BIOTECHNOLOGY INDUSTRY ORGANIZATION

June 7, 2004

BY HAND 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, D.C. 20201

Re: CMS-1380-IFC (Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals) – Comments on Background and Provisions of the Interim Final Rule

Dear Administrator McClellan:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") interim final rule regarding manufacturer submission of manufacturer's average sales price ("ASP") data for Medicare Part B drugs and biologicals, published in the Federal Register on April 6, 2004 (the "Interim Final 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 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

1 69 Fed. Reg. 17935 (April 6, 2004).

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Given the importance of ASP data in setting payment rates and the serious penalties if ASP data are misrepresented, BIO is very concerned by the lack of detailed guidance contained in the Interim Final Rule. Although we appreciate the agency's willingness to provide additional guidance through Open Door Forums as well as questions and answers on the website, much of this information was too little, too late – especially when the most detailed answers were released a mere two days prior to the first quarter filing deadline. Moreover, although we appreciate the general instruction to follow Medicaid rebate program policies in the absence of guidance to the contrary, CMS needs to recognize that no Medicaid rebate regulations have been issued and some of the informal guidances have been incomplete and unclear. In addition, reporting obligations under the Medicaid program are very different from those regarding ASP, primarily because the Medicaid program permits retrospective restatements and corrections of reported pricing data, and therefore its guidance is crafted with such corrective opportunities in mind. Accordingly, we ask that CMS spend the time these critical issues warrant and provide precise and detailed guidance to the open questions raised during the comment period well before next quarter's filing deadline. It is in this spirit that we offer our comments and the section-by-section requests for clarification below.

Throughout this process, we urge CMS to remember the purpose of the reporting requirement and to do what is necessary to put patients first. Data collected under these regulations will be used to set payment rates for drugs and biologicals administered in physician offices and important other settings. If those rates are not adequate, patients could be denied access to critical and potentially life-saving therapies. We ask that CMS do what it can to implement these reforms in a manner that does not impede patient access. For example, in section II. D. 3. below, we suggest that CMS permit the use of a rebate per ASP eligible unit methodology to estimate costs attributable to rebates and chargebacks when there is a lag in the availability of this information. We believe such a smoothing methodology is necessary for some products to prevent dramatic swings in ASP based on the sales volume of a product for a particular quarter. Stability in payment rates is important to minimize disruption to physicians and to ensure patient access to drug and biological therapies. It is in this spirit of ensuring patient access that we offer our comments below.

I. Background

A. Data on Which Drugs and Biologicals Must Be Reported?

The Background section of the preamble to the Interim Final Rule states, "All Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act are subject to the ASP reporting requirements. Certain drugs and biologicals, for example, radiopharmaceuticals, are not paid under these sections of the Act and will not be subject to the ASP reporting requirements."[2]

Because of the serious penalties for failing to report, it is critical that manufacturers have as much guidance as possible regarding which drugs and biologicals must be reported as well as which general categories are excluded. Unfortunately, it is not always easy to determine whether Medicare Part B covers a certain drug or biological under one of the listed statutory provisions. Accordingly, BIO requests that CMS expeditiously provide a list of drugs and biologicals subject to the ASP reporting requirements, both now and as products are added in the future. This way reporting obligations will be clear, and manufacturers and the agency will not be subject to surprises. CMS has expressed some hesitance in releasing a list of reportable drugs and biologicals, and assertions have been made that no such list exists. A couple of weeks after the April 30 filing deadline, however, several of our members received e-mails from the agency regarding products and specific national drug codes ("NDCs") for which no ASP data was reported. Clearly, CMS is using some sort of list to verify reporting, and we do not understand why this list cannot be released publicly.

Alternatively, CMS should detail the steps a manufacturer should take to make a proper determination as to whether a product is subject to the ASP reporting requirement. At a minimum, manufacturers should be able to seek formal determinations from CMS with respect to their reporting obligations for specific products. Through such a process, manufacturers would set out the reasons why they believe reporting is not required, and CMS would provide a timely response with sufficient notice to prepare ASP data in the event that reporting is necessary.

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2 Id.

