BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Kerry Weems, Acting 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-2238-P (Medicaid Program; Prescription Drugs)

Dear Acting Administrator Weems:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Final Rule with comment period regarding the treatment of prescription drugs under the Medicaid Drug Rebate Program (the 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 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new therapies and ensuring patient access to them. The Deficit Reduction Act of 2005 (DRA) includes a number of provisions impacting the operation of the Medicaid Drug Rebate Program.[2] BIO appreciates CMS' effort to bring additional clarity to the calculations of Average Manufacturer Price (AMP) and Best Price (BP), both of which determine Medicaid rebates, and in the case of AMP, federal upper payment limits (FULs) as well. Final implementation will significantly impact patient access to drugs and biologicals, and BIO urges CMS to provide the further additional guidance and clarity described below to ensure continued beneficiary access to important drug and biological therapies.

[1] 72 Fed. Reg. 39,142 (July 17, 2007).
[2] See Deficit Reduction Act of 2005, Pub. Law No. 109-171, §§ 6001-04 (2006).

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Although the Final Rule only asks for comments on a specific set of issues, BIO submits these comments on a broader set of issues due to their significance to the price reporting calculations of AMP and BP. For example, BIO believes that the Final Rule's definition of "bundled sales" differs significantly from the Medicaid Rebate Agreement's definition such that it can only be applied prospectively. BIO asks CMS to further clarify that fees paid to Group Purchasing Organizations (GPOs) are not included in the BP calculation and that manufacturers must only include the lowest price realized by any individual purchaser in the BP calculation. Finally, BIO urges CMS to clearly state that violations to the certification process require intent similar to current Medicaid reporting requirements and that the states must pay for drugs and biologicals billed under a temporary HCPCS code. These issues are discussed in depth below in the order in which they are addressed in the Final Rule.

I. CMS' Final Definition of Bundled Sale Differs Substantially From the Medicaid Rebate Agreement and Can Therefore Only Apply Prospectively.

The Medicaid Rebate Agreement (Agreement) defines a bundled sale as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."[3] This definition explicitly applies solely to products that are physically packaged and purchased together.[4] The definition in the Final Rule, however, includes a broader range of contractual terms as a bundled sale that under the Medicaid Rebate Agreement are not considered as such.

The Final Rule now includes a new, revised and expanded definition of bundled sale. Bundled sale is now defined as:

> [A]n arrangement ***regardless of physical packaging*** under which the rebate, discount, or other price concession is conditioned upon the purchase of ***the same drug***, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product ***or some other performance requirement*** (for example, the achievement of market share, inclusion or tier placement on a formulary), ***or where the resulting discounts or other price concessions are greater than those which would have been***

[3] 56 Fed. Reg. 7049, 7050 (Feb 21, 1991); Medicaid Rebate Agreement at I(e).
[4] The Medicaid drug rebate statute uses the term "packaging" in two places, and in both the term is used to mean physical packaging. *See* Social Security Act §§ 1927(c)(1)(C)(ii)(II) (stating that "[t]he term 'best price'…shall be determined without regard to special packaging"); 1927(k)(5)(A) (defining the term "manufacturer" as any entity engaged in the packaging of drug products).

> ***available had the bundled drugs been purchased separately or outside the bundled arrangement.***[5] (emphasis added).

The expanded definition differs from the Medicaid Rebate Agreement in four significant ways:

- **Physical Packaging**: The new definition states that bundled sales can occur even where the products involved are not physically packaged together. This is a change from the Agreement's definition which clearly required the "packaging" of the drugs.
- **Same Drug**: The new definition applies to arrangements involving the same drug, whereas the Agreement definition required that drugs of different types be involved.
- **Non-Purchase Performance Requirement**: The new definition applies even to arrangements that include a performance requirement that does not include the purchase of a covered outpatient drug. The Agreement's definition applied only to arrangements where a product actually was purchased.
- **Catch-All**: The new definition includes catch-all language that vastly broadens the definition, to include any arrangement that provides discounts that would not otherwise be available outside of the arrangement. Such language simply does not exist in the Agreement's definition.

In addition to these changes to the definition itself, CMS' instruction regarding the reallocation of discounts also significantly departs from the Agreement's requirement. Specifically, it now appears that CMS may be directing manufacturers to include in the discount reallocation calculation discounts and products that are not contingent or linked to other products.[6] BIO urges CMS to clarify that the definition of bundled sale does not require the inclusion of non-contingent discounts and products in the reallocation calculation. In general, the significant changes in CMS policy clearly distinguish the Final Rule's definition from that contained in the Agreement.

