

February 20, 2007

Leslie V. Norwalk, Esquire, 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 Administrator Norwalk:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding the treatment of prescription drugs under the Medicaid Drug Rebate Program (the Proposed 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 treatments and ensuring patient access to them. The Deficit Reduction Act of 2005 (DRA) includes a number of provisions that will impact the operation of the Medicaid Drug Rebate Program.² BIO supports CMS' effort to bring additional clarity to the calculations of Average Manufacturer Price (AMP) and Best Price, both of which determine Medicaid rebates, and in the case of AMP, federal upper payment limits (FULs) as well. The Final Rule has the potential to significantly impact patient access to drugs and biologicals, and BIO urges CMS to provide the additional guidance and clarity described below to ensure continued beneficiary access to important drug and biological therapies. In addition, BIO urges CMS to take steps to ensure that any State implementation of AMP-based reimbursement methodologies, which is not mandated by the Final Rule, also does not impede such access.

In this spirit we offer comments to the Proposed Rule. First and foremost, BIO strongly urges CMS to codify the statutory requirements that limit the amount of manufacturer rebates where a State Medicaid program is a secondary payor and the time

¹ 71 Fed. Reg. 77,174 (Dec. 22, 2006).

² See Deficit Reduction Act of 2005, Pub. Law No. 109-171, §§ 6001-04 (2006).

period in which States can submit rebate claims. BIO also comments regarding certain definitions in the Proposed Rule, including those for the retail class of trade, bundled sale, and bona fide service fee. BIO addresses the Proposed Rule's new guidance regarding patient and other transaction types as well. This letter then discusses the provisions relating to manufacturer recalculation of base date AMP and monthly reporting of AMP. Finally, BIO addresses a number of issues not directly reached by CMS in the Proposed Rule but that BIO believes are crucial to the effective administration of the Medicaid Drug Rebate Program. These issues are discussed in depth below, in the order in which they are addressed in the Proposed Rule.

I. CMS Should Clarify Certain Terms and Definitions Included in the Proposed Rule.

BIO applauds the Proposed Rule's attempt to "bring together existing and new regulatory requirements in one, cohesive subpart."³ Even with the additional guidance contained in the Proposed Rule, BIO has identified a number of key terms that the Proposed Rule either does not define, or includes but are in need of additional clarification. BIO requests that CMS address those issues in the Final Rule. Specifically, BIO urges CMS to clarify that drugs approved under a biologic license approval are single source drugs, to define the term "original NDA," to specify that the "United States" means the fifty states and District of Columbia, to clarify that "net sales" is not tied to a manufacturer's recognized revenue for financial accounting purposes, and, finally, to encourage States to include Medicare special add-on fees when setting dispensing fees.

1. CMS Should Clarify That Drugs Approved Under a Biologic License Application Are Single Source Drugs.

CMS proposes to define single source drug as a "covered outpatient drug that is produced or distributed under an original NDA . . . [or] approved under a product license approval, establishment license approval, or antibiotic drug approval."⁴ This definition is consistent with the Medicaid rebate statute and the Medicaid rebate agreement, but does not address products approved under a biologic license application (BLA).⁵ BIO asks CMS to clarify that drugs approved under a BLA are single source drugs, consistent with those products' designation under the Average Sales Price (ASP) calculation.⁶

2. CMS Should Define the Term "Original NDA" Consistent with the 1995 Proposed Rule.

The Proposed Rule does not contain a definition of "original NDA," although this term is a crucial component in the definition of single source drug. The term is not

³ 71 Fed. Reg. at 77,174.

⁴ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.502).

⁵ See Social Security Act (SSA) § 1927(k)(7)(A)(iv); Medicaid Rebate Agreement at I(z).

⁶ SSA § 1847A(c)(6)(D)(i).

defined in the Medicaid rebate statute, the Medicaid rebate agreement, or the Federal Food, Drug, and Cosmetic Act. CMS previously has recognized the need for a definition of this term.⁷ In the 1995 proposed rule, which never has been finalized, CMS defined the term as “an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA.”⁸ CMS stated then that this definition was consistent with congressional intent to treat separately those drugs able to realize greater profits due to patent or marketing protection. BIO asks CMS to include this definition in the Final Rule.

3. CMS Should Clarify the Definition of Multiple Source Drug

CMS proposes implementation of section 6002 of the DRA, including the development of a top 20 multiple source drug list, in proposed 42 C.F.R. § 447.520. For purposes of that proposed regulation, CMS proposes in 42 C.F.R. § 447.502 to define “multiple source drug” consistent with the Medicaid statute - section 1927(k)(7)(A)(i). BIO agrees that this is the proper definition of “multiple source drug” to utilize in creating this listing, but believe that the top 20 multiple source drug listing is not consistent with either the pertinent statutory definition or the proposed regulatory definition. Specifically, the listing that CMS released in December includes two products - Factor viii recombinant and Factor viii - that do not meet the definition of “multiple source drug” because they are not listed in the Food and Drug Administration's Orange Book. Accordingly, we ask CMS both to correct the top 20 multiple source drug listing to remove these two products and to ensure that the final rule makes clear that drugs that are not listed in the Orange Book cannot appear in the multiple source drug listing.

4. CMS Should Define the Term “United States” As the Fifty States and District of Columbia

The Proposed Rule defines AMP as the average price received by the manufacturer for the drug “in the United States.”⁹ Best Price is defined as the lowest price available from the manufacturer to “any entity in the United States.”¹⁰ The Proposed Rule does not define “United States,” although the agreement defines the term “states” as the fifty states and District of Columbia.¹¹ Consistent with this agreement definition, BIO asks CMS to define the full term “United States” as the fifty states and the District of Columbia.

⁷ See 60 Fed. Reg. 48,442, 48,453 (Sept. 19, 1995).

⁸ *Id.*

⁹ 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

¹⁰ *Id.* at 77,197 (proposed 42 C.F.R. pt. 447.505(a)).

¹¹ 56 Fed. Reg. 7050 (Medicaid Rebate Agreement at 1).

5. CMS Should Clarify That the Term “Net Sales” Is Not Dependent on Revenue Recognition for Financial Accounting Purposes.

The Proposed Rule directs that AMP is to be calculated as “net sales divided by number of units sold.”¹² CMS proposes to define net sales as the “quarterly gross sales *revenue* less cash discounts allowed and all other price reductions . . . which reduce the amount received by the manufacturer” (emphasis supplied).¹³ BIO requests CMS to clarify that the term “revenue” in the “net sales” definition refers only to sales dollars associated with a transaction and not revenue recognized for a transaction for financial accounting purposes. This interpretation is consistent with the position CMS already has taken in the context of ASP reporting: that financial accounting principles are generally inapplicable in the price reporting context.¹⁴ For purposes of the AMP calculation, BIO believes it is appropriate to define net sales as a measure of actual sales made regardless of the financial accounting treatment of the transaction. BIO requests that CMS include this clarification in the Final Rule.