In addition to providing more precise guidance with respect to the reporting obligations for specific drugs and biologicals, BIO requests that CMS explicitly identify additional categories of drugs and biologicals that are not subject to the reporting requirements in the final rule. We appreciate that the Interim Final Rule explicitly excludes radiopharmaceuticals. Further clarification would be helpful, however, with respect to radiopharmaceuticals in which underlying biological products are linked with radioisotopes. This is the case with Zevalin® and Bexxar®. We assume that reporting for the underlying biological product is not required in this circumstance and seek confirmation from CMS in this regard. BIO also asks that the agency specify that manufacturers are not required to report ASP data for blood and blood products, vaccines, hospital only drugs and biologicals, and products that all of Medicare's carriers have determined are not covered by Medicare. Moreover, with respect to blood and blood products, BIO requests that CMS clarify the status of alpha-1 proteinase inhibitor, a therapy derived from human blood plasma to treat genetic emphysema. Will this therapy be recognized as a blood product, thus not requiring ASP submission, or will it be classified as a therapy for ASP-based reimbursement?

BIO also asks that CMS clarify when reporting obligations end for discontinued products. Depending on the expiration dates of the individual product, drugs and biologicals could be administered months and even years after their initial "sale." Under Medicaid drug rebate guidance, a manufacturer is required to report average manufacturers price ("AMP") and best price ("BP") information for four quarters beyond the termination date.3 The termination date is defined as either the date the drug was removed for safety or health reasons or the expiration date of the last batch sold (depending on the reason for termination).4 Because of the time lag between a Medicaid program's reimbursement of a product and the inclusion of that utilization on a state's Medicaid rebate claim, it makes sense for manufacturers to continue to report pricing data for a year past the termination date in the Medicaid context. For ASP purposes, however, reimbursement will be based on the date the drug or biological is administered. Thus, there is no need for a manufacturer to continue to report ASP after a product's termination date. In fact, because ASP

3 The 2001 Medicaid Drug Rebate Operational Training Guide at F7; Medicaid Drug Rebate Program Release to Participating Manufacturers #31 at 2; Medicaid Drug Rebate Program Release to Participating Manufacturers #48 at 3.

4 Id.

will not be a positive number unless the product was sold in the particular quarter, manufacturers may not need to report after the quarter in which the last sale of a discontinued product was made. We ask the agency to clarify this issue in the final rule.

In sum, given the substantial penalties for failing to report ASP data and the difficulties in determining whether certain drugs and biologicals are covered by Medicare Part B under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Social Security Act ("SSA"), BIO requests that CMS provide a list of products for which ASP reporting is required. In addition, we ask CMS' final rule to state that certain categories of drugs and biologicals are not subject to the reporting requirements, including blood and blood products, vaccines, hospital-only drugs and biologicals, and products that all of Medicare's carriers have determined are not covered by Medicare. Finally, we ask that the agency clarify when reporting obligations end for discontinued products.

II. Provisions of the Interim Final Rule

A. Calculation of ASP Data

1. Who Has the Reporting Obligation?

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") specifies that for ASP reporting purposes, the term "manufacturer" has the same meaning as under the Medicaid rebate statute.[5] This definition[6] is broad, however, and in certain circumstances would obligate more than one entity to report ASP for a given NDC. The Medicaid rebate program resolves this issue by placing the rebate obligation on the manufacturer "holding legal title to or possession of the NDC number."[7] Although this also may be an appropriate general rule for ASP reporting purposes, there are at least three circumstances where the owner of the NDC may not be the appropriate reporting entity.

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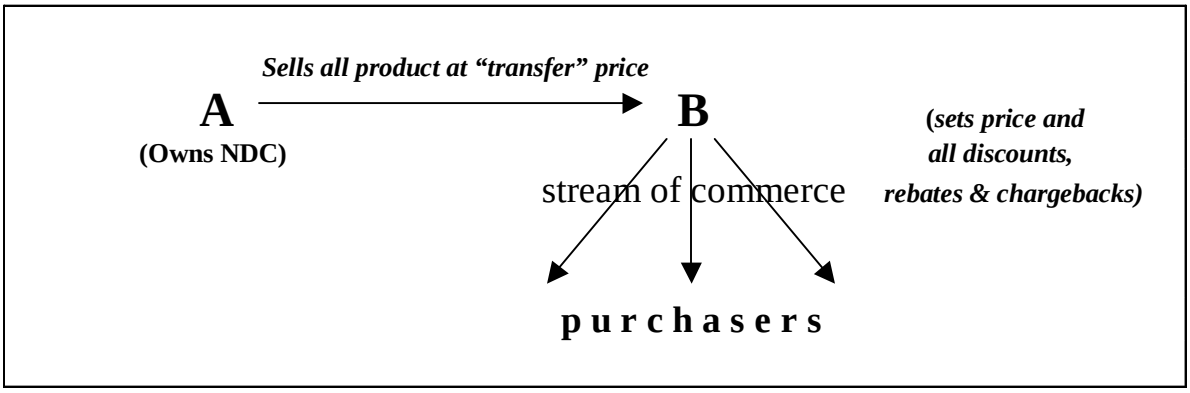
5 SSA § 1847A(c)(6)(A).
6 42 CFR § 414.802.
7 National Rebate Agreement § I(l). The Medicaid rebate proposed rule states that this solution "is necessary to permit a practical means of identifying . . . which manufacturer is responsible for paying the rebate" and "prevents duplicative manufacturer responsibilities for the drug." 60 Fed. Reg. 48442, 48447 (Sept. 19, 1995).

