DK Pierce
& Associates

navigating the complex healthcare environment

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2238-FC,
P.O. Box 8012,
Baltimore, MD 21244-8012

Comments in regard to the definition of physician administered drugs as covered outpatient drugs.

Centers for Medicare & Medicaid Services
42 CFR Part 447
[CMS-2238-FC]
RIN 0938- AO20
Medicaid Program; Prescription Drugs

FFP: Conditions Relating to Physician-Administered Drugs (§447.520)
Page 86
"We proposed, for the purpose of this section, that the term "physician-administered drugs" be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting."

Our comments relate to the definition distinction; "for the purpose of this section". We are concerned that this could be interpreted to mean that physician administered drugs are to be considered "covered outpatient drugs" **only** for the purposes of collecting utilization data and subsequent rebates.

This narrow interpretation currently, and in the future allows state Medicaid agencies to defer coverage and therefore accessibility of new physician administered drugs. In our opinion this is in conflict with CMS's own rules that state; "states must cover a manufacturer's drugs at the start of the Mandatory Effective Date (subject to the exceptions in section 1927 of the Social Security Act)" http://www.cms.hhs.gov/MedicaidDrugRebateProgram/14_NationalDrugRebateAgreement.asp. The rationale given by these states is that they have defined physician administered drugs as **not** covered outpatient drugs per Section 1927 of the Social Security Act[1]

Specifically, many Medicaid agencies currently refer to the SSA drug definition in their state regulations that drugs dispensed **only by prescription** are deemed "covered outpatient drugs". Therefore, this delays physician administered drug coverage for extended periods of time; unlike their retail drug counterparts that must be covered on the mandatory effective date once the rebate agreement is in place. When physician administered drugs are deemed covered, rebates are collected per DRA stipulations but this can take six months to over a year pending agency deliberations such as prolonged medical review or the requirement of a permanent HCPCS code.

We therefore propose that CMS consider defining physician administered drugs as "covered outpatient drugs" more broadly, not just in terms of rebate collection purposes. We would further encourage CMS to specify that physician administered drugs qualify under the mandatory effective date regulations.

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This would place new physician administered drugs in parity with new prescription drugs that must be covered per the stipulations in OBRA 90 and the national rebate agreement; eliminating unnecessary and lengthy waiting periods experienced by Medicaid recipients who need newly approved physician administered drugs.

Thank you for considering these comments.

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December 19, 2007

Rec'd 12-28-07

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–8012

Re: Medicaid Program; Prescription Drugs; Final Rule with Comment Period (CMS-2238-FC)

Dear Acting Administrator Weems:

Amgen is writing to comment on the Final Rule with comment period implementing the provisions of the Deficit Reduction Act of 2005 ("DRA") that pertain to prescription drugs and biologicals under the Medicaid program (the "Final Rule"), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on July 17, 2007.[1] In the preamble to the Final Rule, CMS invited the public to submit comments on the average manufacturer price (AMP) provisions and Federal upper limit outlier provisions set forth in the rule "to assist [CMS] in fully considering issues and developing policies."[2]

As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicaid beneficiaries. For this reason, Amgen comments on the following three areas:

- **Definition of a "bundled sale" and the reallocation of discounts under bundled sales.** For the reasons we discuss beginning on page 2, Amgen recommends that CMS provide additional clarity to manufacturers on applying the new definition and implementing the reallocation methodology.

1 72 Fed. Reg. 39142 (July 17, 2007).

2 72 Fed. Reg. at 39142.

- **Issues related to calculation of the AMP and best price amounts.** For the reasons we discuss beginning on page 6 Amgen makes two recommendations intended to improve the clarity of the agency's guidance to manufacturers on the calculation of AMP and best price.

- **Collection of Medicaid rebates on physician-administered drugs.** For the reasons we discuss beginning on page 8, Amgen recommends that CMS change its policy and direct that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid.

PROPOSED DEFINITION OF "BUNDLED SALES"

Amgen continues to be concerned about potential distortions in reported prices resulting from reallocation of discounts under the new definition of a bundled sale in the Final Rule, but we appreciate the additional clarity that CMS has provided to manufacturers in its preamble discussion of the definition and the reallocation methodology. Given the wide variation in the structure of arrangements that may satisfy the new definition of "bundled sale," Amgen believes that there remain areas where further guidance is needed to help ensure that manufacturers implement the methodology uniformly and consistent with CMS's intent. In the comments below, Amgen raises questions and requests clarification about several aspects of the "bundled sale" definition and provides some recommendations regarding how to implement this new policy.

CMS should clarify whether a contract that does not involve contingent discounts is considered a "bundled sale."