CMS does not provide any explanation in the Final Rule for why it expanded the definition in this way or does it describe policy objectives the changes are intended to promote. Nor does CMS provide any guidance regarding the interpretation and application of the definition, which contains several new terms subject to multiple interpretations. Rather, in finalizing the definition of bundled sale, CMS states that this definition has always been its position, that "[t]he provisions of this final rule do not create a new definition for bundled sales, but merely clarify the existing definition."[7] However, for the reasons stated above, BIO believes that CMS has dramatically

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[5] 42 C..F.R. § 447.502; 72 Fed. Reg. at 39,240.
[6] See 72 Fed. Reg. at 39,159-60 (responding to comments requesting that CMS clarify whether non-contingent drugs and non-contingent discounts should be included in the reallocation calculation).
[7] 72. Fed. Reg. at 39,159.

expanded the definition of "bundled sale" in such a way that it is not a clarification of existing policy. Instead, the new definition represents new requirements and obligations for manufacturers that, consistent with the requirements of the Administrative Procedures Act (APA), can only be effective prospectively.

Under the APA, legislative rules can only be applied prospectively following proper notice and comment rulemaking, they cannot be applied retroactively.[8] An agency rule is a legislative rule if it, "grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests"[9] or "effects a substantive change from the agency's prior regulation or practice."[10] As stated above, BIO believes that CMS' regulatory definition of bundled sale is considerably different from the Medicaid Rebate Agreement's definition. These differences are substantive in nature such that the new requirements for bundled sales represent a legislative rule for the purposes of the APA. As such, CMS can only require manufacturers to apply the new definition of bundled sales prospectively and not retrospectively. BIO urges CMS to clarify that as a result of its expansion of the definition of "bundled sale" these new requirements are effective as of October 1, 2007, the implementation date of the Final Rule.

As CMS implements the definition of "bundled sale" and provides greater clarity, BIO urges the agency to base its decisions on free market principles that will cause the least disruption as possible in the marketplace. Further, BIO urges the agency to issue clear guidelines such that manufacturers can carry out their reporting obligations in compliance with all applicable laws and regulations. Predictability and transparency are essential for compliance and are particularly important if CMS wants to promote consistency in the treatment of bundled sales for purposes of price reporting.

II. BIO Urges CMS to Clarify that the Definition of Best Price Requires Manufacturers to Report the Lowest Price Actually Realized by *Any Individual* Purchaser and Not an Aggregation of Price Concessions Provided to Different Customers.

The statutory, Agreement, and Final Rule definitions of Best Price all define that term by reference to the price received by a particular purchaser or provider, which indicates that the Best Price determination does not require the aggregation of discounts provided to different customers. The preamble to the Final Rule contains a number of responses to comments that could be read to suggest, notwithstanding these definitions and prior silence by CMS on this issue, that such aggregation now may be required. Specifically, the Final Rule preamble states CMS' view that discounts to an entity that

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[8] *See* 5 U.S.C. § 553.
[9] Id.
[10] *Nat'l Mining Ass'n v. Dept. of Labor*, 292 F.3d 849, 860 (D.C. Cir. 2002); s*ee also Croplife America v. E.P.A.*, 329 F.3d 876, 881 (D.C. Cir. 2003) (finding a rule to be legislative where it "reflects an obvious change in established agency practice").

are intended to affect the price available to another entity should be considered in determining BP of the second entity, but the preamble is ambiguous as to whether discounts offered to different entities must be aggregated even where such an intent does not exist. Given the clear and consistent definitions of Best Price in the statute, Final Rule, and Agreement that focus on the price received by a particular entity, BIO urges CMS to clarify that, in the calculation of Best Price, aggregation of discounts across entities is not generally required, with the exception being where a discount is designed to be passed on or otherwise affect the price realized by the recipient's own customer pursuant to a specific agreement with the manufacturer.

The statutory definition of Best Price states:

> The term best price means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug and Cosmetic Act) the lowest price available from the manufacturer during the rebate period to *any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States*.[11] (emphasis added).

This statutory definition identifies BP as the lowest of those prices made available to the entity types listed in the definition, i.e. purchasers and reimbursers of the manufacturer's product. This definition does not focus on the manufacturer's net realized price on a given unit, but rather on the price realized by the purchasing or reimbursing entity.[12] The statute's use of the terms "any" and "or" before and within the list of entities reinforces this conclusion, because it requires a determination of the price realized by each entity individually.