6. CMS Should Encourage States to Include Additional Fees Provided in the 2007 Physician Fee Schedule Final Rule When Establishing Dispensing Fees.

The Proposed Rule includes a general definition of dispensing fee to “assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers.”¹⁵ The Proposed Rule does not mandate that States use a specific formula or methodology for determining dispensing fees for Medicaid drugs, as it has in the Medicare context, but instead opts to provide the States with factors to consider in setting those amounts.¹⁶ As CMS knows, the Medicare program does provide additional or special fees for certain drugs that involve specific pre-administration processing or complicated dispensing procedures. For example, the 2007 Physician Fee Schedule (PFS) Final Rule mandates the additional payments for intravenous immune globulin (IVIG) preadministration-related services “to compensate physicians and hospital OPDs for extra resources expended on locating and obtaining appropriate IVIG products.”¹⁷ Although BIO recognizes that CMS is not required to set dispensing fee rates under the Medicaid statute, BIO does ask CMS to include these additional Medicare payments and fees in the dispensing fee definition as a specific factor for the States to consider when determining dispensing fee amounts.

II. CMS Should Clarify the Treatment of Certain Entities Under the New Definition of Retail Pharmacy Class of Trade.

¹² 71 Fed. Reg. 77,197 (proposed 42 C.F.R. pt. 447.504(i)(2)).

¹³ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(d)).

¹⁴ See 71 Fed. Reg. 69,624, 69,667 (Dec. 1, 2006) (explaining that the treatment of service fees for price reporting purposes may differ from the treatment of service fees for financial accounting or other purposes).

¹⁵ 71 Fed. Reg. 77,176.

¹⁶ See *id.*

¹⁷ 71 Fed. Reg. at 69,679.

Section 6001(c)(3) of the DRA requires the Secretary “to clarify the requirements for, and the manner in which, AMP is determined” in a formal regulation.¹⁸ AMP is defined as “the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the *retail pharmacy class of trade*” (emphasis supplied).¹⁹ The Proposed Rule defines retail pharmacy class of trade as “any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.”²⁰ CMS explained in the preamble to the Proposed Rule that “the retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services.”²¹ BIO welcomes the significant contribution that this definition and preamble guidance will have in standardizing the AMP calculation, but also requests that CMS clarify the status of certain additional entity types in the Final Rule, discussed below.

1. CMS Should Clarify the Retail or Non-Retail Status of Certain Entities.

The Proposed Rule and preamble specify the retail or non-retail status of a number of different entity types, including pharmacy benefit managers (PBMs), long-term care pharmacies, and mail order pharmacies. BIO appreciates this level of clarity and believes that it will aid in the effective and uniform implementation of the revised retail pharmacy class of trade definition. While BIO recognizes the impracticality of attempting to address every entity type in the Final Rule, the absence of a specific classification for a number of entity types, including but not limited to the physician class of trade, home health care providers (specialty pharmacies that provide for the home delivery and administration of product by health care professionals), prisons, and hospices is conspicuous. These entity types represent a significant portion of our members’ direct and indirect sales transactions, particularly in the case of physician sales, and merit individualized attention for that reason. BIO asks CMS to, at a minimum, clarify the retail or non-retail status of each of these entities in the Final Rule.

2. CMS Should Clarify the Treatment Of Contract Pharmacies That Serve Long Term Care Facilities.

The Proposed Rule clarifies that sales to nursing home pharmacies and long term care pharmacies are to be excluded from the calculation of AMP.²² CMS explained that under its proposed definition of the retail pharmacy class of trade, which requires that the entity dispense product to the general public, such pharmacies would not qualify as retail

¹⁸ See 71 Fed. Reg. at 77,175; Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(3).

¹⁹ 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

²⁰ Id. (proposed 42 C.F.R. pt. 447.504(e)).

²¹ Id. at 77,178.

²² Id. at 77,178, 77,196 (proposed 42 C.F.R. § 447.504(h)(6)).

because they dispense to facility residents only. As CMS may know, many nursing home and long term care facilities do not maintain their own pharmacies, but rather contract with an outside pharmacy, often one that specializes in long term care facilities, to supply their residents with medications. The Proposed Rule does not specifically address the treatment of contract pharmacies that dispense product to nursing home and long term care facility residents, and BIO therefore requests that CMS clarify whether manufacturer sales to such contract pharmacies also should be treated as non-retail and excluded from the calculation of AMP.

3. CMS Should Clarify That Manufacturers May Treat Drugs Sold to Hospitals as Sales for Inpatient Use When Manufacturers Cannot Distinguish Between Units Purchased for the Inpatient Versus Outpatient Setting.

The Medicaid rebate agreement and Manufacturer Release 29 both direct that all sales to hospitals are to be excluded from the AMP calculation, without regard to whether the product sold was used in the inpatient or outpatient setting.²³ The Proposed Rule now distinguishes between those settings. CMS *includes* in AMP sales to hospitals “where the drug is used in the outpatient pharmacy,” while continuing to exclude sales to hospitals for inpatient use.²⁴ This distinction presumes that manufacturers can identify the setting in which the product that a hospital purchases is used. That typically is not the case. Manufacturers know only that a hospital has made a purchase, not the setting in which the product will be used. For this reason, BIO requests CMS to clarify that manufacturers may continue to exclude hospital sales from AMP when manufacturers cannot distinguish between units purchased for inpatient use and units purchased for use in the outpatient setting.

4. CMS Should Revise the Proposed Rule to Exclude State, County, and Municipal Entities from the Retail Pharmacy Class of Trade.

The Proposed Rule is silent regarding the retail status of state, county, and municipal-run entities. BIO believes that these entities, which include hospitals and mental health clinics, should be excluded from the retail pharmacy class of trade. As noted above, the retail pharmacy class of trade includes only those entities that sell or provide drugs “to the general public.”²⁵ Entities that are funded or run by states, counties, or municipalities provide or sell drugs to specific classes of persons who are eligible or qualify for their services; these entities do not provide or sell drugs to the general public. For this reason, BIO urges CMS to clarify that state, county, and municipal entities are excluded from the retail pharmacy class of trade.

²³ 56 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(a)); Medicaid Drug Rebate Program Release #29 for Participating Drug Manufacturers (1997).

²⁴ *Id.* at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(3), (h)(4)).

²⁵ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

5. CMS Should Clarify That All Rebates, Discounts, and Other Price Concessions Provided to a PBM Should Be Included in AMP.

