October 20, 2011

BY ELECTRONIC DELIVERY

Larry Reed, Director
Division of Pharmacy
Center for Medicaid, CHIP and Survey & Certification
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Re: Survey Of Retail Prices: Payment and Utilization Rates

Dear Mr. Reed:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Survey of Retail Prices: Payment and Utilization Rates that will be used to develop the National Average Drug Acquisition Cost (NADAC) file, commissioned from Myers & Stauffer LC by the Centers for Medicare and Medicaid Services (CMS). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO believes that appropriate reimbursement based on an accurate payment methodology is essential to protecting beneficiary access to care and encouraging continued investment in innovation. The results of the NADAC survey likely will be used to set State Medicaid programs' reimbursement for drugs and biologicals, therefore it is important that stakeholders understand the pricing information that is included in the published results. As the survey process gets underway, stakeholders would benefit from greater clarity about the timing of the process, the format of the published data, and the potential uses of the data. In addition, it is critical that the survey process include safeguards to ensure the accuracy and integrity of the pricing figures reported to the public. We offer the following comments to help achieve these important goals.

1. <u>CMS Should Rename the "NADAC" to Reflect the Data Collected by the Survey</u>

"NADAC" is a misnomer for the figure that will be calculated from data collected by this survey. As described at the August 4, 2011 stakeholders meeting, the monthly survey will

collect data from retail community and specialty pharmacies' invoice purchase prices.[1] Invoice prices often do not include discounts, and rebates that are provided at a later date and can have a significant effect on a pharmacy's acquisition cost for a drug or biological. Myers & Stauffer noted that it plans to perform a special purpose survey at least annually to gather data on these discounts, but few details were available at the time of the stakeholders meeting on the survey or how it would affect the monthly calculations of NADAC. Unless these discounts, rebates, and chargebacks are included in the reported average prices, the data resulting from the survey cannot accurately be called an "average acquisition cost." Instead, the figure computed from the survey data should be called either the "National Average Drug Invoice Price" (NADIP) or "National Average Drug Invoice Cost" (NADIC) so that all stakeholders understand what the figure represents.

2. CMS Should Provide More Information about the Timeline for the Survey Process and Reporting of the NADAC and the Format of the Published Data

We ask CMS to publish a specific timeline for the survey process and public reporting of the NADAC. In particular, we would appreciate clarification of the timing of the monthly survey process, including the timing of issuance of surveys, submission of data by pharmacies, and generation and publication of the NADACs. We also would like to know when the first NADACs will be released for possible use by state Medicaid programs.

We also are interested in the format in which the NADAC data will be published. Myers & Stauffer indicated that the data would be reported by drug group names, with NADACs reported for brands and generics in each group, but the final format has not yet been determined.[2] The usefulness and clarity of the published NADACs will depend to a great extent on the format in which the data are presented. We urge CMS to publish a draft version of this format for public comment to allow for meaningful stakeholder input before final guidance.

3. Should states use NADAC's to set reimbursement, CMS Should Instruct States to Not Use NADACs to Set Reimbursement in Non-Pharmacy Settings

BIO believes that appropriate reimbursement rates for each setting of care must reflect the prices available in that setting. We believe that a NADAC that is based solely on pharmacy prices would not be appropriate for use in setting reimbursement for drugs in non-pharmacy settings, where the invoice or acquisition costs are likely to be different. For example, a drug could be sold to a physician's office or a clinic as well as to a specialty pharmacy, but at different prices, and the NADAC, as described at the stakeholder meeting, would not reflect the prices paid by the physician's office or clinics. We ask CMS to instruct States to not use NADACs to set reimbursement rates in non-pharmacy settings so that these settings are not subject to payments that are based on the acquisition cost of other providers.

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[1] August 4, 2011 Stakeholders Meeting Presentation, at 10, https://www.cms.gov/Reimbursement/Downloads/8-4-2011Presentation.pdf.
[2] Id. at 16.

4. CMS Should Allow Manufacturers to Identify Low-Volume Drugs to be Excluded from the Survey

Certain drugs that are dispensed by retail and specialty pharmacies in low volumes should be excluded from the survey due to the likelihood that the small sample size for these drugs will produce unreliable pricing information. In particular, we ask that drugs that are not generally dispensed through a retail community pharmacy be excluded from the NADAC survey for reasons explicated further in a subsequent section. Retail community pharmacies likely will constitute a large portion of the respondents to the NADAC survey, with the remainder of responses coming from specialty pharmacies. For those drugs are not generally dispensed through retail community pharmacies, any pricing information collected on these drugs through this survey is not likely to be representative of prices generally paid for these drugs. Orphan drugs also are dispensed in low volumes and should be excluded from the survey as well. We ask CMS to protect against the collection and reporting of unrepresentative pricing information for low-volume drugs by excluding them from the survey. We also ask CMS to work with stakeholders to identify these low-volume drugs so they can be excluded from the survey.