The Medicaid Rebate Agreement similarly defines BP from the purchaser's perspective, stating:

> Best Price means, with respect to Single Source and Innovator Multiple Source Drugs, *the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser* in the United states in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best Price includes prices to wholesalers, retailers, non profit entities or governmental entities within the States (excluding Depot prices and Single Award Contract Prices of any agency of the Federal Government). Federal

[11] 42 U.S.C. § 1396r-8(c)(1)(C)(i)(2007).
[12] The preamble states that only prices available and also realized are included in the calculation of best price. 72 Fed. Reg. at 39,197.

> Supply Schedule prices are included in the calculation of the best price.[13] (emphasis added).

As a result of these clear definitions, manufacturers have calculated BP based upon the lowest price realized by any individual purchaser.[14]

Certain statements made by CMS in the preamble now have created ambiguity regarding this position. Specifically, CMS states:

> *Comment*: One commenter requested that when best price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third party.
>
> *Response*: We do not agree. As we have previously stated, there is no basis to exclude these discounts. Both the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price.[15]

As the second comment specifically asks CMS to confirm that the prompt pay discount and chargeback need not be aggregated when determining BP, the CMS response of "We do not agree" could be read to require aggregation of discounts even when the discounts are provided to different entities, i.e. the prompt pay provided to the wholesaler and the chargeback provided through the wholesaler to the end purchaser. However, the second sentence in the response suggests the response may not be designed to address the aggregation issue but rather whether prompt pay discounts should be included in the BP calculation in the first instance.

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[13] Medicaid Rebate Agreement between the Secretary of Health and Human Services and the Manufacturer, *sample* agreement is available at: http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf. CMS has not amended the Medicaid Rebate Agreement over time to reflect statutory changes that would affect the terms, such as the amendment of the Best Price definition to exclude Federal Supply Schedule Sales and include sales of authorized generics to any entity.

[14] The Best Price definition's focus on the price received by the purchaser or provider is in contrast with the Final Rule's definition of AMP, which is worded in terms of the net price realized by the manufacturer. See 42 C.F.R. § 447.504(a),(i). The AMP definition's focus on the net price received by the manufacturer does suggest the need to aggregate discounts across entities in the AMP calculation because such aggregation is needed when the price received by the manufacturer on a particular product is being measured.

[15] 72 Fed. Reg. at 39,199.

Adding to the confusion is another comment and response that can be read to direct aggregation only where the discounts affect the price available to a single entity:

> *Comment*: Several commenters stated that some industry analysts appeared to misread the proposed rule to suggest that manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price. This would effectively call for the combining of two separate prices, one offered to a PBM and the other to a customer of a PBM. The commenter stated that the statute is quite clear in defining best price as the lowest price to 'any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or government entity * * *.' The commenters argued that if Congress had intended anything other than a customer-by-customer analysis of separate prices the statute would have combined each customer with the word 'and' instead of the disjunctive 'or.' The commenters requested that CMS reaffirm that best price is the lowest price available from the manufacturers reflecting concessions provided by the manufacturers.
>
> *Response*: We do not agree with the commenters. Although we have deleted the requirement that manufacturers include PBM rebates and discounts and other price concessions in best price, there are instances where some PBM rebates and discounts may be designed to adjust prices at the retail or provider level. Best price is designed to reflect the lowest price available from the manufacturer to any purchaser, inclusive of rebates, discounts, or price concessions that adjust the price realized. Where PBM rebates, discounts or price concessions do not operate to adjust prices, they should not be included in the best price calculation.[16]

The CMS response of "We do not agree" again could be read broadly as a rejection of a request to confirm that best price is determined customer-by-customer and reflects the lowest price available from the manufacturer to each customer individually. However, the response also could be read as a rejection only of a broad request that PBM price concessions never need to be aggregated with separate price concessions provided by the manufacturer directly to the PBM's customers. This latter reading is supported by the text of the response, which clarifies that the statement in the comment is not correct, because there are: "instances where some PBM rebates and discounts may be designed to adjust prices at the retail or provider level." In such situations, CMS appears to take the view that the discount to the PBM is considered to have been made available by the manufacturer to the end user, which might be the PBM itself, the PBM's member plans, or its contracted mail order pharmacy.

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[16] Id. at 39,198.

