applicable to entities that do not take title to the product, then BIO again strongly urges CMS to reconsider its position.[13]

In the event CMS moves forward on its proposal to include fees paid to GPOs and PBMs as price concessions, except where the fees meet the bona fide service fee standard, BIO requests that CMS not include as discounts those fees that meet a safe harbor to the anti-kickback law.[14] The anti-kickback law is quite broad,[15] and, as a result, the OIG developed certain safe harbors to permit health care providers to engage freely in business practices that encourage competition

---

12 71 Fed. Reg. at 49,001.

13 This same analysis is also relevant to manufacturer transactions with healthcare plans that are not purchasers. Under these arrangements, the plan does not take title to or possession of the manufacturer's product, but rather reimburses the dispensing pharmacy for the manufacturer's product at an agreed upon price, and then the manufacturer pays the plan a specified rebate amount on each unit of its product reimbursed by the plan.

14 See 42 C.F.R. § 1001.952. In the case of fees paid to PBMs, The Office of Inspector General has explained that manufacturers can protect payment arrangements made with PBMs by structuring them so that they are consistent with the GPO safe harbor. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003).

15 See SSA § 1128B(b).

and economy[16] while also reducing the potential for abuse.[17] Administrative and service fee arrangements that satisfy the safe harbor requirements, or in the case of administrative fees paid to PBMs, are consistent with those requirements, represent arrangements that the OIG already has recognized as acceptable and non-abusive. This approach would ensure a consistent characterization of such fees for purposes of reporting net price to purchasers as required under the discount safe harbor of the Anti-Kickback Act and for ASP calculation purposes BIO urges CMS to exclude from the ASP calculation fees that meet these requirements.

### C. CMS should provide more detailed guidance to manufacturers on the standard for determining when fees qualify as bona fide service fees.

In the Proposed Rule, CMS explains that fees that meet the criteria of a bona fide service fee are not considered price concessions for the purpose of calculating ASP.[18] Although BIO generally supports CMS' proposal regarding bona fide service fees, we ask that CMS provide more detailed guidance to manufacturers on the standard for determining when a fee qualifies as a "bona fide service fee." Moreover, BIO strongly urges that CMS provide this guidance in a formal rulemaking, rather than through program instruction. As discussed, even minor changes in the way ASP is reported can have dramatic impacts on provider reimbursement and, therefore, patient access. BIO asks that guidance provided in this area be through a formal rulemaking so that CMS has access to public comments on this issue and is able to fully understand the ramifications of any rule change.

#### 1. CMS should provide guidance on the fair market value standard.

Bona fide service fees are defined in the Proposed Rule as "fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the

---

16 54 Fed. Reg. 3088 (Jan. 23, 1989).

17 Id.

18 71 Fed. Reg. at 49,001.

manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drugs."[19] CMS stated that it was "considering providing further guidance on or revising the approach or methodology manufacturers must use to determine the fair market value of bona fide services performed on their behalf,"[20] and BIO encourages CMS to do so.

CMS' current guidance on the proper fair market value standard is ambiguous at best. This guidance, found through a Q&A on CMS' website, fails to specify any appropriate methodology for determining fair market value and instead directs only that fees be paid "at the same rate had the[] services been performed by other [non-buyer] entities."[21] This definition assumes that manufacturers are able to choose between purchaser and non-purchaser entities for the performance of services. Many services performed by wholesalers and distributors for a manufacturer only can be performed by a purchaser. For example, manufacturers often enter into data agreements with distributors whereby the distributor provides the manufacturer with data regarding the entities that purchase the manufacturer's products. This data only is available from that entity.

Given that many services performed on behalf of manufacturers must be performed by a purchaser, BIO first requests that CMS confirm that fair market value need not be shown by demonstrating the cost of obtaining the service from a non-purchaser. BIO next requests that CMS clarify that manufacturers may establish fair market value for bona fide services through any accepted industry methodology. Specifically, CMS should provide guidance that any reasonable and supportable method for determining fair market value is appropriate. Acceptable methodologies would include, but not be limited to the income method,[22] the

---

19 Id.

20 Id.

21 See Q&A #4136, located at http://questions.cms.hhs.gov.

22 The income approach to fair market valuation involves the determination of the present value of the future earnings associated with an asset or service. In other words, one would determine the present value of the future earnings a manufacturer could expect as a result of the services rendered.

market method,[23] or the cost method.[24] CMS also should make clear that while documentation to support FMV must be retained by the manufacturer, FMV, which by definition is a range, is not required to be stated in the actual service fee agreement.

BIO also asks that CMS explain further what is meant by requiring that the bona fide service be "itemized." We recognize the value in requiring service fee contracts to specify the services to be performed, but we advocate that no separate itemized payment for each service be required. Manufacturers should be permitted to pay a service fee that covers an array of services provided and still be compliant with the bona fide service fee definition. Moreover, manufacturers should be permitted to obtain a fair market value analysis of the array of services offered rather than for each service individually.

**2. CMS should provide additional guidance on the documentation required to demonstrate that fees paid to an entity have not been passed on to a customer.**

In the Proposed Rule, CMS also states that it is considering giving additional guidance on the methodology to be used to demonstrate that a fee paid to an entity has not been passed on to a customer.[25] BIO asks that CMS clarify that manufacturers need not have an affirmative contract provision in their contracts with distributors that prohibits the passing on of service fees. Instead, the absence of an affirmative requirement in the contract that requires the passing on of fees should be sufficient. A requirement that service fee contracts contain a specific provision prohibiting the passing on of service fees will pose a significant barrier when existing contracts do not contain such a provision. If CMS determines that a specific contract provision is required, BIO asks that manufacturers be given a minimum two quarter implementation period during

---

[23] The market method involves a determination of what others in the market are paying for similar services.