The Proposed Rule clearly states that “[d]iscounts, rebates, or other price concession to PBMs associated with sales for drugs provided to the retail pharmacy class of trade” are included in AMP.²⁶ This provision is consistent with CMS’ conclusion that excluding such price concessions from AMP “could result in an artificial inflation of AMP.”²⁷ In the preamble however, there is language that could be read to limit the price concessions paid to PBMs that are to be included in AMP to those “that affect the net price recognized by the manufacturer” for drugs provided to the entities in the retail pharmacy class of trade, i.e. those price concessions passed on to retail pharmacies.²⁸ CMS itself noted in the preamble that manufacturers typically do not know what price concessions paid to PBMs are passed on to the PBM’s network pharmacies or member plans, and so BIO does not believe CMS intended to limit the requirement in this way.²⁹ BIO does not disagree with a requirement to include all PBM price concessions in AMP but asks CMS to clarify that this requirement applies to all such price concessions without regard to whether a PBM passes on any portion of those amounts to any other entity.

6. CMS Should Revise the Proposed Rule To Include Sales and Discounts to HMOs that Do Not Purchase or Take Possession of Product in the AMP Calculation.

The Medicaid rebate agreement explicitly excludes sales to health maintenance organizations (HMOs) from the AMP calculation,³⁰ and the Proposed Rule seeks to adopt this exclusion as well.³¹ The exclusion contained in the Proposed Rule does not distinguish between HMOs that purchase drugs and distribute them to members through the HMO’s own closed-door pharmacies, and HMOs that do not purchase drugs but rather act as third-party payors that reimburse retail pharmacies for drugs dispensed to members.³² The former type of HMO does not provide or sell drugs to the general public, only its own enrollees, and is appropriately excluded from the AMP calculation as non-retail. Sales to HMOs that are not purchasers, on the other hand, are more analogous to Medicaid sales, Medicare Part D sales, and sales to State pharmaceutical assistance programs (SPAPs). The preamble to the Proposed Rule explains that these entities are included in AMP because their sales “are determined by entities that are actually in the

²⁶ Id. (proposed 42 C.F.R. pt. 447.504(g)(3)).

²⁷ Id. at 77,179.

²⁸ Id.

²⁹ See Id.

³⁰ 56 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(a)).

³¹ 71 Fed. Reg. at 77,179.

³² See 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(5)).

sales chain” and “should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade.”³³

CMS’ analysis is equally applicable to HMOs that do not purchase and take possession of drugs, but rather act as reimbursers to pharmacies that do. Inclusion of non-purchaser HMOs in AMP is consistent with CMS’ guidance regarding other reimbursing entities and also avoids the anomalous result of excluding non-purchaser HMO transactions from AMP where the HMO contracts directly with a manufacturer for discounts, but including such transactions in AMP where the HMO chooses to contract with a PBM to do so. BIO urges CMS to revise the Proposed Rule to specifically include in the AMP calculation sales and discounts to HMOs that do not purchase or take possession of product.

7. CMS Should Clarify That the Prices Negotiated By a Qualified Retiree Prescription Drug Plan for Its Retirees As Well As for the Retiree’s Dependents Are Excluded from Best Price.

CMS proposes to exclude from Best Price the price for covered Medicare Part D drugs negotiated by a qualified retiree prescription drug plan “on behalf of individuals entitled to benefits.”³⁴ This provision is also described by CMS in the preamble where the agency states that payments made by a qualified retiree prescription drug plan on behalf of “eligible individuals” are excluded from Best Price.³⁵ BIO supports this exclusion but notes that it does not address the treatment of prices on retiree dependent utilization. Manufacturer rebate contracts for qualified retiree plan utilization typically do not distinguish between the utilization of the retiree and his/her dependents, because the utilization data supplied by the plans does not distinguish between the two populations. The two groups are treated as a single population because they are both covered by the same benefit. BIO requests that CMS address this issue in the Final Rule.

8. CMS Should Revise the Proposed Rule to Exclude All Patient Transactions from the AMP and Best Price Calculations.

One of BIO’s central principles is ensuring patient access to biologic therapies. Our members employ a number of different mechanisms to make certain that patients maintain their access to needed therapies, including sales directly to patients, patient coupons, and patient assistance programs. The Proposed Rule for the first time addresses the treatment of such patient transactions in the AMP and Best Price calculations, and in the case of patient assistance programs, explicitly excludes them from the calculations.³⁶ BIO strongly supports the exclusion of patient assistance programs from these calculations, as these programs provide a crucial safety net for those patients lacking insurance coverage and without sufficient income to acquire needed medications.

³³ Id. at 77,180.

³⁴ Id. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(5)).

³⁵ Id. at 77,182.

³⁶ Id. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(9)).

The Proposed Rule also addresses direct patient sales and coupon programs but directs their inclusion in AMP and Best Price,³⁷ with one limited exception for patient coupons.³⁸ BIO is concerned that the Proposed Rule will have the unintended effect of endangering these critical programs. BIO does not interpret the Medicaid rebate statute to support the inclusion of these patient transactions in either calculation and also disagrees with CMS' stated rationale for doing so. BIO asks CMS to exclude these transactions from AMP and Best Price in the Final Rule.

A. Patient Sales. The Proposed Rule directs the inclusion of manufacturer direct sales to patients in the calculations of AMP and Best Price.³⁹ In the case of AMP, the Proposed Rule does so despite its explicit acknowledgment that such transactions do not involve a sale transaction to a retail entity, but rather a service arrangement with a distributor to provide storage, delivery, and billing services for product that the distributor ships to patients on the manufacturer's behalf.⁴⁰ CMS asserts that such distributors are acting as "wholesalers" and the sales are to the retail pharmacy class of trade.⁴¹

BIO believes that direct patient sales should be excluded from AMP and Best Price because, in the case of AMP, patients are not part of the retail pharmacy class of trade, and, in the case of Best Price, patients are not one of the entity types included in the statutory definition of Best Price.⁴² Only an entity that purchases drugs and "subsequently sells or provides the drugs to the general public" is retail under the Proposed Rule.⁴³ Patients, even as direct purchasers of drugs, obtain drugs for their personal medical use; they do not sell or provide drugs to the general public. Nor does the service arrangement with the distributor transform this arrangement into a retail sale, as the distributor never purchases the product at issue. CMS has not provided a basis for its conclusion that patients are retail and BIO can find no support for this position in the text of the rebate statute, rebate agreement, or Proposed Rule. As noted above, BIO also does not believe that patient sales are within the scope of the statutory definition of Best Price. BIO strongly urges CMS to revise its proposal regarding direct patient sales and exclude them from both calculations.

B. Patient Coupons. CMS also proposes to include in the AMP and Best Price calculations patient coupons redeemed by an entity other than the consumer.⁴⁴ BIO asserts that because patients are not part of the retail pharmacy class of trade, price

³⁷ *Id.* at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(11), .505(c)(12)).

³⁸ *Id.* at 77,197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

³⁹ *Id.* at 77,180-81, 77,197 (proposed 42 C.F.R. pt. 447.504(g)(7)).

⁴⁰ *Id.* at 77,180-81.

⁴¹ *Id.*

⁴² SSA § 1927(c)(1)(C)(i) ("The term 'best price' means . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States.").