We ask that CMS address each of these circumstances in the final rule and clearly articulate which entity has the reporting obligation and, if more than one entity must report, which ASP will be used to set payment rates. These situations are particularly prevalent in our industry where companies tend to be small and look to larger companies for sales and marketing expertise, especially with first products or products outside a particular specialty focus.

a. Situation One – Transfers

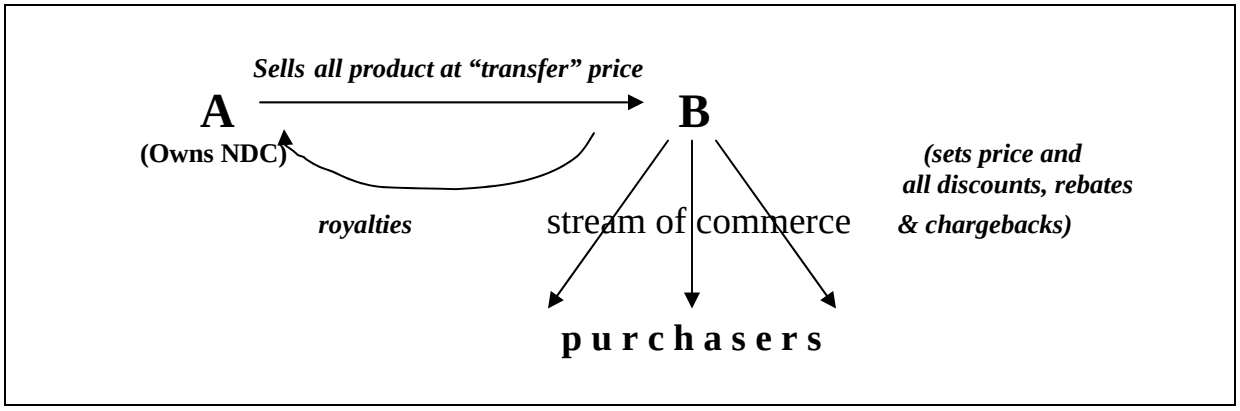
- A manufactures a product and owns the NDC.
- A sells the product only to B at a low "transfer" price.
- B is solely responsible for placing the product into the stream of commerce by marketing, selling, and distributing it.
- B sets the price and provides and handles all discounts, rebates, and chargebacks. A is not involved in the pricing of the product and does not have access to B's sales and marketing information.



b. Situation Two – Transfers with Royalties

The second situation is similar to the first – A and B have entered into a transfer agreement.

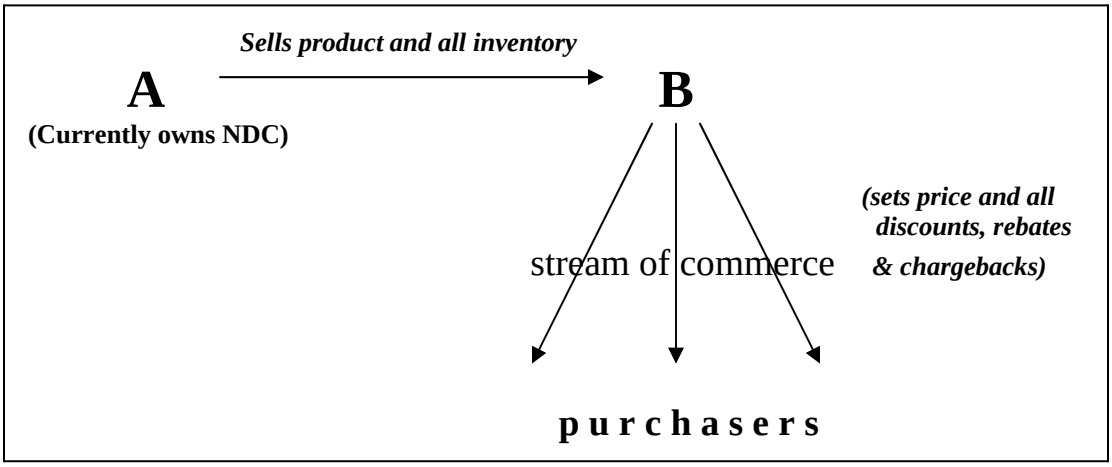
- Unlike the first example, B makes royalty payments to A based on sales, and there may or may not be reductions in this amount based upon sales, marketing expenses, or a splitting of such expenses.
- Again, A sells only to B at a "transfer" price.