[24] The cost method to fair market valuation requires the manufacturer to determine the cost of replacing the service. Specifically, the manufacturer would need to determine how much it would cost to have a third party provide the service.

[25] 71 Fed. Reg. at 49,001.

which they can amend their service fee contracts before such a requirement becomes effective.

### 3. CMS should specify the types of services that qualify as bona fide services.

CMS has explained that it is considering providing guidance on the types of services that may qualify as bona fide services for purposes of the ASP calculation.[26] BIO urges CMS to provide a list of services that are illustrative and non-exhaustive to allow for multitude of particular situations that might arise in the future. For example, many services performed by distributors, such as inventory management (i.e. stable purchasing patterns that do not have excessive highs or lows), ensuring timely delivery of product to the end-user, patient education, and data services, are important functions performed on behalf of the manufacturer that a wholesaler or distributor need not perform as part of its business model. Manufacturers cannot perform these services themselves, and they provide a great value to the manufacturer. Certain types of products require different types of services. For example, certain drugs may have specific patient education requirements, whereas other products may require little in the way of patient education. Accordingly, rather than specify the types of services that can qualify as bona fide services, BIO requests that CMS provide a standard for manufacturers to use when determining the types of services that can qualify as bona fide services. BIO recommends that CMS specify that a bona fide service include any service performed by an entity on behalf of the manufacturer that provides a value to the manufacturer**.**

### 4. CMS should recognize explicitly that ASP reporting standards differ from financial accounting standards.

BIO appreciates that CMS has requested guidance on how Medicare's treatment of service fees for ASP may differ from the treatment of such fees for financial accounting purposes and the implications this may have for manufacturers. The rules and requirements for price reporting differ significantly from the rules and requirements applicable to financial accounting. Most

---

[26] Id.

significantly, in the financial accounting realm many fees that would qualify as bona fide service fees for ASP calculation purposes may be required to be counted as a reduction in revenue for financial accounting.

Pursuant to the Financial Accounting Standards Board (FASB) guidance, fees paid to a distributor, even when the fees are for an itemized service performed on behalf of the manufacturer, must be included as a price concession if the identified benefit to the manufacturer is not sufficiently separable from the recipient's purchase of the vendor's products such that the vendor could have entered into an exchange transaction with a party other than a purchaser of its products in order to receive the benefit.[27] As discussed above, many of the services performed by distributors on behalf of a manufacturer are not "sufficiently separable" from the sale of product under this standard. For instance, data provided by distributors to a manufacturer typically involves information on the resale of a manufacturer's products, and thus the data service provided could not be performed by a non-purchaser of the manufacturer's products. In another example, manufacturers have paid service fees to ensure that their products are delivered by distributors to healthcare providers within a specified time frame often related to patient need or stability requirements. This timely delivery is a benefit to the manufacturer because it encourages providers to use its products. This service, however, is tied to the purchase of its product and could not be performed by a non-purchaser entity, and thus may be required to be treated as a discount for financial reporting purposes.

CMS should not amend its guidance on the proper treatment of service fees to be consistent with financial reporting standards. Instead, CMS explicitly should recognize the different purposes served by these standards. Whereas ASP is meant to determine average acquisition cost for a manufacturer's products and is used by CMS to set reimbursement rates, financial accounting standards are meant to show the financial position of a business. Accordingly, CMS should clarify that a manufacturer need not treat service fees as discounts for ASP when it must do so for purposes of its financial accounting.

---

[27] FASB Guidance, EITF 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products).

### D. BIO requests that CMS clarify that the proposed estimation methodology does not apply to non-purchasers and applies prospectively only.

The Social Security Act requires manufacturers to exclude from the ASP calculation those sales that are exempt from the Medicaid best price calculation.[28] As recognized by CMS, manufacturers identify many ASP-ineligible sales through chargeback and rebate data that may not be available at the time the ASP is calculated.[29] BIO generally supports CMS' proposal to establish a uniform approach to estimating lagged exempt sales that is similar to the estimation methodology employed to estimate lagged price concessions. As noted by CMS, the use of similar methodologies for estimating lagged exempt sales and lagged price concessions should reduce errors in the ASP calculation and reduce the likelihood of quarter to quarter variations in ASP.[30] However, BIO urges CMS to clarify that the proposed estimation methodology does not apply to ASP-ineligible entities **that are payors rather than purchasers, e.g., SPAPs and Part D plans.**

#### 1. CMS should provide clarifications regarding the removal of certain ASP-ineligible sales from the ASP calculation.

Although not addressed in the Proposed Rule, BIO asks that CMS provide additional guidance on the removal of certain ASP-ineligible sales from the ASP calculation. First, BIO asks that CMS clarify that only those units sold to possession-taking ASP-ineligible entities, as opposed to units reimbursed by ASP-ineligible entities, be removed from the ASP calculation. As discussed above, ASP is intended to be an average price to purchasers and is used by Medicare to set provider reimbursement rates that are tied to acquisition cost.[31] Indeed, one impetus behind the use of ASP as a reimbursement rate was the recommendation

---

28 SSA § 1847A(c)(2).

29 71 Fed. Reg. at 49,001.

