



October 14, 2005

***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, D.C. 20201

**Re: Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.804 (CMS-10110)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed revisions to the requirements regarding manufacturer submission of average sales price (ASP) data for Medicare Part B drugs and biologicals.<sup>1</sup> 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.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO is greatly concerned about the impact of Medicare's reimbursement on access to drugs and biologicals. If Medicare's payment rates do not compensate providers adequately for their acquisition costs,

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<sup>1</sup> 70 Fed. Reg. 48770 (Aug. 19, 2005).

Medicare beneficiaries may be denied access to essential drugs and biologicals. Over time, if physicians and hospitals are not able to provide innovative drugs and biologicals to their patients, manufacturers could be discouraged from developing new therapies.

Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), payment for Medicare Part B drugs and biologicals is based on manufacturers' reported ASP data. Using these data, CMS calculates a single ASP for each Healthcare Common Procedure Coding System (HCPCS) billing code. In some cases, CMS also must determine whether payment should be based on wholesale acquisition cost (WAC) instead of ASP. It is important, therefore, that CMS collect from manufacturers the information it needs to determine the appropriate basis for reimbursement and to calculate rates accurately.

Currently, for each ASP drug or biological, manufacturers must report the National Drug Code (NDC), its ASP per NDC, and the number of NDC units sold. Based on its experience during the first six reporting quarters, CMS has determined that requiring manufacturers to report additional data would help the agency better carry out the ASP methodology. BIO thanks CMS for continuing to refine the ASP reporting requirements to ensure that Medicare rates are accurate and appropriate. We encourage the agency to continue to provide guidance regarding ASP reporting requirements and to finalize the interim final rule regarding manufacturer submission of manufacturer's ASP data for Medicare Part B drugs and biologicals, published in the Federal Register on April 6, 2004.<sup>2</sup> Given the importance of ASP data in setting payment rates and the serious penalties if ASP data are misrepresented, BIO continues to be very concerned by the lack of detailed guidance regarding ASP reporting and urges CMS to remedy this situation promptly.

## **I. Reporting Name of Product and Strength, Volume, and Number of Items Per NDC**

As CMS notes in the supporting documentation for the proposed revisions to the reporting requirements, the agency must convert manufacturers' reported ASP data to the billing unit level to accurately set payments.<sup>3</sup> To perform this

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<sup>2</sup> 69 Fed. Reg. 17935 (April 6, 2004).

<sup>3</sup> CMS 10110 Addendum – Q&A, available at <http://www.cms.hhs.gov/regulations/pr/>.

conversion, CMS needs to know the total volume of product in each NDC. Although the published drug pricing compendia describe the volume of each NDC, CMS has found that the compendia may not be accurate or updated on a timely basis. Additionally, to determine which HCPCS code a drug or biological is assigned, CMS must identify the name of the drug or biological represented by each NDC. Rather than continuing to rely upon flawed sources of information, CMS proposes to require manufacturers to report the strength of the product (i.e., the dosage in one item), the volume per item, and the number of items per NDC. CMS also proposes to require manufacturers to report the name of the drug or biological to help the agency assign NDCs to the appropriate HCPCS code.<sup>4</sup>

BIO supports these proposals because they will help to ensure that CMS has the correct and up-to-date information it needs to calculate accurate ASPs for each HCPCS code. This proposal also will help CMS implement much needed improvements to the formula for calculating the ASP per HCPCS code when multiple NDCs share a single billing code. CMS' current formula first converts the reported ASP for each NDC into the ASP per billing unit, then weights each ASP per billing unit by the total number of NDC units sold.<sup>5</sup> As we explained in our comments on the physician fee schedule proposed rule, because CMS does not convert the number of units sold to the billing unit level, this formula fails to produce a true weighted average ASP for most therapies.<sup>6</sup> We urged CMS to revise this formula for most products to weight the ASP per billing unit for each NDC by the number of billing units sold. By requiring manufacturers to report data on the volume of product in each NDC, CMS will ensure that it has the data it needs to accurately convert reported ASPs and numbers of NDC units sold to the billing unit level and calculate true weighted average ASPs for each HCPCS code. BIO urges CMS to finalize this proposal.

