Biotechnology Industry Organization

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BY ELECTRONIC DELIVERY

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Dear Mr. Reed:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs, 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 NARP survey have the potential to impact how State Medicaid programs set reimbursement for drugs and biologics, therefore it is important that stakeholders understand the types of transactions that are included in the published results. As CMS continues to take steps to create and publish a monthly pricing database for Medicaid covered outpatient drugs, BIO encourages the Agency to provide greater clarity as to what it intends the NARP to represent as an "average drug price benchmark." Specifically, we urge CMS to issue a revised methodology report that provides greater detail around the data sources and processes associated with reporting NARP input data to Myers & Stauffer and CMS, the rationale for the inclusion or exclusion of certain types of claims data, whether and how the inclusion or exclusion of specific types of claims data may impact the NARP, and the potential sources of distortion from data exclusions/inclusions. We offer the following comments to help achieve these important goals.

I. Transparency

A. <u>CMS Should Approach the Collection and Reporting of Data Used to Calculate the NARP with the Same Rigor, Transparency, and Specificity That It Applies to Other Reimbursement Methodologies.</u>

In its methodology, CMS states that the NARP is intended to represent "the combined prices paid for drug ingredient costs, customer pay amounts, and dispensing fees

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from actual market transactions."[1] CMS suggests that the NARP is meant to provide states with an alternative drug price benchmark that they can use to evaluate their Medicaid pharmacy reimbursement methodology. Because CMS intends to capture what the various customer types *pay* for outpatient drugs and biologics, BIO is concerned that NARP as an acronym may create confusion as 'price' is a relative term, and the measurement is supposed to reflect the average reimbursement paid to pharmacies. To clarify the data the survey actually are collecting, CMS should rename the measure the "National Average Reimbursement Amount (NARA)." This terminology better communicates that the survey aims to measure pharmacies' average reimbursement, and not the average price charged to different customers.

We also ask CMS to specifically identify which pharmaceutical data suppliers will be gathering retail price data, what data they will collect and report, the mechanisms in place to ensure consistent data collection and reporting between data suppliers, and how potentially variable data will be homogenized to calculate the NARP. We also ask CMS to provide an explanation of how the data suppliers will ensure they are collecting robust, quality data that avoids selection bias, under or oversampling from one type of pharmacy (chain or independent) or customer (cash pay, commercial third party insurers, or Medicaid), or other types of errors that could skew the NARP. CMS should give stakeholders an opportunity to comment on these details once provided. In addition, we encourage CMS to establish a channel of communication for future methodological inquiries.

B. <u>CMS Should Clarify What the NARP Actually Represents by Making Its Calculations More Accessible.</u>

The purpose of the NARP is to publish a monthly pricing database for Medicaid covered outpatient drugs that is based on actual monthly market transactions. To fulfill that purpose, the data and calculation methodology used must actually reflect average retail prices. To improve the accessibility of the NARP calculation methodology, CMS should provide a practical interpretation of the calculated margin of error and its likely and reasonable bounds, and describe the likelihood that the quality assurance validation process will identify errors and the procedures for correcting those errors once a NARP has already been published. It is important that stakeholders understand exactly what the NARP reflects and what it does not, to avoid misinterpretations by those using it to evaluate and impact reimbursement policy. It should be noted that a similar layman's terms description was provided from the calculations of pharmacy acquisition costs for Medicaid outpatient pharmaceuticals—for the NADAC (National Average Drug Acquisition Cost)—which was successful in aiding stakeholder understanding. The formulas included in the draft NARP methodology are less readily-understandable than those included in the NADAC methodology document and therefore stakeholders may be unable to fully appreciate and comment upon those methodologies.

C. <u>CMS Should Describe the Rationale for and Criteria Used to Exclude or Include Claims in the NARP Calculation and Ensure All Best-Price Exempt Transactions Are Excluded from the NARP Calculation.</u>

[1] CMS. June 2012. Part I: Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs, p.5, http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NARPDraftMethodology.pdf.

The draft methodology report lists the types of retail claims that will be excluded from the NARP calculation, but does not provide a broader rationale for how exclusions are determined.[2] To ensure the NARP accurately represents an average reimbursement rate across customer types, it is essential that there be a consistent and logical rationale for including or excluding various types of transactions from the calculations. This rationale was not clearly stated anywhere in the methodology report. For example, CMS states that claims "associated with discount card, co-pay card, or patient assistance programs"[3] are excluded from the NARP, but it does not describe an overarching rationale for how this exclusion was determined. This introduces ambiguity regarding how other pharmacy-managed and point-of-sale discounts will be accounted for, such as the Wal-Mart four dollar generics program or discounts associated with the Medicare Part D Coverage Gap Discount Program. Similarly, as CMS made clear on the July 26 webinar, claims associated with the 340B discount program will be included in the NARP calculation, but again did not provide a rationale for inclusion. Transaction exclusions must be based on a clearly stated and logical principle. Without such a principle, stakeholders are unable to determine whether the principle has been consistently applied in identifying the transactions CMS has proposed to exclude. Thus, BIO urges CMS to clarify this principle before publishing the NARP file. Additionally, CMS should clearly describe in its methodology whether sufficient granularity exists to identify proposed exclusions and other discounts. If this level of granularity does not exist, CMS should recommend a strategy that addresses the consequences of these distortions. Along with clarifying exclusion and inclusion criteria, we ask CMS to explain the process for identifying and excluding these claims from larger data sets, the reliability and likely error rate of the exclusion process, and the potential volume of these claims. This information is crucial to understand exactly what the NARP represents. What data is included and how it is treated will determine if the NARP accurately reflects pharmacies' average reimbursement.