30 Id. at 49,002.

31 See SSA § 1847A(c)(1).

by the Government Accounting Office that providers be reimbursed "at levels reflecting providers' acquisition costs."[32]

Certain ASP-ineligible entities, such as Part D plans and state pharmaceutical assistance plans, do not purchase product themselves, but instead reimburse providers for their purchase of product. Therefore, removing sales in which these ASP-ineligible entities reimbursed an ASP-eligible purchaser will unfairly distort the ASP calculation by removing sales made to ASP-eligible purchasers. For example, a sale of an oral oncology product to a retail pharmacy should be included in ASP. Under the current ASP methodology, when the retail pharmacy is reimbursed for the product by a State Pharmacy Assistance Program, the sale is removed from the ASP calculation despite the fact that the initial sale to the retail pharmacy is an ASP-eligible sale. Accordingly, CMS should clarify that manufacturers should not remove sales reimbursed by ASP-ineligible entities from the ASP calculation.

In the event CMS does not adopt this proposal, BIO asks that it recognize that manufacturers need not (and cannot) remove ASP-ineligible utilization when they are unable to identify it. In calculating ASP, manufacturers are directed to exclude all best price exempt sales and units.[33] The Medicaid drug rebate statute excludes from best price "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title."[34] Manufacturers typically identify such transactions through rebate data. For example, when a Medicare Part D plan reimburses a provider for a drug, it subsequently sends the manufacturer a rebate claim that allows the manufacturer to identify that transaction in order to exclude it from the ASP calculation. Identifying sales to qualified retiree prescription drugs plans, however, is more problematic.

---

[32] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H.R. Rep. No. 108-391.

[33] SSA § 1847A(c)(2).

[34] SSA § 1927(c)(1)(C).

Typically, rebates made available to qualified retiree prescription drug plans are included in a contract with a PBM that includes commercial plans as well. The rebate claims submitted to the manufacturers under these contracts typically do not separately quantify the utilization for the qualified retiree plans. To address this situation, BIO asks CMS to confirm that a manufacturer's inability to remove such utilization based on lack of data does not render the calculated ASP inaccurate for purposes of the statute, certification, and civil monetary penalties provision. BIO also notes that the best-price exemption for these plans can be interpreted to apply only to the rebates paid on the qualified retiree utilization and not that of the dependents who also are covered by the qualified retiree plan.[35] Even where utilization can be separately quantified for the qualified retiree plan, such utilization data often does not distinguish between the retiree and his or her dependents. To address this situation, BIO asks CMS to clarify that where qualified retiree plan utilization is available, manufacturers may exclude the entirety of that utilization from the ASP calculation without regard to whether or not that utilization includes retiree dependents.

**2. CMS should clarify the ineligible sales estimation methodology, specify that it is to be applied prospectively only, and provide sufficient lead time for implementation.**

In describing the estimation methodology, CMS explains that the rolling average percentage estimate is to be applied to the ASP denominator and that "manufacturers must make a corresponding adjustment to the numerator of the ASP calculation to ensure that the total in dollars for the reporting quarter does not include revenue related to lagged exempted sales excluded from the denominator using the proposed estimation methodology."[36] BIO requests that CMS specify that manufacturers make the adjustment to the numerator by applying the calculated ratio to the sales dollars counterpart to the units figure to which the Proposed Rule directs the application of the ratio. In addition, BIO requests that

---

[35] The Medicaid drug rebate statute excludes from best price "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title." Id. Typically, it is only the retiree who is entitled to benefits under Part A or Part B, and, therefore, only prices charged to the retiree are to be excluded from ASP.

[36] Id.

CMS specify that manufacturers may develop the estimate ratio either on a class of trade specific basis or across all ASP-ineligible classes of trade.

BIO asks that CMS clarify in its final rule that use of the estimation methodology for lagged exempt sales is required on a prospective basis only and postpone the implementation date until the quarter that is two full quarters after a final rule is issued. Although many manufacturers already may have adopted an ineligible sales estimation methodology, some manufacturers may not have done so, and those with existing methodologies may need to revise those methodologies to comply with the rule. In either case, the methodology should be applied prospectively only, and manufacturers should be provided with the significant lead time necessary to ensure that compliant and accurate ASP figures result.

### E. CMS should adopt the definition of nominal sales found in the DRA in order to ensure consistency across the Medicaid and Medicare programs.

In the Proposed Rule, CMS recognizes that changes to the definition of a nominal sale for purposes of Medicaid mandated by the DRA will have implications for ASP reporting as well.[37] Under the ASP reporting statute, manufacturers are required to exclude from the ASP calculation sales that are merely nominal in amount, as that term is defined under the Medicaid statute, "except as the Secretary may otherwise provide."[38] Currently, for both Medicaid and ASP reporting purposes, a nominal sale is a sale at a price less than 10 percent of the AMP in the same quarter for which the AMP is computed. The DRA made several significant changes to the Medicaid statute, including, effective January 1, 2007, to the definition of a nominal sale.[39] Under the current ASP reporting rule, this change also will apply to the definition of nominal sale for purposes of the ASP calculation.[40]

---

37 Id.

38 SSA § 1847A(c)(2)(B).

39 DRA, § 6001(d)(2), Pub. L. No. 109-171. The DRA amended the definition of nominal sales so that only sales to specified entities, such as 340B Public Health Service covered entities and state-owned or operated nursing homes, can be considered nominal in amount.