⁴³ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

⁴⁴ *Id.* at 77,181, 77,183.

concessions available to them should not be included in AMP or Best Price. To the extent that CMS is concerned that patient coupons redeemed by an entity other than the consumer affect the price realized by the entity that redeems the coupon to the manufacturer on the patient's behalf, BIO would like to take this opportunity to explain why that is not the case and to ask CMS to revise the Proposed Rule to exclude all patient coupon transactions from the AMP and Best Price calculations.

Manufacturers have a number of different types of patient coupon programs but they fall into three general categories. The first type is a mail-in rebate coupon. These coupons typically are submitted by the consumer directly to the manufacturer, along with proof of purchase, for a rebate. This type of coupon would be excluded from AMP and Best Price under the Proposed Rule because consumers redeem mail-in rebates directly to the manufacturer.⁴⁵ BIO asks CMS to clarify, however, that such coupons are excluded even when redeemed through a third-party vendor that does not purchase product but administers the coupon program on the manufacturer's behalf. The involvement of a non-purchasing third-party to administer the program creates no impact on price for any entity that does purchase product, and therefore should not prevent the exclusion of these types of programs from the calculations.

A second type of patient coupon is a copayment assistance or dollars-off coupon. These coupons are presented by consumers at the point-of-sale, entitling them to some amount off of their copayment or co-insurance obligation. If the consumer has no insurance, these coupons act to reduce the consumer's overall cost for the prescription. A retail pharmacy that honors such a coupon provides the coupon's discount directly to the consumer at the time of sale, and then submits the coupon to the manufacturer (or a third-party vendor) for reimbursement. The manufacturer then reimburses the redeeming pharmacy for its out-of-pocket expense, i.e, the face value of the coupon, and also a fair market value processing fee. This reimbursement does not affect the price realized by the pharmacy for the drug that was the subject of the coupon because the manufacturer only reimburses the pharmacy for its actual expenses. For these reasons, BIO asks CMS to clarify that copayment and dollars-off coupons are excluded from AMP and Best Price.

The final coupon type is a free goods coupon. These coupons offer a patient a certain number of units of a drug at no cost, and have grown in importance as a means of providing patients with a period of free "trial" or "sample" product where their prescriber is either unable or unwilling to store PDMA-compliant sample product from the manufacturer. A retail pharmacy accepting a free goods coupon will provide the drug at no cost to the patient and, as with co-pay assistance coupons, seek reimbursement from the manufacturer. A manufacturer may reimburse the redeeming pharmacy in one of two ways. First, the manufacturer may reimburse the pharmacy with replacement product and a fair market value dispensing fee. When the manufacturer reimburses the pharmacy in kind, there is no affect on the price realized by the pharmacy on the drug at issue because the pharmacy receives exactly that which it dispensed for free, and the transaction should be excluded from AMP and Best Price. A manufacturer instead may choose to reimburse

⁴⁵ See id. at 77,197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

a pharmacy for the cost of the drug it dispensed, again with a fair market value dispensing fee. Manufacturers typically cannot determine a pharmacy's actual acquisition costs and so employ a formula to estimate that amount. Where the manufacturer uses such a formula, meant to approximate the pharmacy's acquisition price and therefore make the pharmacy whole, the transaction between the manufacturer and the pharmacy is revenue neutral and there is no effect on the price realized by pharmacy. CMS should clarify that such transactions are, therefore, excluded from AMP and Best Price.

The manner in which CMS handles patient transactions is crucially important. Manufacturers are able to provide significant benefits to patients through their patient sales and patient coupon programs. Without clear guidance from CMS on how these transactions are to be treated for AMP and Best Price purposes, such valuable programs are at risk of being curtailed. BIO therefore strongly encourages CMS to categorically exempt all patient transactions from the AMP and Best Price calculations to ensure their continued availability.

III. CMS Should Provide Additional Guidance Regarding the Treatment of Particular Transactions for AMP and Best Price Purposes.

CMS has taken the opportunity in the Proposed Rule to address the treatment of certain transaction types in the calculations of AMP and Best Price. BIO appreciates CMS' attention to these issues in the Proposed Rule and comments below regarding the proposed treatment of administrative and service fees, bundled sales, customary prompt payment discounts, nominal sales, and returned goods.

1. CMS Should Clarify that Administrative and Service Fees Paid to GPOs Are Excluded From AMP and Best Price.

The Proposed Rule revises CMS existing position regarding the treatment of administrative and service fees in the calculations of AMP and Best Price. CMS' long-standing position has been that such fees are included in the calculations to the extent they affect the price realized by an entity that is eligible for the calculations.⁴⁶ The Proposed Rule would require the inclusion of all fees that do not satisfy the definition of a bona fide service fee, even if the entity receiving the fee does not take title to product.⁴⁷

The preamble to the 2007 Physician Fee Schedule Final Rule included extensive substantive discussions of the bona fide service fee definition adopted in that Final Rule, and which CMS now proposes to adopt for purposes of the AMP and Best Price calculations as well. Should CMS proceed to include this definition in the Final Rule, BIO urges CMS to confirm that manufacturers may rely on that preamble discussion to interpret the definition for purposes of the AMP and Best Price definition. This

⁴⁶ Medicaid Drug Rebate Program Release #14 for Participating Drug Manufacturers (1994).

⁴⁷ Id. at 77,195, 77,197-98 (proposed 42 C.F.R. pt. 447.502, .504(i), .505(e)(1)).

clarification would ensure uniform application of the definition across calculations and facilitate manufacturer compliance with this new term.

In that preamble, CMS specifically declined to provide guidance with respect to the application of this definition to group purchasing organizations (GPOs), and instead directed manufacturers to continue to make documented, reasonable assumptions regarding their treatment of such fees.⁴⁸ BIO urges CMS to now address this issue definitively and specify that fees paid to GPOs are excluded from AMP and Best Price.

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. As GPOs are not purchasers, any fees paid by a manufacturer to a GPO should not be considered a price concession that is eligible for the AMP calculation.

The Office of Inspector General has studied GPOs and their relationships with their members and found that there are situations in which a GPO may share some portion of the fee paid by a manufacturer with its members, who are purchasers.⁴⁹ Manufacturers have no control over these arrangements and typically are unaware of the contractual terms between the GPO and its members.⁵⁰ Accordingly, even when the GPO shares some portion of a manufacturer fee with its members, those fees should not be considered discounts provided by the manufacturer to a purchaser.

A requirement to treat GPO administrative fees as a discount in either of the above situations also would face a significant practical hurdle. Specifically, manufacturers would have no basis for determining the amount of the fee that is shared with the member purchasers or to which product the fee should be attributed as a price concession. Without this information, manufacturers have no basis for including these fees in the AMP calculation.