The Final Rule defines a "bundled sale" as an arrangement under which the discount is conditioned on the purchase of the same drug or a drug of a different type or another product 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.*"[3] Amgen asks that CMS provide additional clarity to manufacturers regarding the meaning of the language italicized above. In particular, Amgen asks that CMS clarify whether the bundled sale definition would include a contract that offers non-contingent discounts on a series of different drugs which may or may not share the same NDC-9 but are not otherwise linked except through their presence on the same contract. Manufacturer calculations would obviously be simplified if such contracts were not included in the new definition of "bundled sale."

CMS should clarify whether all price concessions must be reallocated in a "bundled sale."

In the preamble to the Final Rule, CMS instructed manufacturers to allocate the total value of all discounts to all of the drugs in the bundle:

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3 72 Fed. Reg. at 39240 (42 C.F.R. § 447.502) (emphasis added).

> For example, if Drug A is discounted to a purchaser if the purchaser achieves a set market share of Drug B, Drugs A and B are part of a bundled arrangement. The total discount for Drug A and any discount on Drug B must be proportionately allocated to both drugs.[4]

CMS also stated, in response to a comment asking for clarification about the reallocation of discounts when a bundled sale arrangement includes both contingent and non-contingent discounts and rebates, that it considered "all contingent and non-contingent *drugs* to be within the bundled sale if any drug must be purchased in order to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price."[5]

Based on these two sets of comments and responses, Amgen requests CMS to confirm that this guidance means (1) where a contract offers both contingent and non-contingent discounts on products included in a bundle, all discounts in the bundled arrangement, contingent and non-contingent, should be allocated proportionally among the drugs in the arrangement; and (2) where a contract includes a bundled sale involving drugs A and B, as well as a non-contingent discount on drug C, drug C sales and discounts should also be included in the reallocation methodology. This additional clarity will help to ensure that manufacturers employ a uniform approach for reallocating discounts under a bundled arrangement.

CMS should limit reallocation to the covered outpatient drug products in the bundle to accrue the full benefit of manufacturer rebates to the Medicaid program

Amgen supports CMS's position that a bundled sale can exist where a non-drug product is included in the arrangement.[6] However, CMS did not instruct manufacturers as to how to treat these non-drug products in the reallocation calculation. The definition of a bundled sale directs that:

> For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.[7]

This methodology refers only to "drugs" under the bundled arrangement and does not address how the discounts should be reallocated where the bundled sale also

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4 Id. at 39160.

5 Id. at 39159.

6 Id. at 39240 (42 C.F.R. § 447.502) ("Bundled sale means an arrangement . . . under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types . . . or another product . . .").

7 Id.

includes a non-drug product. For the Medicaid program to accrue the full benefit of manufacturer rebates, Amgen urges CMS to clarify that when all discounts in the bundled arrangement are subject to reallocation; all discounts (including discounts on products that are not covered outpatient drugs) are to be reallocated only across those products which are covered outpatient drugs under the Medicaid statute.

The Office of Inspector General (OIG) has determined that in order for a contingent discount to come within the discount safe harbor to the federal anti-kickback statute, "the goods and services [must be] reimbursed by the same Federal health care program using the same methodology."[8] In addressing this safe harbor, the OIG explained that contingent discounts do not pose a risk of program abuse and may benefit Federal health care programs through lower costs or charges "where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment."[9] A bundled arrangement that includes products that do and do not constitute covered outpatient drugs would appear to be outside of the OIG's safe harbor for purposes of the anti-kickback rule. For example, a bundled arrangement that included both a covered outpatient drug and a product that does not meet that definition could adversely affect Medicaid, as some of the discounts on the drug would likely be allocated to the other product, resulting in potentially distorted rebate amounts and federal upper limits for the covered outpatient drug. Accordingly, Amgen asks CMS to clarify that the discounts subject to reallocation (including discounts on products that are not covered outpatient drugs) are to be reallocated solely across the covered outpatient drugs included in the "bundled arrangement."

CMS should clarify the treatment of discounts where multiple periods are at issue.

Amgen recommends that CMS provide clarification regarding the treatment of discounts where the sales from a prior period may be used to qualify for discounts in a later period. In responding to public comment on this issue, CMS stated that:

> The data used in the determination of bundled sales arrangement should reflect and apply to the month or quarter being used in the determination, for example, in a situation where a manufacturer must achieve a certain market share of the product in one quarter to achieve a discount in the second quarter, CMS would treat the contingent discount as a bundle. The quarter for the prior purchase and current purchase would be used in the determination of the bundled sale arrangement.[10]

CMS did not specify in its response how the two quarters should be used in the determination of the bundled arrangement nor how the discounts should be reallocated. Amgen asks that CMS confirm that the market share discounts should

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8 42 C.F.R. § 1001.952(h)(5)(ii).