40 71 Fed. Reg. at 49,002.

CMS is seeking comments on whether the Secretary of Health and Human Services (the "Secretary") should establish an alternative definition of nominal sales for ASP purposes as permitted by the Social Security Act.[41] BIO strongly supports CMS' current proposal that manufacturers continue to use the Medicaid definition of nominal sales for purposes of the ASP calculation.[42] As noted by CMS, this approach helps "maintain continuity in the ASP calculation and minimizes manufacturers' reporting burden."[43] The reporting burden for manufacturers is lessened to the extent continuity is maintained between Medicaid and Medicare price reporting.

Although BIO generally supports CMS' proposal, we ask that CMS consider providing manufacturers the option of using the prior quarter's AMP for calculating its nominal prices in order to assist manufacturers with the timely reporting of ASP. Use of the current quarter's ASP forces manufacturers to wait until their quarterly AMP is finalized before calculating ASP. This can impose significant time pressure on some manufacturers. Therefore, manufacturers should have the option of using the prior quarter's AMP so long as a manufacturer uses the same methodology across all products. In addition, BIO asks that CMS further explain how the DRA's requirement for the monthly reporting of AMP translates into a quarterly AMP for purposes of establishing a nominal price.

We also recommend that CMS clarify the definition of safety net provider for purposes of nominal sales determinations. Under the Social Security Act, the Secretary may designate any facility or entity "that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate," based on factors enumerated in the statute. Currently, manufacturers cannot always readily determine whether an entity would qualify as a safety net provider. It would promote accuracy and consistency in ASP reporting if CMS maintained and posted a list of entities that the Secretary determines to be qualifying safety net entities for ASP reporting purposes.

---

41 Id.

42 Id. at 49,003.

43 Id.

### F. BIO supports CMS' proposals regarding the estimation of lagged price concessions for (1) National Drug Codes (NDCs) with less than 12 months of sales, and (2) redesignated NDCs.

BIO appreciates CMS' willingness to provide additional guidance on the proper estimation methodology to be used to determine lagged price concessions when a product has less than 12 months of sales data. BIO supports CMS' proposal to clarify in the rule that the period used to estimate lagged price concessions for products with less than 12 months of sales is the total number of months the NDC has been sold.[44] This revision is reasonable, and it provides manufacturers with needed guidance on this issue.

BIO also generally supports CMS' proposal related to redesignated NDCs. CMS has proposed that when an NDC is changed as the result of a modification of its package design or other non-drug feature of the NDC and the price concessions offered for the prior NDC remain in effect for the redesignated NDC, manufacturers must use 12 months of sales and price concession data from both the prior and redesignated NDCs to estimate the lagged price concessions applicable to the redesignated NDC.[45] BIO supports this proposal and understands the importance of preventing manufacturers from restarting the 12 month period when no product change has occurred.

BIO requests, however, that CMS provide further guidance on the types of situations to which this rule will apply. In the preamble discussion, CMS refers to situations when the labeler code is changed or when the manufacturer modifies its package design or other "non-drug feature" of the NDC.[46] BIO asks that CMS provide further details on the types of situations to which this rule will apply, as well as those situations for which it will be inapplicable (such as where a product receives a new NDC-9). Moreover, BIO asks that CMS provide further details regarding the appropriate application of this rule when both the prior NDC and the redesignated NDC remain on the market. For example, CMS should

---

44 Id.

45 Id.

46 Id.

explain whether, in such a situation, the manufacturer is required to combine the price concession data for both products to create a single ratio that is used to estimate lagged price concessions for both products. Additionally, CMS should clarify for how long the data on the two products must be combined. For example, CMS should explain whether the combination of data should extend through the period in which the last lot of the prior NDC expires.

Finally, BIO urges CMS to revisit this issue following the issuance of the Food and Drug Administration's (FDA) final rule on establishment registration and listing. An NDC consists of a labeler code, product code, and package code. Under the current regulations, FDA issues a manufacturer a labeler code, and the manufacturer assigns to its own drugs the product and package codes pursuant to certain parameters set forth by the FDA.[47] Under the proposed rule on establishment registration and listing, the FDA would begin assigning all parts of the NDC to a drug, i.e., the labeler code, product code, and package code.[48] FDA's assumption of the NDC assignment process could alter the need for and application of the Proposed Rule. Accordingly, once the FDA takes over responsibility for assigning NDCs, this issue should be revisited to determine the necessity of the provision.

### G. Bundled Price Concessions

BIO appreciates that CMS has requested industry comments to better understand the impact of "bundled price concessions" on the calculation of ASP as the agency considers providing further guidance in this regard. Because of the sensitive competitive and individual company business issues inherent in these arrangements, BIO is unable to provide detailed comments on bundling arrangements and urges the agency to proceed methodically. As stated later in our comments, we welcome the opportunity to work with CMS to find solutions to ASP issues that are market-based and preserve beneficiary access to innovative therapies.

---

47 21 C.F.R. § 207.35.

48 71 Fed. Reg. 51,276, 51,280 (Aug. 29, 2006).

BIO supports clear guidelines to ensure that manufacturers can carry out their reporting obligations in compliance with all applicable laws and regulations. Predictability is essential for compliance reasons. Yet at the same time, we are concerned that any methodology adopted may be inelastic and fail to foster beneficial arrangements. To help ensure that any additional guidance that CMS ultimately may issue on the treatment of "bundled price concessions" in ASP calculations provides the clarity, elasticity, and predictability, CMS should publish a specific proposal in draft form and give manufacturers, physicians, beneficiaries, and other stakeholders a meaningful opportunity to comment before it is finalized.