## II. Reporting Wholesale Acquisition Cost

CMS proposes to require manufacturers to report WAC during the initial period in which data are not available to calculate an ASP for a drug or biological and every quarter for NDCs assigned to single source drug and biological billing

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<sup>4</sup> 70 Fed. Reg. at 48771.

<sup>5</sup> 70 Fed. Reg. 45764, 45844 (Aug. 8, 2005).

<sup>6</sup> Letter from James C. Greenwood, President and CEO, BIO, to Mark McClellan, Administrator, CMS, Sept. 30, 2005.

codes.<sup>7</sup> The Medicare statute requires payment to be based on WAC instead of ASP in two circumstances: (1) when the WAC-based rate is less than the ASP-based rate for a single source drug or biological,<sup>8</sup> and (2) during an initial period in which data are not sufficiently available from the manufacturer to compute ASP.<sup>9</sup> We support CMS' proposal to require manufacturers to report WAC in these circumstances because it will help to ensure that CMS has the data it needs to set appropriate rates.

### III. Reporting Dates the NDC Was First Marketed and First Sold

We also support the proposal to require manufacturers to report the date an NDC was first marketed and first sold.<sup>10</sup> As CMS explains, this information is necessary to identify the initial period in which CMS must set rates based on WAC.<sup>11</sup> BIO believes that this proposal should be implemented. We note, however, that the definition of "marketed" here appears to be different from the definition used for Medicaid price reporting. The Medicaid Rebate Agreement defines the date a drug is "marketed" as the date the drug is "first sold by a manufacturer in the States after FDA approval."<sup>12</sup> In the ASP proposal, CMS uses "marketed" to mean "launched" or "made available for purchase." We recommend that CMS clarify that, for ASP reporting purposes, the date a drug first is marketed is the date on which the drug is first made available for purchase, not the date of the first sale of the drug. We also suggest that CMS clarify that manufacturers are not required to report the date on which the drug first is sold until the drug actually has been purchased in an ASP-reportable sale. CMS proposes to require manufacturers to submit this date with their first data submission, but it may not be possible to report the date of the first sale in the first submission if the sale does not happen in that quarter.

We also ask CMS to clarify that although a manufacturer's ASP reporting obligation for a new drug begins in the quarter of its first sale, the initial period in which payment is based on WAC extends from the date the drug is first marketed

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<sup>7</sup> 70 Fed. Reg. at 48771.

<sup>8</sup> Social Security Act (SSA) § 1847A(b)(4).

<sup>9</sup> SSA § 1847A(c)(4).

<sup>10</sup> 70 Fed. Reg. at 48771.

<sup>11</sup> CMS 10110 Addendum – Q&A, available at <http://www.cms.hhs.gov/regulations/pr/>.

<sup>12</sup> Medicaid Sample Rebate Agreement, § I.m., available at <http://www.cms.hhs.gov/medicaid/drugs/drebate.asp>.

until the first quarter in which an ASP-based rate could be effective for use in payment. For example, if a drug first is marketed in the first quarter of the year and its first sale occurs in the second quarter, the reported ASP would not be effective for use in setting payment rates until the fourth quarter of the year. CMS should clarify that payment will be based on WAC or 95 percent of average wholesale price (AWP), as required by the statute, until a rate based on reported ASP data is available for use.<sup>13</sup>

#### **IV. Reporting Expiration Date of the Last Lot Manufactured**

Finally, BIO supports CMS' proposals to require manufacturers to report the expiration date of the last lot manufactured and to terminate a manufacturer's reporting obligation for a given drug or biological on this date. CMS correctly concludes payment no longer should be determined using ASP data for that NDC after the expiration date of the last lot manufactured. We agree that manufacturers should not be required to report ASP data after a drug cannot be sold and the data are not needed to set payment rates. We ask CMS to implement this proposal.

#### **V. Conclusion**

BIO supports CMS' proposed revisions to manufacturer submissions of ASP data. We believe these revisions are logical and should help ensure that CMS has the data it needs to set correct payment rates for Part B drugs and biologicals. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik 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/

Jim Greenwood  
President and CEO  
Biotechnology Industry Organization

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<sup>13</sup> SSA § 1847A(c)(4)(A) and (B).