c. Situation Three – Divested Products

In the third situation,

- A owns the NDC for a product from which it has divested completely.
- B has purchased the product from A as well as all existing inventory. Eventually, B will have its own NDC for the product, but B currently is selling the existing inventory with A's NDC.
- Although A technically still owns the NDC, it has no information about B's sales of the product or B's discounts, rebates, and chargebacks.
- Likewise, B may not have access to A's information about discounts, rebates, and chargebacks over the past year.



Again, BIO is concerned that in these three situations, the reporting obligation would not be appropriate for the entity owning the NDC and better rests with the entity that actually puts the product into the stream of commerce and has ready access to sales, discount, rebate, and chargeback information. Even more important, payment rates based on the "transfer" price from one entity to another in these situations would be inappropriate because it does not accurately reflect market price to the end user. Use of the transfer price could impede patient access to critical therapies. Accordingly, we request that CMS address each of these circumstances in the final rule and clearly articulate which entity has the reporting obligation and, if more than one entity must report, which ASP will be used to set payment rates. In addition, we ask that CMS specify in the final rule when a manufacturer's reporting obligations end for a product that has been sold entirely to another manufacturer and to articulate whether and how this is different than for products that are discontinued altogether.

2. Sales to All Purchasers in the United States

Section 1847A(c)(1)(A) of the SSA provides that ASP be calculated using the manufacturer's sales to all purchasers in the United States. Section 210(i) of the SSA defines the United States to include Puerto Rico, Guam, the Virgin Islands, and American Samoa. For Medicaid rebate purposes, however, these territories are excluded.[8] Indeed, manufacturers may have marketing and licensing agreements governing sales to the territories and may not have ready access to information regarding sales, discounts, rebates, and chargebacks in these territories. Conversely, some manufacturers may have difficulty "backing out" these sales.

On April 28, 2004, CMS posted a series of questions and answers on its website regarding ASP reporting requirements. Question and answer nine clarified that "US sales do not include sales in the commonwealth territories,

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8 Agency policy in this regard was set forth in the Medicaid rebate proposed rule: "[I]n accordance with out understanding of Congressional intent, we are applying the drug rebate requirements only to the 50 States and the District of Columbia." 60 Fed. Reg. 48442, 48442-3 (Sept. 19, 1995). This policy is implemented via the National Rebate Agreement, which defines "States" as "the 50 States and the District of Columbia. National Rebate Agreement § I(aa).

trust territories, and protectorates."[9] We ask that CMS formally reiterate this guidance in the regulations or permit each manufacturer to decide whether to include these sales or not.

3. Definition of Unit

Section 1847A(b)(2)(B) of the SSA defines "unit" as "the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids." The statute specifies that the manufacturer is to specify the unit associated with each NDC as part of the data submission.[10] For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units.[11] The regulation, however, defines "unit" as the product represented by the 11-digit NDC.[12] It does not require the manufacturer to specify the unit associated with each NDC, and this information is not requested as part of Addendum A.

BIO asks that CMS clarify whether manufacturers should report using the statute's definition of unit or the regulation's definition of unit or both. In addition, we request for the agency to state expressly in the final rule whether the manufacturer should specify the unit associated with each NDC, and, if so, where. We are concerned that without this information, CMS will need to look up the number of units for each NDC in the Red Book or other source in order to calculate the weighted average and corresponding payment rates. This time-consuming step could be avoided if the statutory definition were used or if manufacturers were required to specify the units for each NDC.

BIO also asks CMS to clarify in the final rule that the "number of units" column in Addendum A refers to the total number of units sold in non-exempt United States sales during the quarter and not the total number of units sold in the United States during the quarter. This clarification was made during the April 20, 2004 Open Door Forum but also should be made in the final rule. We would like to know how CMS plans to use this information. Finally, we ask

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9 CMS, ASP Reporting Requirements Questions and Answers at 2, available at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf (last visited May 4, 2004) [hereinafter "ASP Q&As"].