5. CMS Should Take Steps to Protect the Integrity, Accuracy, and Confidentiality of the Data Collected by the Survey

We have several concerns about the accuracy, integrity, and confidentiality of the data that will be collected by the survey. First, we are concerned that pharmacies could game the submission process by submitting only the highest invoice price during the month, rather than the last or most recent invoice. Pharmacies also might opt to not participate in the survey, potentially withholding relevant pricing data. We ask CMS to discuss with stakeholders steps it can take to encourage pharmacies to participate, clarify the methodology being used to define what constitutes relevant invoice data, and to submit all of the relevant data. CMS also should explain how the NADAC will be calculated if few or no pharmacies submit data for a particular drug. This scenario is of particular concern in the realm of specialty pharmacies given the small pool of entities available for surveying and the voluntary nature of the survey. We ask CMS to clarify how it will remedy this problem if it arises and ensure that the resulting lack of quality data does not produce skewed and unrepresentative results. Again, this explanation should be published and made available for public comment to ensure proper stakeholder input.

Second, BIO also asks CMS to explain its plans to address delays in the survey's recognition of changing market conditions, including manufacturer price increases. After pharmacies complete the monthly survey, Myers & Stauffer will need time to review the data and calculate the NADAC for each drug, creating a lag between the monthly collection of invoice data from pharmacies and public reporting of a NADAC calculated from those data. Changes in market conditions during that intervening period, such as more limited availability of a drug or manufacturer price increases, might not be reflected in the NADAC until at least two months later. As a result of this delay, any reimbursement rates that are based on the reported NADAC could be inappropriately low during the lag period and could harm patients' access to needed therapies. In the presentation to the stakeholders' meeting, Myers & Stauffer acknowledged that some drugs in their state surveys have required an "off cycle update due to a

change in the average acquisition cost."[3] We ask CMS to explain how it will ensure that the NADAC accounts for price fluctuations in a timely manner. CMS could consider implementing a smoothing approach to protect against significant price fluctuations, for example.

Third, we are concerned that the survey process appears to lack measures to ensure the quality of the data collected and reported to the public. Myers & Stauffer noted that the survey process will include a "quality review,"[4] but it has not explained the steps it or CMS will take to identify and rectify submission errors. Identifying and correcting these errors will be particularly important in light of the tight timing for calculation of NADACs. We ask CMS to develop and explain the measures that will be used to address submission errors. We urge CMS to publish these measures for public comment to allow for stakeholder participation. In addition, neither CMS nor Myers & Stauffer have explained whether the survey process will include opportunities for stakeholders to question or challenge a calculated NADAC. We believe it is essential that the process include opportunities to dispute a calculated NADAC and to raise questions about the process.

Fourth, Myers & Stauffer plans to survey 2,500 pharmacies each month and conduct separate monthly surveys of independent/chain and specialty pharmacies.[5] It is possible that separate NADACs could be reported for each type of pharmacy based on these surveys. The integrity of the data collected under these surveys will require accurate selection of pharmacies to participate in the survey and classification of each survey as independent/chain, specialty or mail-order. We ask CMS to publish the data source that will be used to identify and classify pharmacies, as well as detail the process that will be followed to prevent skewed results, for public comment to allow for meaningful stakeholder input that will ensure that pharmacies are appropriately identified. Additionally, given the small number of specialty pharmacies, we ask that CMS clarify the statistical methods that will be employed for the specialty pharmacy survey. Specifically, we are concerned that the subset of specialty pharmacies that participate in the survey may be too small to produce accurate data on drug acquisition.

Fifth, we are concerned about cross-survey sharing of data collected by Myers & Stauffer. Myers & Stauffer is conducting average acquisition cost surveys for three states, in addition to the NADAC survey for CMS. It is possible that data collected under the CMS-commissioned survey could be shared with other government entities, in spite of the confidentiality requirements under Myers & Stauffer's contract with CMS. We ask CMS to publish a draft of the controls that will prevent data from being shared across government entities for public comment to allow for meaningful stakeholder input before final guidance.

Finally, we ask CMS to provide opportunity for public input on the development and implementation of the special survey on discounts, rebates, and chargebacks. This survey could play an important role in calculating an actual average acquisition cost, rather than an average invoice price, but no details were provided about this survey at the stakeholders meeting. We

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[3] Id. at 18.
[4] Id. at 13.
[5] Id. at 9.

strongly recommend that CMS publish this survey for public comment to help ensure that it collects accurate and relevant data.

BIO thanks CMS for this opportunity to comment on the NADAC survey. We look forward to continuing to work with the agency to ensure that accurate and appropriate data are available for use in setting Medicaid reimbursement rates for drug and biological therapies. Please contact me at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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