BIO understands that the Health Industry Group Purchasing Association submitted comments (dated January 2, 2007) to CMS regarding their discussion of GPO fees in the preamble to the 2007 Physician Fee Schedule Final Rule. Section I of that letter is consistent and supportive of the positions articulated above and requests that

⁴⁸ Id. at 69,669.

⁴⁹ The Office of Inspector General (OIG) found in an audit conducted of three large GPOs that the GPOs retained a significant amount of the administrative fees and that their practices regarding passing on administrative fees to members differed. See Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

⁵⁰ BIO recognizes, however, that where the contract between the manufacturer and the GPO directs the GPO to pass on service fees to the GPO's members, the manufacturer indirectly would be paying

fees to a purchaser, and, therefore, the bona fide service fee standard should be applied to the portion of the fee passed on to the members.

CMS create a calculation safe harbor for GPO fees. The proposed safe harbor, as modified to apply under the Proposed AMP Rule, would be included in the definition of bona fide service fee and read:

For purposes of 42.C.F.R. § 447.504(i) and 447.505(e), fees paid by a manufacturer to a bona fide group purchasing organization, as defined at 42 C.F.R. § 1001.952(j)(2), will not constitute a price concession by the manufacturer unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization.

BIO strongly supports the creation of such a safe harbor and urges CMS to include such a provision in the Final Rule.

2. CMS Should Refrain From Finalizing the Revised Definition of Bundled Sale At This Time.

The Medicaid rebate agreement currently 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.”⁵¹ The Proposed Rule now includes a new, revised definition of this term: “an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types . . . or some other performance requirement . . . or [] where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.”⁵²

This proposed definition of bundled sale represents a significant change from the definition provided in the Medicaid rebate agreement. CMS does not provide any explanation in the Proposed Rule for why it proposes to change the definition in this way or 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, or the methodology to be used to reallocate discounts included in bundled sales. The Proposed Rule does not even reference this term in the regulatory provisions governing the calculation of AMP and Best Price. BIO is unable to provide any meaningful comments on this new definition in the absence of such content and therefore requests that CMS refrain from finalizing the revised definition of bundled sale at this time. Should CMS wish to pursue this new definition, BIO requests that CMS provide additional information regarding the new

⁵¹ 71 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(e)).

⁵² 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. pt. 447.502).

definition and provide another opportunity for comment before the definition is finalized. In the interim, BIO strongly urges CMS to clarify that manufacturers may continue to rely on the definition of bundled sale included in the rebate agreement.

3. CMS Should Clarify That Manufacturers May Make Reasonable Assumptions in Applying the Proposed Definition of Customary Prompt Pay Discounts.

Section 6001(c) of the DRA amends the Medicaid rebate statute to exclude from the AMP calculation customary prompt pay discounts extended to wholesalers.⁵³ This language is included in the definition of AMP in the Proposed Rule and BIO supports its inclusion.⁵⁴ CMS has proposed to define customary prompt pay discounts as “any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time.”⁵⁵ BIO supports this definition but urges CMS to confirm that manufacturers may make reasonable assumptions in applying this definition to their AMP calculations and in their reporting of such discounts each quarter.

4. CMS Should Issue Any Further Guidance on Nominal Sales Through Notice-and-Comment Rulemaking and Clarify That Until Such Guidance Is Issued Manufacturers May Exclude Any Nominal Sales that Meet the DRA Definition From the Best Price Calculation.

The Medicaid rebate statute excludes from the Best Price calculation prices that are merely nominal in amount.⁵⁶ The Medicaid rebate agreement defines nominal as any price that is less than 10% of the AMP for the product in the same quarter for which Best Price is being calculated.⁵⁷ Section 6001(d)(2) of the DRA amended the Medicaid rebate statute to clarify that nominal prices are excluded from Best Price only when offered to a list of specifically identified “safety net” providers.⁵⁸ The DRA also authorized the Secretary to identify additional categories of safety-net providers that could be excluded from Best Price should they receive a nominal price.⁵⁹ CMS indicated in the preamble to the Proposed Rule that it was declining to exercise this authority at this time.⁶⁰

CMS also included in the preamble additional commentary regarding the nominal price exception. Specifically, CMS stated its concern that “the nominal price exclusion will continue to be used as a marketing tool” and indicated that it is considering issuing

⁵³ Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c).

⁵⁴ Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

⁵⁵ Id. (proposed 42 C.F.R. pt. 447.504(c)).

⁵⁶ SSA § 1927(c)(1)(C)(ii)(III).

⁵⁷ 56 Fed. Reg. at 7051 (Medicaid Rebate Agreement at I(d), (s)).

⁵⁸ Deficit Reduction Act of 2005, Pub. Law No. 109-171, §6001(d)(2).

⁵⁹ Id.

⁶⁰ 71 Fed. Reg. at 77,184-85.

additional guidance on this topic.⁶¹ BIO asks CMS to issue any further guidance on the use of nominal prices as a marketing tool through formal notice-and-comment rulemaking. BIO also asks CMS to clarify that until such guidance is issued, and in accordance with the DRA language itself, manufacturers may exclude from Best Price nominal price sales to entities listed in the DRA definition without regard to the manufacturer's intent in providing such prices.

5. BIO Supports Excluding Returns Made in Good Faith from the AMP Calculation.

CMS guidance currently requires manufacturers to include in AMP returned goods credited to the manufacturer.⁶² As CMS recognized in the preamble to the Proposed Rule, this position has generated problems for manufacturers by substantially reducing AMP or resulting in a negative AMP for the quarter in which the return is credited.⁶³ BIO supports CMS decision to exclude returns made in good faith from AMP⁶⁴ and urges the agency to retain this provision in the Final Rule. BIO also requests that CMS clarify that returns transactions also have no impact on the determination of Best Price.

IV. CMS Should Provide Additional Guidance Regarding the Various Requirements for Manufacturers in the Proposed Rule.

The Proposed Rule also addresses a number of “requirements for manufacturers.” BIO supports CMS’ decision to allow manufacturers to recalculate base date AMP and asks the agency to clarify that the recalculation should take into account the exclusion of customary prompt pay discounts from the AMP calculation. BIO also requests that CMS revise the new manufacturer price reporting form registration process, so that manufacturer personnel need not supply their Social Security Numbers in order to obtain access to that reporting route. CMS proposes to adopt the Medicare ASP certification requirement and language for Medicaid submissions, but BIO notes that the standards for imposing liability differs under the two programs and asks CMS to ensure that the certification requirement takes this into account.

1. BIO Supports CMS’ Decision To Allow Manufacturers to Recalculate Base Date AMP and Asks CMS To Clarify That the Recalculation Should Take the Exclusion of Customary Prompt Pay Discounts into Consideration.

Section 1927(c)(2) of the Social Security Act requires manufacturers of single source and innovator multiple source drugs to pay an “additional rebate” when the AMP for a specific reporting period exceeds by a certain percentage the AMP calculated in the

⁶¹ Id. at 77,185.

⁶² Id. at 77,181.