### H. CMS should seek the authority to exclude prompt payment discounts from the ASP calculation.

CMS should seek authority from Congress to exclude prompt payment discounts from the ASP calculation so that ASP better approximates provider acquisition costs and to bring about consistency between the Medicaid and Medicare programs. Although BIO recognizes that, as of now, the ASP statute requires manufacturers to include prompt payment discounts as price concessions in the ASP calculation,[49] we ask CMS to urge Congress to amend the statute to exclude such discounts.

ASP is used by CMS to set provider reimbursement rates and is meant to be a measure of provider acquisition costs. Prompt payment discounts are typically unavailable to providers because providers do not purchase directly from the manufacturer. Instead, they purchase through a distributor. As such, the inclusion of this discount in the ASP calculation serves to lower the ASP, and subsequently provider reimbursement, despite the fact that the vast majority of providers have no access to this discount.

The exclusion of prompt payment discounts from the ASP calculation also is consistent with Congress' recent amendments to the Medicaid statute. In amending the Medicaid statute so as to use AMP to set payment rates,[50] the DRA also amended the statute to not include prompt payment discounts in the

---

[49] Id. § 1847A(c)(3).

[50] See DRA § 6001(a)(2), Pub. L. No. 109-171 (2005).

calculation of AMP.[51] CMS should urge Congress to similarly amend the ASP statute. By excluding prompt payment discounts from the ASP calculation, the ASP will better reflect provider acquisition costs and will be more consistent with the AMP calculation.

### I. CMS should clarify that civil monetary penalties stop accumulating as of the date a manufacturer notifies CMS of a correction.

Under the ASP regulations, a civil monetary penalty in an amount of up to $10,000 may be applied "for each price misrepresentation and for each day in which the price misrepresentation was applied."[52] As CMS may not always revise its published reimbursement rates in response to a manufacturer's submission of corrected ASP figures, BIO requests that CMS clarify that the civil monetary penalties cease to apply as of the date the manufacturer submits the corrected figures. Such a rule will encourage manufacturers to submit corrected figures as soon as possible because such a submission will stop the accumulation of any potential penalties, whether or not CMS chooses to revise reimbursement rates in response to the corrected submission.

## IV. BIO welcomes the opportunity to work with CMS to find solutions for certain inadequacies in the use of ASP to determine provider reimbursement.

As CMS has recognized, ASP is an imperfect metric for determining real-time provider acquisition costs for the purpose of setting reimbursement rates. The two-quarter lag between the quarter for which an ASP is calculated and the quarter for which that ASP sets a reimbursement rate can lead to significant payment inaccuracies. Most significantly, this lag means that the reimbursement rate is too low for at least a two-quarter period following any price increase. In addition, this lag means that when a generic enters the market and it uses the same Healthcare Common Procedure Coding System (HCPCS) code as a more expensive branded product, the government overpays for the generic for at least

---

51 Id. §§ 6001(c)(1)(A), 6003(b)(2).

52 42 C.F.R. § 414.806.

two quarters because during that lag the ASP is based on a weighted average of the ASPs of branded product within the same HCPCS code. The OIG, in its 2007 work plan, has expressed interest in this issue and proposed studying the top ten multi-source drugs purchased by a sample of oncology practices to determine whether the Government would benefit if Medicare reimbursed multi-source Part B drugs based on the ASP of their individual NDCs.[53] BIO would welcome the opportunity to work with CMS to find solutions that ensure the government purchases products at an appropriate price and providers are reimbursed adequately. If ultimately recommended by the OIG, BIO would support a proposal to reimburse multi-source Part B drugs based on the ASP of their individual NDCs, at least for the first two quarters after a generic enters the market.

There are also situations in which Medicare underpays providers for certain drugs and biologicals. In a 2005 report, the OIG found four payment codes used by physicians practicing hematology and oncology in which physicians were unable to purchase the therapies at ASP plus six percent.[54] BIO believes that CMS should develop a system for tracking the sufficiency of ASP-established payment rates. Additionally, CMS should have the discretion to adjust physician payment rates upward when the OIG or the agency determines that physicians are being under-reimbursed for specific drugs or biologicals. Again, BIO would welcome the opportunity to collaborate with CMS to find a mutually agreeable mechanism to monitor rates and adjust them systematically in order to ensure that physicians are reimbursed adequately for critical therapies.

## V. BIO supports increasing the clotting factor furnishing fee.

CMS has proposed, consistent with the Social Security Act,[55] to increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending in

---

53 See HHS OIG 2007 Work Plan, located at http://oig.hhs.gov/publications/docs/workplan/2007/Work%20Plan%202007.pdf.

54 See Adequacy of Medicare Part B Reimbursement to Physician Practices for the Treatment of Cancer Patients, OIG Report A-06-05-00024 (September 2005).

55 SSA § 1842(o)(5)(C).

June 2006.[56] BIO supports this proposal and requests that CMS publish the updated furnishing fee in the final rule once the CPI data becomes available.

## VI. CMS should place limits on its substitution of WAMP or AMP for ASP to set reimbursement.

The Medicare statute allows the Secretary to substitute the WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[57] 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.[58] The proposed regulation states, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2007, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price."[59] Not only does this regulation fail to provide for any procedural or substantive safeguards to ensure the reliability of the data, but it does not express the Secretary's discretion in determining whether to substitute WAMP or AMP for ASP.