1. CMS Should Exclude From NARP Any Discounts Exempt from Best Price.

The CMS presentation on the draft methodology stated that 340B claims would be included in the NARP calculations, but did not clarify the potential impact of the inclusion of 340B data on the NARP.[4] Similarly, it is unclear how Medicare Part D Coverage Gap Discount Program discounts will be treated. Claims impacted by either of these mandatory discount programs may misrepresent the average reimbursement of covered outpatient pharmaceuticals paid to pharmacies, depending on how individual insurers account for the discounts in their payments (to pharmacies or directly to patients). In order to consistently account for these discounts, BIO recommends that CMS exclude from the NARP calculation all discounts that are exempt from Best Price (as defined by Title 42 § 447.505 [d][5]), including but not limited to those from the 340B and Medicare Part D Coverage Gap Discount Program discounts, as well as those under the Tricare retail pharmacy program. The types of claims exempted from Best Price reflect such mandated discounts and their subsequent impact on private payer contracting. Excluding such discounts from the NARP

[2] *Id*. at 7.
[3] *Id*. at 9.
[4] CMS. July 26, 2012. Webinar on Part I of the Survey of Retail Prices. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html.
[5] Code of Federal Regulations. 2007. § 447.505 (d): Determination of best prices. http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol4/pdf/CFR-2010-title42-vol4-sec447-505.pdf.

calculation ensures the NARP truly reflects "actual market transactions".[6] CMS should also clarify whether it is possible to identify 340B claims and Medicare Part D Coverage Gap Discount Program and Tricare data, and if so, the rationale for including these claims in the NARP. If that level of data granularity is not available, we ask CMS to describe the impact of these discounted claims, depending upon the estimated volume of such claims, on the NARP and potential consequences of states relying on the NARP to set reimbursement rate policy.

2. CMS Should Detail How Retail Claims Reflecting Discounts and Co-Pays Will Be Identified and Excluded from NARP Calculations and Exactly What Discounts Qualify for This Exclusion.

The draft methodology excludes claims "associated with discount card, co-pay card, or patient assistance" for purposes of calculating the NARP.[7] CMS should describe how these claims will be accurately identified from larger data sets for exclusion.

We also ask CMS to describe the impact of including other pharmacy-managed discounts in the NARP calculation. Programs like the Wal-Mart four dollar generics program or others that solely benefit the "cash pay" customer category (e.g., discounts to "self pay" customers) may result in an inaccurate and unreliable NARP. These programs, depending on which pharmacies participate and what outpatient pharmaceuticals are included, may skew the comparison between average retail prices at independent and chain pharmacies, the latter likely to drive higher volumes and participate in these pharmacy-managed discount programs. CMS should propose or seek proposals on mechanisms to identify and exclude such claims from these types of programs to avoid this miscalculation.

II. Data Management

A. BIO Supports CMS' Exclusion of Specialty Pharmacies From the NARP Survey.

BIO supports CMS' exclusion of specialty pharmacy data from the survey to ensure NARP is truly representative of the average reimbursement rate for Medicaid covered outpatient drugs to retail pharmacies. The small pool of specialty pharmacies' data available may not accurately represent the average pharmacy reimbursement rates from the various payer categories, and therefore has the potential to skew the NARP calculation. Ensuring robust data collection from such a limited group is also difficult, as is correcting for the error introduced by such a small sample size.

B. CMS Should Ensure the Third-Party Customer Category Is Truly Reflective of Commercial Transactions Alone.

The draft methodology report outlines three categories of pharmacy customers: cash paying, insured with a commercial third party, and Medicaid. A NARP will be published for each of these three customers for independent and chain pharmacies. Clarity on the sources of claims incorporated into each category is important to be able to appropriately interpret the NARP from each category. For this reason, we ask CMS to describe the impact of grouping claims associated with Medicaid Managed Care payments in the "third party" payer

[6] CMS. June 2012. Part I: Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs, p.3, http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NARPDraftMethodology.pdf.
[7] *Id.* at 9.

category rather than in the Medicaid category.[8] It is likely that Medicaid Managed Care reimbursement rates differ significantly from those of other third party payers. If included in this category, Medicaid Managed Care claims may artificially skew the average prices reportedly paid by commercial third parties.

C. CMS Should Clarify the Method Used to Determine the Minimum Reporting Standard and Clarify the Potential Consequences of the Current Low Threshold.

The draft methodology report states that in order for an outpatient drugs' average retail price to be included in the NARP calculation, at least 30 claims from each payer type must be reported.[9] CMS should explain how it calculated this minimum threshold and provide greater clarity about the potential consequences of such a low threshold, such as unreliable pricing information resulting from a small sample size. It is our position that certain drugs that are dispensed by pharmacies in such low volumes should be excluded from the survey. We also ask that CMS exclude prices of drugs that are not generally dispensed through a retail community pharmacy from the NARP calculation, including orphan drugs dispensed in low volumes. We ask that CMS work with stakeholders to identify these low-volume drugs so they can be excluded.

III. Conclusion

BIO thanks CMS for this opportunity to comment on the NARP 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 biologic therapies. Please contact me at (202) 449-6384 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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[8] *Id*. at 7.
[9] *Id.* at 9.