⁶³ Id.

⁶⁴ Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).

product's base date quarter. To ensure that manufacturer liability for additional rebates does not increase due to changes in the definition of AMP, CMS has included a provision in the Proposed Rule giving manufacturers the option to recalculate their base date AMPs.⁶⁵ BIO supports this provision and asks CMS to include it in the Final Rule.

BIO also recommends that CMS apply the recalculated base date AMPs retroactively to the first quarter of 2007 for the calculation of rebates. CMS itself recognized the inherent inequity created by the change in the AMP definition and in the preamble on the recalculation issue stated, "We propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP."⁶⁶ Further on, CMS states, "However, we decided that retaining the current base date AMP is unwarranted because it would create a financial burden on manufacturers that was not intended by Section 6001 of the DRA".⁶⁷ The only way to alleviate that additional financial burden is to apply the recalculated base date AMP retroactively to the first quarter of 2007 when the provisions of the DRA that changed the AMP definition first were effective. BIO understands that this may create additional workload due to restating prior periods, however we believe this is a necessary step to achieve the appropriate outcome.

The text of the recalculation provision states that the recalculation of base date AMP "must only reflect the revisions to AMP as provided for in § 447.504(e)."⁶⁸ That provision includes the new definition for the retail pharmacy class of trade, but does not address the new requirement to exclude customary prompt payment discounts from the AMP calculation.⁶⁹ We believe this was an oversight, as CMS stated in the preamble to the Proposed Rule that it was allowing recalculation to "reflect the changes to AMP as set forth in the DRA."⁷⁰ The DRA specifically changes the AMP calculation by excluding customary prompt pay discounts.⁷¹ BIO requests CMS to clarify that the recalculation of base data AMP should reflect not only the changes to the definition of the retail pharmacy class of trade, but also the exclusion of customary prompt pay discounts from the AMP calculation.

Finally, BIO asks CMS to confirm that manufacturers retain complete discretion regarding the decision to recalculate base date AMP figures, and may make that decision on a product-by-product basis. CMS itself recognized that manufacturers will need to evaluate the availability of data needed to perform any recalculation and weigh the administrative costs of doing so against the savings to be gained.⁷² Data availability and the related cost analysis of performing recalculations necessarily will vary by product,

⁶⁵ Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(c)).

⁶⁶ Id. at 77,185.

⁶⁷ Id. at 77,194.

⁶⁸ Id.

⁶⁹ Id. at 77,196.

⁷⁰ Id. at 77,185.

⁷¹ Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(1).

⁷² 71 Fed. Reg. at 77,185.

and therefore manufacturers should be able to perform that analysis for each of their products individually. CMS' discussion of this issue in the preamble suggests that is CMS' intent, and BIO asks CMS to confirm the acceptability of this approach.

2. BIO Asks CMS to Allow Manufacturers to Submit Reports Using a Randomly Generated Identification Number Rather than an Individual's Social Security Number.

CMS has issued a new data reporting format and system for manufacturer submissions of rebate data – the Drug Data Reporting or DDR system. The instruction form for the application for access to this new reporting system requires that the manufacturer employee who will be accessing the system provide CMS with his/her social security number. This information is highly sensitive personal information and BIO requests that CMS remove this requirement from the application. The application requires the provision of other, less sensitive, personal information that still will enable CMS to identify the manufacturer personnel with access to the reporting system such that a social security number should not be necessary. BIO urges CMS to remove this requirement as soon as possible.

3. 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 Proposed Rule seeks to adopt for both monthly and quarterly manufacturer submissions the same certification that manufacturers currently must submit with their quarterly ASP figures.⁷³ BIO believes that the ASP certification language must be revised if used in relation to AMP and Best Price data because the civil monetary penalty standard applicable to the reporting of AMP and Best Price contains an explicit “knowing” requirement.

The civil money penalty provision of the Medicaid statute provides that manufacturers are subject to penalty only for “knowingly” providing false information to CMS.⁷⁴ BIO therefore believes that this knowledge requirement must modify all representations included in any certification. The full text of the ASP certification reads as follows: “I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.”⁷⁵ This certification does not clearly qualify the certification of “calculated accurately” with the “to the best of my knowledge and belief” language. As the Medicaid civil monetary penalty provision applies only to the knowing submission of false information, BIO believes any representation that the AMP and Best Price figures were

⁷³ Id. at 77,198.

⁷⁴ SSA § 1927(b)(3)(C).

⁷⁵ 69 Fed. Reg. 17,935, 17941 (April 6, 2004).

"calculated accurately" also should be explicitly qualified by the "to the best of my knowledge and belief" language. To accomplish this, BIO urges CMS to revise the certification to read:

To the best of my knowledge and belief, the reported Average Manufacturer and Best Prices were calculated accurately and all information and statements made in this submission are true, complete, and current. I understand that information contained in this submission may be used for Medicaid reimbursement purposes.

V. CMS Should Safeguard Immunosuppressives in the Federal Upper Limit Methodology.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the AMP for the least costly drug in each multiple-source group.⁷⁶ In implementing this provision, CMS has proposed to use its rulemaking authority to establish safeguards to ensure that the FUL is set at a price that is “adequate . . . to ensure that a drug is available for sale nationally as presently provided in our regulations.”⁷⁷ Specifically, CMS has proposed not to include in a FUL calculation: (1) the AMP of an NDC that has been terminated; or (2) an AMP that is less than 30 percent of the next highest AMP in the relevant multiple source drug group.⁷⁸

BIO urges CMS to adopt an additional safeguard in the FUL methodology to ensure that Medicaid beneficiaries have access to anti-rejection immunosuppressives. Immunosuppressives must be taken by transplant patients to prevent organ rejection; therefore, access to these medications is critical. Missing even a few days of an anti-rejection immunosuppressive regimen can cause graft failure, resulting in loss of the organ and catastrophic consequences for the patient.

The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards under Part D for these therapies and five other drug classes of “clinical concern.”⁷⁹ CMS has stated that this safeguard is “necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”⁸⁰ This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government

⁷⁶ SSA § 1927(e)(5).

⁷⁷ 71 Fed. Reg. at 77,187.

⁷⁸ *Id.* at 77,188. CMS proposed that the 30% outlier policy not apply when calculating the FUL for a multiple-source group that includes only the innovator and the first generic to enter the market.

⁷⁹ The other classes protected by this Part D safeguard are antidepressants, antipsychotics, anticonvulsants, HIV/AIDS drugs, and antineoplastics.

⁸⁰ Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formulary*, at 7.

Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.⁸¹

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives and other critical medications. We recommend that CMS base the FUL for immunosuppressive multiple-source drug groups on the lowest AMP that is not less than 70% of the next-highest AMP in the multiple-source drug group. In addition, we urge CMS to apply this safeguard to all FULs containing these critical medications, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor. Such a safeguard would ensure that implementing the new FUL methodology does not harm Medicaid beneficiaries' access to critical medications at the pharmacy level.