The regulation's language is inconsistent with section 1847A(d)(3)(A) of the Social Security Act that specifies that the Secretary "may" disregard ASP where the ASP exceeds WAMP or AMP by a certain threshold. Accordingly, we ask that this regulation be clarified to specify that the Secretary has discretion as to whether to substitute WAMP or AMP for ASP. Moreover, BIO urges CMS to obtain public input prior to determining whether to make such a substitution given that many drugs and biologicals have unique market dynamics that could skew

---

[56] 71 Fed. Reg. at 49,004.

[57] See SSA § 1847A(d)(3)(A).

[58] 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").

[59] Proposed 42 CFR § 414.904(d)(3); 71 Fed. Reg. at 49,083.

these studies. Without obtaining all relevant information, CMS may reduce payment rates where it should not, ultimately harming patient access to important therapies.

BIO specifically requests that CMS revise its regulatory test to modify 42 C.F.R. § 414.904(d)(3) to read: "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2007, the Secretary may, after notice and an opportunity to comment, revise the payment limit in the quarter following the transmittal of this information to the Secretary to the lesser of the widely available market price of 103 percent of the average manufacturer price." It is imperative that CMS provide the public an opportunity to comment on any substitution of ASP before the agency proceeds. Moreover, in order for the public to comment meaningfully, BIO urges CMS to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, a description of any surveys and how they were conducted, and CMS's plans to use the data.

CMS specifically requested comments on the timing and frequency of the price comparisons, as well as the effective date and duration of the rate substitution. Although BIO does not have generally applicable comments on these issues, given the significance of this provision, we request that CMS issue a proposed rule so that all stakeholders have the opportunity to comment on a specific proposal.

## VII. BIO urges CMS to clarify the payment of infusion drugs and biologicals furnished through DME.

The Medicare statute establishes payment for infusion drugs furnished through an item of DME on or after January 1, 2004 at 95 percent of the average wholesale price for the drug in effect on October 1, 2003, with one exception. That exception provides that, for DME infusion drugs furnished in a DME competitive acquisition area on or after January 1, 2007, the payment will be at the amount provided in the DME competitive bidding statute (SSA § 1847).[60] In the

[60] SSA § 1842(o)(1)(D).

DME competitive bidding proposed rule issued earlier this year, CMS indicates that the initial phase of the competitive bidding program is not likely to be implemented until October of 2007.[61] CMS has not explained the impact of the competitive bidding program on payment for DME infusion drugs, and BIO asks that CMS address two issues in the final rule in this regard:

1. What will the payment rate be for DME infusion drugs in 2007, and what will happen if such products are included in a competitive bidding program in late 2007?

2. Because class III devices under the Federal Food, Drug, and Cosmetic Act are excluded from the DME competitive bidding program,[62] CMS needs to identify how drugs that are necessary for the effective use of a class III device will be reimbursed, as it would be unusual to include the drug in competitive bidding when the device would not be.

Finally, BIO asks that CMS maintain and update the DME infusion drug portions of its quarterly released ASP file. When CMS first established the ASP file, it included some columns on the spreadsheet for DME infusion drugs. For the most part, however, these columns have not been updated since then. This is especially problematic for new DME infusion drugs, as CMS' unwillingness to include such therapies in the file creates difficulties with Medicare contractors.

## VIII. BIO recommends that CMS instruct its contractors to include resources involved in compounding when pricing compounded drugs and biologicals.

In recent ASP transmittals that CMS has released,[63] the agency indicates that pricing for compounded drugs and biologicals is performed by local

---

61 71 Fed. Reg. 25654, 25690 (May, 1, 2006).

62 SSA § 1847(a)(2)(A).

63 E.g., "October 2006 Quarterly ASP Medicare Part B Drug Pricing File, Effective October 1, 2006, and Revisions to January 2006, April 2006 and July 2006 Quarterly ASP Medicare Part B Drug Pricing Files" Transmittal 1059 (Sept. 15, 2006), available at http://www.cms.hhs.gov/transmittals/downloads/R1059CP.pdf).

contractors, with no further direction offered to the contractors. With the lack of guidance from CMS, Medicare contractors have approached pricing in a multitude of varied ways. This situation is reminiscent of the manner in which payments for drugs were calculated prior to the establishment of the Single Drug Pricer, with rates varying significantly. Ultimately, CMS stepped in to create standardization across the country through the Single Drug Pricer.

There is a similar need to promote standardization with regard to compounded drugs and biologicals, particularly with regard to ensuring that pricing for these therapies recognizes the costs incurred to produce the compounded drug or biological that a physician has ordered. For example, some physicians that specialize in pain management maintain the equipment, conditions, and personnel in their office or clinic to prepare and administer currently available intrathecally administered drugs. Most intrathecally administered products are purchased from the manufacturer, however, and are prepared for administration by compounding pharmacists that specifically are trained in the technique for preparing these compounds and have the necessary laminar flow hood to assure that the specific conditions for product preparation are met. The physician then purchases the prepared product from the pharmacy and bills through current Part B billing channels to the Medicare carrier. The list of sterile compounding requirements is extensive and the process is expensive, but both requirements *and* process ultimately serve to deliver *quality patient care*. Due to the strict regulations levied by the state boards and FDA, however, pharmacies incur additional expenses that greatly *exceed* the cost of the required pharmaceutical powders. Indeed, one contractor recently announced that it was discontinuing payment of a compounding fee for no apparent reason. [64]