10 SSA § 1847A(b)(2)(A).

11 SSA § 1847A(b)(2)(B).

12 42 CFR § 414.802.

that the agency provide an explanation of precisely how payment rates will be calculated and released and how information provided on an NDC basis will be translated into the Health Care Procedural Coding System ("HCPCS") codes. Including a hypothetical example of reported information and the corresponding rate calculation would be particularly helpful.

4. Zero and Negative ASPs

As recognized by question 17 of the ASP questions and answers, "zero and negative manufacturer ASP amounts are possible."[13] Question 10 acknowledges that ASP cannot be calculated if no units of the NDC are sold in the quarter and that manufacturers then should report zero sales for the NDC.[14] Under Medicaid rebate guidance, zero or negative AMPs should not reported, however. Instead, the manufacturer should report the last calculated AMP with a positive value.[15]

BIO asks that CMS formalize its guidance with respect to zero or negative ASPs in the final rule. In addition, we ask that the agency clarify how payment rates will be set for drugs and biologicals that do not have positive ASPs. We urge CMS to use a methodology that will help ensure that back-orders, seasonal sales, manufacturer shut downs, and similar anomalies do not cause dramatic swings in payment rates that could affect patient access to important therapies. Should payment rates be based on the last reported positive ASP, CMS may want to require manufacturers that have zero or negative ASPs to report this information.

5. Accounting for Returns

Neither the statute nor the regulation specifies whether and how manufacturers should account for returned goods in the calculation of ASP. The answer to question 11 in the ASP questions and answers states, "Manufacturers should subtract the value of the returns from the numerator of the ASP calculation and subtract the number of units returned from the denominator."[16] The answer does not explain how these returns should be

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13 ASP Q&As at 3.
14 Id. at 2.
15 Medicaid Rebate Release 38 (Nov. 20, 1998).
16 ASP Q&As at 2.

valued, however. BIO asks CMS to formally reiterate its policy with respect to returns in the final regulation. We also request that the agency state expressly that the valuation methodology will be left up to the individual company, following its usual business practice, or provide specific guidance regarding how these returns should be valued.

B. Sales Exempted from ASP Calculation Other Than Nominal Sales

Section 1847A(c)(2)(A) of the SSA exempts those sales from ASP that also are exempt from the determination of BP. The rule likewise exempts those sales.[17] Sales to State Pharmacy Assistance Programs ("SPAPs") and AIDS Drug Assistance Programs ("ADAPs") that are covered entities under the Public Health Service ("PHS") Drug Pricing Program are exempt from inclusion in the BP determination.[18] Sales to these entities typically are identified through rebate claims only, however, and because such rebate claims typically lag by at least one quarter, these sales are not known at the time the ASP calculation must be performed. Although the statute and Interim Final Rule's methodology for estimating lagged rebate data appears to be a reasonable approach for estimating these sales, neither the statute nor the rule directs the use of the estimation methodology for the estimation of units sold, as opposed to discount, data. BIO therefore requests that CMS specify in the final rule that the discount estimation methodology (as revised by our recommendations below) may be used to estimate SPAP and ADAP sales.

CMS identified five criteria that a state program generally must satisfy in order to constitute a SPAP and be eligible for exclusion from BP in Medicaid Drug Rebate Program Release to Manufacturers 59 ("Release 59"). Release 59 does not specify, however, the type of documentation or representation from the state that a manufacturer may rely upon to determine that a state program does or does not satisfy those criteria. Indeed, CMS to date has declined to promulgate a list of those state programs that qualify for SPAP status. This reliance standard is significant to the ASP calculation, as it will determine whether a state program's sales and related discounts are included or excluded from the ASP calculation. BIO therefore requests that CMS specify in the final rule the type of documentation or representation on which a manufacturer may

17 42 C.F.R. § 414.804(a)(4).
18 SSA § 1927(c)(1)(C)(i)(I), (III).

rely in determining whether a state program is compliant with Release 59 and thus excludable from the ASP calculation as a SPAP.

C. Sales to an Entity That Are Nominal in Amount Are Exempted from the ASP Calculation

Section 1842A(c)(2)(B) of the SSA requires that sales to an entity that are merely nominal in amount be excluded from the ASP calculation. These sales are defined for purposes of section 1927(c)(1)(c)(ii)(III) of the SSA for the Medicaid rebate program. Question 14 of the ASP question and answer document further explains that nominal sales are defined as sales less than 10 percent of the manufacturer's AMP, calculated under the Medicaid rebate program agreements.[19]

Again, CMS should include this guidance in the final rule. In addition, the agency should acknowledge that in identifying nominal sales to be excluded from ASP, manufacturers must use the AMP calculated for use in the initial submission for the quarter at issue. This calculation necessarily cannot take into account any actual rebate or other late-arriving price concession data but may take into account accruals for such data if included in the manufacturer's AMP methodology. In other words, AMP frequently is modified to take into account actual rebates and other price concession data. Because ASP is a snapshot in time and cannot be updated, nominal sales calculated at less than 10 percent of AMP also must use an AMP from a snapshot in time. Manufacturers should not be liable for misrepresentations if AMP subsequently is modified, changing the nominal sales figures. CMS should make this assurance in the final rule.