VI. CMS Should Address a Number of Additional Issues in the Final Rule That Are Crucial to the Operation of the Medicaid Drug Rebate Program.

BIO believes that there are additional issues related to the program that CMS should address in the Final Rule. These include the proportionality of rebate payments when Medicaid is a secondary payor, the period of manufacturer liability for rebate claims, the affect of the changes in AMP on Medicare reimbursement rates, the provision of additional payments for blood clotting factors, and the form of future guidance regarding the AMP and Best Price calculations.

1. CMS Should Limit Manufacturer Rebate Liability to the Proportion of a Claim Actually Paid by Medicaid.

Although not addressed by CMS in the Proposed Rule, BIO believes that the issue of proportionality for manufacturer rebate liability when Medicaid is a secondary payor is of crucial importance to the Medicaid Drug Rebate Program. Through various program releases over the years, CMS has articulated its position that “if a state Medicaid agency pays any portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug.”⁸² BIO believes this position is inconsistent with the Medicaid rebate statutory language and legislative intent and also procedurally defective as it has never been subject to notice-and-comment rulemaking.

BIO understands it is CMS' position that the statute requires payment of the full rebate amount in all circumstances because of the statute's direction that the manufacturer pay the rebate amount defined in “subsection (c) of this section” for each unit of a drug for which payment was made under a State plan, and subsection (c) provides only for the full rebate amount.⁸³ This mandate, however, must also be read in

⁸¹ GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

⁸² Medicaid Drug Rebate Program Release #54 for Participating Drug Manufacturers (May 7, 2002).

⁸³ Social Security Act § 1927(b)(1)(A).

conjunction with the statute's other requirement in the immediately following paragraph – that the rebate be considered “a reduction in the amount expended” – which clearly presumes the rebate amount will not and should not exceed the State's payment amount.⁸⁴ These authorities together lead to the single conclusion that Congress did not intend or provide for the payment of rebates that exceed a State's expense and CMS should implement the statute accordingly.

CMS' position also is inconsistent with the purpose of the Medicaid rebate statute. The legislative history repeatedly demonstrate that Congress enacted the statute to enable States to access the same discounts for covered drugs that manufacturers were offering other purchasers.⁸⁵ At the time of enactment Medicaid was paying *more* than other purchasers for the same drugs.⁸⁶ The Medicaid rebate program was thus enacted to ensure that Medicaid paid the *same* prices as the other purchasers.⁸⁷ When States are able to obtain full rebates for the drug utilization that they submit, regardless of their actual expenditures, they are not getting the same discounts as other providers; they are getting an unjustified windfall.

Senator Grassley, former Chairman of the Senate Finance Committee has confirmed that Congress intended Medicaid rebates to be proportional to Medicaid expenditures, in a letter sent to former CMS Administrator Mark McClellan.⁸⁸ In that letter, Senator Grassley clarified that “[f]ederal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program.”⁸⁹ He explained that the DRA language amended the Medicaid rebate statute so to provide that States must seek rebates “for drugs administered *for which payment is made under this title*,” with this language clarifying that “the Medicaid rebate is only available for the Medicaid portion of the payment.”⁹⁰ BIO strongly urges CMS to adopt guidance implementing this statutory language as Senator Grassley suggested.

BIO also believes that CMS' current position is procedurally invalid. Under the Administrative Procedures Act (APA), only rules promulgated through formal notice-and-comment rulemaking can be binding.⁹¹ CMS has indicated that it intends its

⁸⁴ *Id.* at § 1927(b)(1)(B).

⁸⁵ See 136 Cong. Rec. S12954-01 (1990), as reprinted in 1990 U.S.C.A.N.N. 2017, 2108.

⁸⁶ See H-Rep. 101-88, at 96 (1990).

⁸⁷ In fact, Senator Pryor, one of the sponsors of the Medicaid rebate statute opposed the drug manufacturers' proposed plan that would have provided a \$1.36 rebate for each Medicaid prescription. As Senator Pryor explained, a 1000-pill bottle of a drug could be purchased for \$3.00. If that bottle was used to fill 10 prescriptions of 100 pills each, the State could claim a rebate of \$13.60, realizing a gain of \$10.60. Senator Pryor, rightly, found it grossly unfair that manufacturers could be forced to pay \$4.00 for every \$1.00 of sales. 136 Cong. Rec. S12954-01, S12960.

⁸⁸ Letter from Chairman Charles E. Grassley to Administrator Mark B. McClellan (Aug. 14, 2006).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ 5 U.S.C. § 533(c); *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979). To the extent that CMS would argue that the rule is merely an interpretative rule not subject to notice-and-comment rulemaking, it would not have the power to bind. *Heckler v. Ringler*, 466 U.S. 602 (1984).

interpretation with regard to proportionality to be binding on drug manufacturers.⁹² However, CMS has never issued this guidance pursuant to APA's formal rulemaking procedures. CMS' interpretation is thus invalid because it purports to bind manufacturers but has never been subject to notice-and-comment rulemaking.

Even if the provision were valid, it would not be entitled to a court's deference.⁹³ Only guidance issued through formal notice-and-comment rulemaking is accorded deference,⁹⁴ and that is not the case here. Although informal guidance may be given "respect" if it is persuasive,⁹⁵ BIO asserts that CMS' position is not persuasive because it contravenes the statutory text and, rather than ensuring that Medicaid receives the best price available for a drug, creates a windfall for the States and an unjustified financial burden on manufacturers.

The capability to calculate pro-rated rebates exists. The State invoice form, Form R-144, has a column for States to report the amount reimbursed by Medicaid and a column for States to report the amount reimbursed by another payor. With this information, manufacturers can calculate the ratio of Medicaid's payment to the total amount reimbursed and apply that ratio to the full rebate amount to determine what portion of the rebate should be paid to the State. Pro-ration is not only feasible, but, in BIO's estimation, required. BIO strongly encourages CMS to take the opportunity to revise its position in the Final Rule.

2. CMS Should Implement the Statutory Time Limit on State Submission of Rebate Claims.

The Medicaid rebate statute requires States to submit drug utilization data to manufacturers "not later than 60 days after the end of each rebate period."⁹⁶ This statutory language is explicit and without exception. CMS nevertheless has stated previously that it does not believe that this statutory provision relieves manufacturers of liability for rebate claims submitted beyond the 60 day limit.⁹⁷ CMS has never provided any rationale for this interpretation or explained how it can be reconciled with the statute's explicit direction to the contrary. BIO urges CMS to implement this statutory requirement immediately through the Final Rule.

CMS previously has recognized a need to impose a time limit on State rebate claims.⁹⁸ At the same time that CMS stated this prior position, in the 1995 proposed rule, CMS proposed to establish a "maximum time limit of 1 year from the end of a rebate

⁹² See Medicaid Rebate Program Release #27 for Participating Drug Manufacturers (1997) ("[W]e believe it is inappropriate for manufacturers to routinely, quarter after quarter, dispute rebates" when Medicaid is a secondary payor.)