BIO believes that it is inappropriate for a contractor not to account for the costs that are incurred in producing a compounded therapy. By its nature, work must be undertaken to mix products according to the physician's prescription and the labor and costs of doing so properly and safely are not negligible. Indeed, CMS has acknowledged this in the Medicare Part D context – "the labor costs

---

[64] See, "Medicare B News," Issue 227 (Apr. 4, 2006), at 45, located at https://www.noridianmedicare.com/p-medb/news/bulletins/docs/Medicare_B_News_Issue_227_April_4,_20061.pdf (Noridian discontinues payment of compounding fee effective May 1, 2006).

associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees." 70 Fed. Reg. 4194, 4232 (Jan. 28, 2005). Accordingly, BIO asks that CMS' instructions to its contractors on pricing for compounded drugs and biologicals include a direction to recognize the costs of compounding in its pricing of these therapies.

## IX. BIO urges CMS to continue the payment for preadministration-related services for standard and specialty IVIG.

As you know, BIO has been very concerned about Medicare beneficiary access to standard and specialty IVIG over the past few years as a result of the changes in the Medicare payment methodologies for drugs and biologicals. BIO was pleased that CMS recognized the unique aspects of this therapy, as well as its importance to Medicare beneficiaries, through the establishment of a payment for preadministration-related services for IVIG in last year's physician fee schedule final rule, with physicians billing G0332 to receive this payment. Although there is no discussion of the preadministration-related services payment in the preamble to the Proposed Rule, the inclusion of "D" as a status indicator in Addendum B suggests that the agency intends to eliminate this payment.[65]

If the agency's intent is to discontinue this payment, BIO is very disturbed by both the policy determination and the lack of explanation. As noted above, we believe that CMS made positive strides in ensuring access to IVIG through the preadministration-related services payment, and the elimination of the payment would be a significant step backward. All of the costs that CMS identified last year that physicians incur related to standard and specialty IVIG will continue to be incurred next year, and CMS offers no evidence that these costs would not continue to be incurred. As such, the cost must continue to be reimbursed.

BIO also notes that it is very problematic to make significant policy changes such as this without explaining the basis for the change in a proposed rule. Accordingly, BIO believes that CMS must articulate its reasons for discontinuing

---

[65] 71 Fed. Reg. at 49,235.

the payment and solicit and respond to comment on the proposal before finalizing a determination to discontinue the preadministration-related services payment. Unless this happens before January 1, 2007, CMS should continue to pay physicians for preadministration-related services related to standard and specialty IVIG.

## X. BIO supports CMS' decision to reimburse all ESRD drugs and biologicals at ASP plus six percent ["ESRD Provisions"].

BIO continues to support CMS' decision to reimburse all ESRD drugs and biologicals at ASP plus six percent when separately billed by freestanding or hospital-based ESRD facilities.[66] 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.

## XI. BIO is troubled by the current system of setting payment rates for new outpatient clinical diagnostic laboratory tests ["Clinical Diagnostic Lab Tests"].

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Secretary to develop, through regulations, procedures for determining the basis for, and the amount of, payment for new clinical diagnostic lab tests. The provision also requires CMS to provide opportunities for public input on the proposed new tests and pricing methodologies and amounts, and to take into consideration such input when developing the payment amounts. In implementing this section of the MMA, CMS essentially takes the position that its current process for providing for public consultation on the establishment of payment amounts for new lab tests already is consistent with Section 942(b), and the only thing left to be done is to codify the existing procedures.

Although BIO certainly appreciates the opportunity to have more transparency in CMS' pricing of new lab tests and to provide CMS with recommendations and data, the current methodologies of crosswalking and gap-

---

[66] Id. at 49,005.

filling, and CMS' application of them, are not adequate for many of the new diagnostics being developed. If the era of personalized medicine is to become a reality, personalized medicine diagnostics must be seen as the entryway, and must be evaluated in a new manner. Many of the newer lab tests, and even more of those in development, represent a whole 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, and the likelihood of recurrence of certain cancers. 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 than ever has been possible before, and will save money and lives by avoiding futile or even dangerous therapies while helping to ensure the use of the most appropriate treatment. Indeed, diagnostic tests increasingly will be inextricably linked with certain therapeutics, with the diagnostic test result being a prerequisite to determine whether to prescribe the therapeutic at all, or to establish the treatment regimen. We are concerned, however, that maintaining the current system for setting payment for such tests will not provide sufficient incentive to encourage these innovations.

Developing and bringing to market this new generation diagnostic tests typically is far more costly and complex than the traditional lab test. And even under CMS' gap-filling methodology, aimed at new tests for which there is no comparable, existing test, we are concerned that pricing variations among carriers 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 is later 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 gap-filled 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.

BIO urges CMS to engage in discussions, both internally and with external stakeholders, to explore the research, therapeutic and economic environments in which these new 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 carriers who 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 towards the realization of personalized medicine.

## XII. CMS should ensure adequate reimbursement for drug administration services.

As discussed in depth in our comments on CMS' proposed notice regarding the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology under the physician fee schedule,[67] BIO is very concerned that the agency's proposed changes to the work and practice expense RVUs for drug administration services, combined with the projected substantial cut to the conversion factor, will harm beneficiary care. As noted in the Proposed Rule, the conversion factor is projected to decrease by 5.1 percent in 2007 under the current statutory formula.[68] Accordingly, BIO urges CMS not to implement any cuts to reimbursement for drug administration services until it has confirmed that beneficiary access to quality care will not be harmed by the changes.