Section 1927(b)(3)(A)(iii) of the SSA requires manufacturers to submit information on sales that were made at a nominal price; however, the regulation is silent regarding this issue. Question 20 of the ASP questions and answers clarifies that although manufacturers may choose to separately report information on these sales, CMS currently is not requiring this information to be separately reported for ASP.[20] We ask CMS also to include this clarification in the final regulation.

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19 Id. at 3.
20 ASP Q&As at 4.

D. Inclusion of Rebates and Other Price Concessions in the ASP Calculation

1. Administrative Fees

Section 1847A(c)(3) of the SSA requires that in calculating ASP, a manufacturer must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase agreement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program). Question 16 of the ASP questions and answers directs that administrative fees should be included in the calculation of ASP when paid in relation to sales to an entity whose sales are included in the calculation of ASP and if they ultimately affect the price actually realized by the manufacturer. BIO is concerned that this instruction is overly inclusive. Manufacturers have a variety of fee-for-service arrangements whereby they purchase services from wholesalers, distributors, and indirect purchasers as well. These services include reimbursement assistance, expedited shipping to end users, and the provision of detailed end user sales data. These fee-for-service arrangements should not be viewed as a price reduction to the purchaser, but rather a fee for a service that has been rendered. Accordingly, they should not be treated as a discount for purposes of the ASP calculation. We ask that CMS address this issue in the forthcoming rule and allow manufacturers, wholesalers, specialty distributors, and other interested parties an opportunity to comment.

2. Prompt Pay Incentives to Wholesalers and Specialty Distributors

BIO strongly believes that usual and customary prompt pay incentives to wholesalers and distributors should not be included in the ASP calculation. Including these payments will decrease ASPs inappropriately, possibly impeding patient access to critical drug and biological therapies. Prompt pay incentives to wholesalers and specialty distributors are not "discounts" at all, but instead recognize the time value of money and induce the prompt payment of bills in advance of the contract terms. Indeed, the Office of Inspector General ("OIG") recognized that these prompt pay incentives were not discounts designed to induce purchase when deciding not to include prompt pay

incentives in the discount safe harbor.[21] Moreover, prompt pay incentives are widespread and customary in most industries, not just for drugs and biologicals.

Although section 1847A(c)(3) of the SSA states that manufacturers should include prompt pay discounts when calculating ASP, CMS has the discretion to clarify in the final regulation that this does not include usual and customary prompt pay incentives to wholesalers and distributors. The regulation could clarify that prompt pay incentives above the usual and customary amount should be included, however, in the same way that the OIG stressed that it would "continue to scrutinize closely 'prompt pay' discounts to make sure that they are not payments made for an illegal purpose cloaked under a legitimate label."[22]

Again, BIO firmly believes that eliminating usual and customary prompt pay incentives to wholesalers and distributors from the ASP calculation is necessary to preserve patient access to drugs and biologicals. Wherever possible, we urge CMS to use its discretion to put patients first in implementing these reforms.

3. Estimation Methodology for Rebates and Chargebacks

Section 1847A(c)(5)(A) of the SSA provides that "insofar as there is a lag in the reporting of the information on rebates and chargebacks . . . so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks." This section also permits the Secretary to establish a uniform methodology to estimate and apply such costs in years after 2004. The regulation provides, "To the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase agreement, chargebacks and rebates (other than rebates under the Medicaid drug rebate program) are available on a lagged basis, the manufacturer should add the data for the most recent 12-month period available and divide by 4 to determine the estimate to apply in calculating the manufacturer's average sales price for the quarter being submitted."[23]

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21 "With respect to prompt pay discounts, we have made no change to include such discount arrangements. No change is necessary because, by definition, they are designed to induce prompt payment, and thus do not appear to violate the statute." 56 Fed. Reg. 35952, 35979 (July 29, 1991).

22 Id.

23 42 CFR § 414.804(a)(3).