⁹³ See *United States v. Mead Corp.*, 533 U.S. 218 (2001).

⁹⁴ *Id.*

⁹⁵ *Christen v. Harris County*, 529 U.S. 576, 587 (2000).

⁹⁶ SSA § 1927(b)(2)(A).

⁹⁷ 60 Fed. Reg. at 48,460.

⁹⁸ *Id.*

period for States to bill a manufacturer for a rebate.”⁹⁹ CMS never finalized this requirement, and BIO urges CMS to implement a limitation on the period of manufacturer liability, as mandated by statute, as soon as possible.

CMS’ previous consideration of this issue evaluated a number of important factors and determined that a one-year statute of limitations was a reasonable limit on State claims.¹⁰⁰ CMS found that a one-year time limit is consistent with the timeframe for pharmacies to bill States and for States to reimburse pharmacies. CMS also determined that a one-year limit accounts for circumstances that might prevent States from being able to generate Medicaid utilization data within 60 days while at the same time allowing manufacturers to close their books within a reasonable amount of time. BIO believes that the Medicaid rebate statute requires CMS to implement a limitations period, and urges CMS to do so immediately. As the 60 day time limit has always existed in statute, CMS should implement this time limit effective with the Final Rule and as of that date prohibit States from submitting rebate claims for periods that precede the specified time limit.

3. CMS Should Take the Change to AMP into Consideration When Setting the ASP Threshold Percentage.

The changes to AMP provided in the DRA and Proposed Rule are likely to affect the AMP calculation for many covered drugs. These changes in AMP may have unintended consequences for Medicare reimbursement rates, which are normally calculated using a formula based on the ASP for a drug. The Social Security Act requires the Secretary to substitute the lesser of the widely available market price (WAMP) or 103% of AMP when the ASP for a drug or biological exceeds WAMP or AMP by the “applicable threshold percentage.”¹⁰¹ The applicable threshold percentage is currently 5% but is subject to adjustment by the Secretary each year.¹⁰²

BIO is concerned that the revisions to the calculation of AMP included in the Proposed Rule could cause AMP to decrease for certain drugs and biologicals and thus increase the likelihood that the applicable threshold percentage will be triggered, forcing the substitution of AMP for ASP. The substitution of AMP is inappropriate where the triggering of the threshold results solely from the revision to the AMP definition. In such circumstances, which could occur as soon as with the submission of AMP for the first quarter 2007, CMS should refrain from substituting AMP for ASP. BIO asks CMS to closely monitor this issue in 2007 and refrain from substituting AMP for ASP where the threshold is triggered due to the revised definition of AMP and consider the revised definition of AMP when setting the ASP threshold percentage for future years.

⁹⁹ Id.

¹⁰⁰ Id.

¹⁰¹ SSA § 1847A(d)(3).

¹⁰² SSA § 1847A(d)(3)(B); 71 Fed. Reg. at 69,680, 69,788 (codifying 42 C.F.R. § 414.904(d)(3)).

4. CMS Should Reference the Separate Additional Payment for Blood Clotting Factors Under Medicare Within the Final Rule

BIO believes that the final rule should reference the blood clotting factor separate additional payment under Medicare as required by the Medicare Modernization Act.¹⁰³ This reference will provide valuable knowledge to state Medicaid Pharmacy Directors, should they use AMP as a basis to determine Medicaid reimbursement rates. This separate additional payment, which under Medicare is added onto the statutory reimbursement of ASP plus 6% was determined to be \$0.152 per unit of blood clotting factor for 2007.¹⁰⁴ Under Medicare, this separate additional payment has served to enhance patient access by recognizing the costly and unique attributes and services associated with providing blood clotting factors and reimbursing more appropriately. BIO has concern that without such a reference in this final rule, Medicaid Pharmacy Directors will be unaware of the need for this separate additional payment and not consider its value should they look at AMP based payment rates. BIO believes that a separate additional payment would also serve to improve patient access under Medicaid, should an AMP based reimbursement model be pursued in a particular state. At the very least, BIO believes that reference to the precedent of the separate additional payment for blood clotting factors should be incorporated into the final rule in order to provide such knowledge to state Medicaid departments as they determine reimbursement rates moving forward.

5. CMS Should Issue Additional Guidance Through Notice-and-Comment Rulemaking Whenever Feasible and Apply Guidance Issued Through Program Releases Prospectively Only.

The preamble to the Proposed Rule includes a discussion of future clarifications of AMP. In that discussion, CMS stated that it believes that it needs “to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace of the sale of drug. We plan to address further clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed.”¹⁰⁵ BIO encourages CMS consider providing continuing guidance on other elements of the rebate program as well, and not just the definition of AMP.

In the past, CMS has provided guidance to manufacturers and States exclusively through informal means such as program releases and the Operational Guide. BIO recognizes that formal rulemaking will not always be possible, and that certain issues do not merit such a process. BIO nevertheless urges CMS to issue guidance through notice-and-comment rulemaking whenever possible to ensure that policy changes and new developments are evaluated and addressed by all interested parties. CMS also should confirm that any guidance it issues that is not subject to formal rulemaking, including

¹⁰³ SSA § 1842(o).

¹⁰⁴ CMS 1321-FC. Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

¹⁰⁵ 71 Fed. Reg. at 77,181.

guidance issued through Releases, Frequently Asked Questions posted on the CMS website, and Policy Guides, will comply with the OMB Final Bulletin for Agency Good Guidance Practices.¹⁰⁶ BIO urges CMS to specify that its guidance, in whatever form, is to be applied prospectively only. Where that is not CMS' position, CMS should clearly articulate the administrative basis for retrospective application and subject the proposal to full notice-and-comment rulemaking.

6. CMS Should Clarify that the Final Rule Is Prospective in Application Only and Permit Additional Time For Manufacturer Implementation.

CMS notes in the preamble to the Proposed Rule that the Rule's provisions represent changes and clarifications to CMS' prior informal guidance and in some cases represent CMS' first pronouncements on an issue. For this reason, CMS should clarify that the Final Rule necessarily is applicable on a prospective basis only. Given the magnitude of the changes required by the Proposed Rule, BIO also requests that CMS mandate compliance with the Final Rule no earlier than four full quarters following its publication. Implementation will require manufacturers to train and even hire new personnel, create new government pricing methodologies, and then validate those procedures. In light of CMS' proposed certification requirement, it is critical that manufacturers have sufficient time to ensure a compliant implementation effort. BIO therefore urges CMS to provide participating manufacturers with the time they need to ensure this result.

* * *

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed 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 into its Final Rule. Please feel free to contact me at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
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Biotechnology Industry Organization

¹⁰⁶ OMB Final Bulletin for Agency Good Guidance Practices, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.