The language that CMS uses in these responses creates ambiguity because it could be read to contradict the statutory, Final Rule, and Medicaid Rebate Agreement definition of BP. Manufacturers have long understood that the BP calculation only includes the lowest price realized by any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States and that the calculation does not require an aggregation of discounts across the distribution channel. Regrettably, the preamble to the Final Rule introduces confusion on this issue and BIO therefore urges CMS to clarify that the BP calculation does not require manufacturers to aggregate discounts on the same unit. Rather, consistent with the statute and the Medicaid Rebate Agreement, manufacturers need only calculate the lowest price realized on the unit to any single purchaser.

III. CMS Should Explicitly State that Administrative and Service Fees Paid to GPOs Are Excluded From Best Price.

The Final Rule adopts a definition of bona fide service fee and explains in the preamble that fees paid to Group Purchasing Organizations ("GPOs") are to be excluded from the calculation of AMP only where those fees satisfy that definition. The preamble and Final Rule do not specifically address the treatment of these fees in the calculation of Best Price, however, and BIO urges CMS to clarify that such fees need not be included in the calculation of Best Price, regardless of whether they satisfy the definition, unless they are paid, directly or indirectly, to an entity included in the Best Price definition. As discussed above, the definition of Best Price focuses on the price received by particular purchaser and provider entities, and therefore fees paid to a GPO are relevant to the calculation of Best Price only when provided to such entities.

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, in general, do not themselves purchase drugs and biologicals, but instead negotiate contracts that providers use in making their own purchases.[17] Where a GPO is not a purchaser or provider, and does not otherwise pass back any portion of the fees it receives to its own members that are purchasers or providers, BIO strongly believes that the definition of Best Price does not require their consideration. BIO agrees with CMS, however, that if the manufacturer has an agreement with a GPO that specifies that certain fees are passed on directly to a GPO member that this fee is a discount and must be included in the BP calculation. This is the only way that manufacturers can identify discounts that are passed through to GPO members as opposed to monies distributed to GPO members for other reasons. Therefore, BIO strongly believes that the definition of BP does not require their consideration in the BP calculation.

[17] 42 C.F.R. § 1001.952(j)(2).

Other discussions in the preamble relating to Pharmacy Benefit Managers (PBMs) support this position. Specifically, in the preamble CMS directs that "except in those situations where PBM rebates are designed to provide price concessions, discounts or rebates, *or to adjust prices recognized by providers or retailers*, PBM rebates should not be included in best price calculations."[18] This approach applies equally to GPOs: where the GPO itself is not a purchaser, fees paid to it should not affect Best Price unless those fees adjust the prices received by the GPO's members. BIO urges CMS to make this needed clarification.

IV. CMS Should Clarify That the "Knowledge" Requirement of the Medicaid Civil Money Penalty Provision Is Included for All Elements of AMP and Best Price Certification.

The civil money penalty provision of the Medicaid statute provides that manufacturers are subject to penalty only for "knowingly" providing false information to CMS.[19] BIO therefore believes that this knowledge requirement must modify all representations included in any certification. The full text of the AMP certification reads as follows:

> **I hereby certify, to the best of my knowledge, the data being sent to CMS with this submission is complete and accurate at the time of this submission, and was prepared in accordance with the manufacturer's good faith, reasonable efforts based on existing guidance from CMS and the manufacturer's reasonable assumptions regarding the provisions of section 1927 of the Social Security Act, the National Medicaid Drug Rebate Agreement, and applicable federal regulations. I understand that the information contained in this submission may be used for Medicaid rebate and payment purposes and that civil monetary penalties and/or termination from the Medicaid Rebate Program may be enforced if the information provided is found to be misrepresented. I further certify that I am authorized to submit this information in accordance with 42 CFR 447.510(e).**

BIO appreciates that CMS has expressly included as a modifier to all representations in the first sentence the qualification that those representations are being made to the "best of [the certifier's] knowledge." This qualification is not specified in the second sentence, however, and BIO is concerned that the term "misrepresented" could be construed as not requiring a knowing submission of false data. Given that the Medicaid statute limits the application of civil monetary penalties to "knowingly" provided false information, BIO believes that the term "knowingly" must be inserted into the certification before the term "misrepresented." BIO requests that CMS modify the certification accordingly.

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[18] 72 Fed. Reg. at 39198 (emphasis added).
[19] Social Security Act § 1927(b)(3)(C).