BIO generally believes that the regulation's approach to estimating rebates and chargebacks is good and straightforward. We are concerned that for some products, however, simply adding the 12-month data and dividing by 4 could lead to volatile ASPs that swing dramatically depending on the sales volume for the product in the quarter. Instead, we ask CMS expressly to permit manufacturers to use the rebate[24] per ASP eligible unit methodology outlined below. Should the agency adopt a uniform methodology after 2004 as permitted by the statute, we believe this rebate per ASP eligible unit should be included in the standard.

To illustrate why a smoothing methodology is crucial, we provide the following example. Assume that the sales price is $1 per unit and 2003 sales were $40 million with $6 million in rebates. Also assume that first quarter sales were $1 million, and second quarter sales were $10 million in 2004. Under CMS' current methodology, the manufacturer would take the $6 million in rebates for 2003 and divide by 4 to apply a rebate of $1.5 million for the first quarter ASP filing. The first quarter of 2004 ASP then would be calculated as $1 million minus $1.5 million divided by 1 million or negative 50 cents. The second quarter ASP would be $10 million minus $1.5 million divided by 10 million or 85 cents.

Using a rebate per ASP eligible unit methodology instead, the manufacturer would take the total rebates on ASP eligible sales over the last 12 months and divide them by the total ASP eligible units in that same time period to calculate an average rebate per ASP eligible unit. This average rebate per ASP eligible unit then is multiplied by the ASP eligible units in the current quarter to determine the rebate to be applied in the current quarter. In the present example, the $6 million in 2003 rebates would be divided by 40 million units in 2003 to yield a 15 cent rebate per ASP eligible unit sold. In the first quarter of 2004, the ASP would be $1 million minus $150,000 ($1 million times 0.15) divided by $1 million or 85 cents. Likewise, ASP for the second quarter would be $10 million minus $1.5 million ($10 million times 0.15) divided by $10 million or 85 cents.

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24 We refer to this methodology as rebate per ASP eligible unit; however, we contemplate that it also would be used for chargebacks, discounts and other data that is not available at the time of reporting and must be estimated.

Because payment rates in 2005 and beyond will be based on ASP, BIO believes it is critical for manufacturers to be permitted to use a rebate estimation methodology that will not create dramatic swings in ASP based on the sales volume of a product for a particular quarter. Stability in payment rates is important to minimize disruption to physicians and to ensure patient access to drug and biological therapies. Accordingly, we ask that CMS state in the final rule that use of the rebate per ASP eligible unit methodology is acceptable. Should the agency adopt a uniform methodology after 2004 as permitted by the statute, we request that this rebate per ASP eligible unit methodology be incorporated into the standard.

E. Reporting of ASP Data to CMS

1. Filing Logistics

Neither the statute nor the Interim Final Rule specifies where and how a manufacturer's ASP data must be filed. Although the preamble to the Interim Final Rule provides that manufacturers must report ASP data in "Microsoft Excel using the template provided in Addendum A",[25] this requirement is not included in the regulation. The ASP questions and answers document explains that submissions should be made only electronically – not using e-mail – and gives a precise address to which manufacturers should send their ASP filings.[26] This information should be incorporated into the final rule. Moreover, BIO urges CMS to explore methods of receiving ASP data through e-mail securely as well as electronic means of ensuring receipt.

2. Reporting WAC

Section 1927(b)(3)(A)(iii) of the SSA requires manufacturers to report WAC if required to make payment under section 1847A, yet neither the regulation nor Addendum A includes such a requirement. Question 19 of the ASP questions and answers document discusses this issue and states that manufacturers must report WAC if the ASP during the first quarter of sales is unavailable[27] or, for a single source drug or biological, WAC is less than the

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25 69 Fed. Reg. at 17936.
26 ASP Q&As at 4-5.
27 For new products, we believe it will be necessary to base payment rates on WAC or the methodology in effect on November 1, 2003 for two quarters until adequate ASP data are available. This is due to the two

ASP for a quarter.[28] Again, this answer should be incorporated into the regulation. In addition, Addendum A should be revised to include a section to report this information.

3. Certification

The regulation provides that the manufacturer's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO must certify each ASP report.[29] The statute provides no such certification requirement, however. BIO believes the certification requirement is unnecessary and adds a needless level of complexity to the ASP reporting system. The extensive penalties associated with failing to submit timely and accurate ASP data already provide a sufficient deterrent from submitting false or incomplete data. The additional CEO/CFO certification is not necessary, and we ask that it be eliminated.