---

[67] Letter from Jayson Slotnik, Director, Medicare Reimbursement and Economic Policy, BIO, to Mark McClellan, Administrator, CMS (Aug. 21, 2006), available at: http://www.bio.org/healthcare/medicare/20060821.pdf.

[68] 71 Fed. Reg. at 49,077.

BIO remains particularly concerned about the proposed changes to the payment rates for administration of therapeutic doses of radioimmunotherapies. If the proposed 5.1 percent reduction in the conversion factor is implemented, payment for Current Procedural Terminology (CPT) code 79403 (radiopharmaceutical therapy, radiolabeled monoclonal antibody, by intravenous infusion) would decrease by 12 percent under the 2007 transitional RVUs and 34 percent under the fully implemented RVUs. This could seriously harm patient access to critical radioimmunotherapies such as Zevalin® and Bexxar® in freestanding centers, and BIO therefore again urges CMS not to implement these changes.

BIO also is concerned that Medicare does not provide a separate payment for the intravenous administration of echocardiographic imaging drugs. These drugs are critical for optimizing echocardiographic images, and the costs for their administration are not insubstantial. We urge CMS to remove any edits from the Correct Coding Initiative (CCI) that combine intravenous injection code(s) into codes for the associated echocardiography procedures. Providing for the separate payment for the administration of these drugs should encourage appropriate use of contrast enhancement to help salvage images when the echocardiographic image is suboptimal.

We appreciate CMS' efforts to promote quality care for Medicare beneficiaries and believe that adequate reimbursement is an imperative part of this process. Along this line, we ask that CMS continue the oncology demonstration project, improved as necessary, because it serves not only to gather data regarding quality, but also as an opportunity to promote evidence-based best practices that may lead to improved patient outcomes.

Moreover, BIO remains concerned about CMS' recent guidance to Part D plans suggesting that payment of administration fees available under Part B applies only to vaccines covered by Part B. In guidance issued to Part D plans on May 8, 2006, and again on July 11, 2006, CMS stated that Part B administration fees cover only those vaccines specifically covered under Part B. This new interpretation is drastically different from the policy specified in the final Part D rule and in subsequent guidance, in which CMS stated that costs related to the administration of Part D vaccines could be paid as a component of physician fees

under Part B.[69] In the instructions specified in the final rule, CMS explained the importance of covering vaccine administration in a manner that ensures that Part B and Part D provide a seamless benefit and that CMS' regulations reflect Congressional intent that Part D provide beneficiaries with access to vaccines not covered under Part B. In its Coordination of Benefits guidance for 2006, CMS reiterated this policy, expressly stating that "costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals."[70]

As discussed, Congress intended that Part B and Part D together provide a seamless benefit to Medicare beneficiaries. The recent CMS guidance on this issue will lead to beneficiaries losing access to important vaccines if the cost of administering the vaccines is not also covered. Congress clearly intended that vaccines not covered under Part B be covered under Part D, expressly defining these vaccines as "Part D drugs." That Congress expressly included vaccines in the statutory definition of Part D drugs, strongly suggests that Congress' intended for Part D to provide access to those vaccines not covered under Part B. Beneficiaries are not afforded meaningful access to vaccines where the costs of administering those vaccines are not also covered by Medicare.

CMS' new approach to the administration of Part D vaccines will greatly limit access to these highly effective, safe, and cost-saving therapies. In addition to being inconsistent with stated CMS policy and guidance, this approach is contrary to the recent pro-active, public health-oriented approaches being taken by CMS to encourage vaccinations and other preventive health interventions in the Medicare population. Indeed, CMS has recently increased provider payment rates for the administration of Part B vaccines, such as influenza and pneumococcal vaccines. From both a public health and economic policy perspective, it is clearly in the interest of the federal government and CMS to eliminate economic barriers for Medicare beneficiaries in accessing these critical vaccines.

---

[69] 70 Fed. Reg. 4,194, 4,328, 4,231 (Jan. 28, 2005).

[70] Part D Coordination of Benefits Guidance for 2006 (July 1, 2005).

BIO strongly urges CMS to issue a Healthcare Common Procedure Coding System (HCPCS) code for Part D vaccine administration, consistent with the codes already available for administering Part B vaccines. Another option for providing meaningful coverage of vaccines would be to expand the definition of dispensing fees, as CMS suggested in the proposed Part D rule,[71] to include the professional services necessary to administer a Part D drug or biological such as a vaccine.

Finally, although BIO has appreciated the clarification that CMS has offered regarding the appropriate billing for chemotherapy administration, the agency has not completed its task. In addition to including the administration of monoclonal antibodies under chemotherapy administration, CMS should clarify that standard and specialty IVIG and DNA or RNA based therapies are biologic response modifiers that also should be billed under chemotherapy administration codes. BIO asks CMS to make this clarification in the final rule.

* * *

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. 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. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions into its final rule. Please feel free to contact me at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

---

[71] 69 Fed.Reg. at 46,632, 46,648 (Aug. 3, 2004).

Jayson Slotnik
Director, Medicare Reimbursement &
Economic Policy
Biotechnology Industry Organization (BIO)