V. CMS Should Remind States of Their Legal Obligation to Pay for Drugs and Biologicals Billed with a Temporary HCPCS Code.

The Medicaid statute requires drug manufacturers to enter into a rebate agreement with the Secretary in order for federal funds to be made available to pay for the manufacturer's products under the Medicaid and Medicare Part B programs.[20] The statute further states that the Medicaid rebate agreement applies to "covered outpatient drugs of the manufacturer."[21] The statute states that covered outpatient drug means:

> a biological product, other than a vaccine which—
> (i) may only be dispensed upon prescription,
> (ii) is licensed under section 351 of the Public Health Service Act, and
> (iii) is produced at an establishment licensed under such section to produce such product[22]

BIO understands that some states are denying Medicaid patients access to certain innovative therapies because the product is billed with a temporary Healthcare Common Procedure Coding System ("HCPCS") code and not a permanent one. We understand that the states are denying coverage because of the difficulty associated with cross-walking a temporary code to a particular product's National Drug Code ("NDC") and the resulting barrier to collecting a rebate from the manufacturer. The states have stated that they will continue to deny coverage until the permanent billing code is assigned – a process that can take well over a year after a product's launch – so that they can more readily identify the product NDC and therefore collect a rebate.

CMS repeatedly has made clear that states must cover all drugs of a manufacturer that has signed a Rebate Agreement. Medicaid Drug Rebate Program Release to State Medicaid Directors 19 states that "the Omnibus Budget Reconciliation Act of 1990 requires coverage of all non-excludable or non-restricted drugs of a participating manufacturer."[23] State Release 102 states that a state Medicaid program may elect to cover a manufacturer's products at any time after the optional effective date, but must

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[20] Social Security Act § 1927(a)(1); 42 U.S.C. § 1396r-8(a)(1).
[21] Social Security Act § 1927(k)(2)(B); 42 U.S.C. § 1396r-8(k)(2)(B).
[22] Social Security Act § 1927(b)(1)(A); 42 U.S.C. § 1396r-8(b)(1)(A). We understand that certain states also are denying coverage based on the mistaken belief that the first prong of this definition requires that a product be dispensed only through a prescription written on a prescription pad, and that a physician order, in a patient's chart, will not suffice. As the statutory language makes clear, however, this requirement relates solely to a product's prescription versus over-the-counter status, and not the documentation used to communicate the physician's direction that the patient receive it.
[23] CMS, Medicaid Drug Rebate Program Release to State Medicaid Directors No. 19, available at: www.cms.hhs.gov/medicaiddrugrebateprogram/03_DrugMfrReleases.asp.

cover the products after the mandatory effective date.[24] State Release 97 further directs that "[w]hen a manufacturer's rebate agreement becomes effective in a State, all of its covered drugs must be included at that time."[25] There is no exception to this coverage requirement for coding status. Nor does the difficulty in cross-walking a temporary code to a particular NDC provide a basis for non-coverage. To the contrary, the Deficit Reduction Act requires states to obtain NDC level data for single source drugs that are physician administered, as of January 1, 2006.[26]

There is no ambiguity in this guidance regarding a state's coverage obligations, and the DRA's requirement to obtain NDC level data has eliminated any basis for non-coverage based on coding status. Where a manufacturer has complied with its statutory obligation for coverage – execution of the Medicaid Rebate Agreement – state Medicaid programs should fulfill their obligations as well. We request CMS to immediately contact the states who are denying access to physician administered drugs billed with a temporary code to remind them of their legal obligation to cover these therapies for their Medicaid patients. We also request that CMS include this issue in its next State Release and direct States to cover all covered outpatient drugs of a participating manufacturer regardless of whether those drugs have a temporary or permanent billing code assigned to them.

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BIO greatly appreciates the opportunity to comment on the important issues raised by the Final Rule, and we look forward to working with CMS to ensure that Medicaid 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 John Siracusa at (202) 312-9281 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

John Siracusa
Manager, Medicare Reimbursement
& Economic Policy

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[24] CMS, Medicaid Drug Rebate Program Release to State Medicaid Directors No. 102, available at: www.cms.hhs.gov/medicaiddrugrebateprogram/03_DrugMfrReleases.asp.
[25] CMS, Medicaid Drug Rebate Program Release to State Medicaid Directors No. 97 available at, www.cms.hhs.gov/medicaiddrugrebateprogram/03_DrugMfrReleases.asp.
[26] DRA § 6002(a).