Should CMS decide to retain the certification requirement, it is even more imperative that the agency issue precise guidance promptly in a final rule addressing the many ambiguities and omissions in the current regulation. As the regulation currently is written, it is very difficult, if not impossible, for a CEO or CFO to certify that ASPs were calculated accurately. Moreover, the final rule should clarify whether delegated authority must be in writing. In addition, we ask that the sample certification contained in Addendum B be amended to refer to the fact that reasonable assumptions were made. The final rule also should specify precisely how Addendum B should be used and how the certification could be modified if necessary. Finally, the final rule should explain if and how manufacturers should rectify honest mistakes and inadvertent errors such that they will not be held liable for misrepresentations.

4. Making Reasonable Assumptions

Answer 21 in the ASP questions and answers document states, "In the absence of specific guidance in the Social Security Act or Federal regulations,

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quarter lag in the submission of ASP information and its use in determining payment rates. We ask that CMS verify such treatment in the forthcoming rule.

28 Id. at 3-4.

29 42 CFR § 414.804(a)(6).

the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the intent of the Social Security Act, Federal Regulations, and its customary business practices. These assumptions should be submitted along with the ASP data."30 Although BIO applauds the fact that CMS has recognized that the guidance it has given with respect to ASP reporting is far from clear and complete and that manufacturers had to make reasonable assumptions in order to proceed with filing by the April 30 deadline, we are concerned that this recognition occurred in an informal document on the website rather than in the regulation itself. We ask that CMS remedy this situation in the final rule and explain that reasonable assumptions are permissible and should be submitted with the ASP data.

5. Need for an Exceptions Process

BIO repeatedly has expressed concerns that reimbursement at ASP plus six percent may not adequately reimburse some physicians for the drugs and biologicals they are administering. First, "average" prices are not available to all purchasers. Second, some widespread physician networks that purchase drugs and resell them to their members mark drugs and biologicals up substantially before selling them to their members. Third, some products only are available through specialty distributors that also mark them up significantly. This is particularly true for some of our members' products that are costly, infrequently used, or have unique storage and handling requirements. We urge CMS to implement an exceptions process for these situations.

Such an exceptions process would allow providers, manufacturers, and other interested parties to petition the agency for more appropriate rates for a particular drug should ASP plus six percent not be adequate. Similar to the process that currently exists in the hospital outpatient prospective payment system, physicians, manufacturers, and others could provide external data to show that the payment rate is not appropriate, and CMS would set a more reasonable rate for the drug. We believe that an exceptions process is crucial to ensure patient access to all drugs, including those with substantial mark-ups and unusual distribution costs.

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30 ASP Q&As at 4.

III. Conclusion

Section 303 of the MMA makes sweeping changes in the way drugs and biologicals will be reimbursed under Part B of the Medicare program. Whether Medicare beneficiaries will continue to have access to drug and biological therapies will in large part be dependent on manufacturer reporting of ASP data and the adequacy of reimbursement at ASP plus six percent. As CMS reviews comments and promulgates both the ASP reporting final rule as well as the proposed and final Part B drug and biological payment rates for 2005, BIO urges the agency to put patients first and to resolve open policy issues in a manner that ensures patient access to these therapies. Unless reimbursement rates cover providers' costs, patient access to critical drug and biological therapies will be compromised. Inadequate payment rates in physicians' offices could lead to treatment shifts to more costly hospital settings or to widespread delays for Medicare patients seeking care. Neither of these situations is acceptable.

BIO also asks CMS to be mindful of the importance of providing precise and detailed guidance regarding the ASP reporting requirements, especially if CEOs and CFOs are required to certify the accuracy of the calculations. As highlighted throughout these comments, the Interim Final Rule is fraught with ambiguities and omissions that make it difficult to assure accuracy and consistency. Given the importance of using ASP data to set payment rates and the serious penalties associated with misrepresentations of these data, we urge CMS to spend the time these critical issues warrant and to provide additional guidance regarding the issues raised in our comments in a final rule. These issues include clarifications with respect to data on which drugs and biologicals must be reported; which entity has the reporting obligation; how units are defined; the handling of zero and negative ASPs, returns, sales to SPAPs and ADAPs, nominal sales, administrative fees, and prompt pay incentives; and how precisely ASP data should be reported to CMS. In addition, we urge the agency to recognize the need for a smoothing methodology in the way lagged rebate and other data are estimated so that ASPs and corresponding reimbursement amounts do not vary dramatically from quarter to quarter. Stability in payment rates is crucial to minimize disruption to physicians and to ensure patient access to drug and biological therapies.

BIO appreciates the opportunity to comment on the important issues raised in the Interim Final 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 sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Michael Werner at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Carl B. Feldbaum /s/
President,
Biotechnology Industry
Organization