9 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999).

10 72 Fed. Reg. at 39159.

be allocated solely to sales made in the quarter during which the discount was realized, and that sales from the baseline quarter are not to be included in the reallocation.

CMS should permit manufacturers to use the reallocation methodology for prior months of the 12-month rolling average ratio for lagged price concessions.

Given the significant changes to bundled sales definition contained in the Final Rule, an additional important area where Amgen believes additional guidance is needed is on the question of whether manufacturers should reallocate bundled discounts for months prior to October 2007 for purposes of calculating lagged price concessions. Amgen recommends that CMS clarify that manufacturers may reallocate price concessions under the bundled sale definition for all 12 months in the 12-month rolling average ratio.

If the bundled sale definition is effective as of October 1, 2007 the first monthly reporting period to which the definition applies would be October 2007. As the Final Rule directs inclusion of the reporting month in the 12-month period,[11] the 12-month period to be used for the October 2007 calculation is November 2006 through October 2007. Amgen asks CMS to specify that manufacturers may choose to reallocate bundled sale price concessions relating to the 11 months prior to October 2007 that are included in the 12-month rolling average. Permitting manufacturers to immediately adopt the reallocation methodology at once for all 12 months, rather than proceeding piecemeal based on the month being reported, may reduce the computational complexity involved in updating current AMP systems and testing and validating the results of those modifications. Because discounts under a bundled arrangement will generally be lagged price concessions, as that term is defined by the Final Rule,[12] reallocating discounts for all 12 months in the 12-month rolling average ratio will also avoid an 11-month delay in reported AMPs fully reflecting CMS' reallocation policy. Amgen recommends, nonetheless, that manufacturers be permitted to choose between immediate adoption or a monthly phase-in implementation, to allow the flexibility needed to accommodate individual manufacturer calculation systems.

REVIEW OF RECOMMENDATIONS ON "BUNDLED SALES"

For the reasons outlined above, Amgen provides the following recommendations for the agency's consideration:

- ***Recommendation 1:*** Clarify whether a contract that does not involve contingent discounts is considered a "bundled sale."

- ***Recommendation 2:*** Confirm that all non-contingent drugs and price concessions must be reallocated in a "bundled sale."

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11 See 72 Fed. Reg. at 39,210.

12 See 42 C.F.R. § 447.502.

- ***Recommendation 3***: Confirm that where non-drug products are included in the bundle, all discounts in the arrangement should be reallocated only to the covered outpatient drug(s) included in the arrangement.

- ***Recommendation 4***: Confirm that where multiple periods are at issue, the discounts should be allocated to sales made in the quarter during which the discount was realized, and that the baseline quarter is not included in the reallocation.

- ***Recommendation 5***: Clarify that manufacturers are permitted to use the reallocation methodology for months preceding October 2007 that are included in the 12-month rolling average ratio for lagged price concessions.

ISSUES RELATED TO CALCULATION OF AMP AND BEST PRICE AMOUNTS

CMS should permit manufacturers to estimate lagged price concessions and lagged ineligible sales for monthly and quarterly AMP calculations using the methodology applied in the average sales price (ASP) context.

In the Final Rule, CMS decided "to require manufacturers to use a 12-month rolling average to estimate the value of lagged price concessions in their calculation of monthly and quarterly AMPs."[13] However, CMS did not specify which sales should be included in this 12-month rolling average nor did it provide any other detail as to how manufacturers should implement this estimation methodology. Amgen asks that CMS confirm that for the monthly and quarterly AMP calculations, manufacturers may use the same methodology for estimating lagged price concessions that CMS has adopted for purposes of the ASP calculation.[14] The application of the ASP methodology in the context of AMP reporting would require manufacturers to develop a 12-month rolling average ratio of AMP-eligible price concessions to AMP-eligible sales and then apply that ratio to the total AMP-eligible sales in the reporting period.

Amgen believes that building upon the estimation methodology that CMS developed for purposes of ASP will reduce administrative and implementation burdens on both manufacturers and the agency. The ASP estimation methodology already has been subject to review and comment by industry, and manufacturers of Medicare Part B drugs have already developed estimation formulas that are consistent with the 2006 ASP Final Rule. Using the same approach for both ASP and AMP reporting would reduce confusion among manufacturers, lower the risk of error in AMP calculations, and minimize the volatility of AMP data. This is particularly important now that states may be using AMP to calculate pharmacy reimbursement rates.

The Final Rule does not address whether manufacturers may estimate lagged ineligible sales (i.e., those ineligible sales identified through lagged price

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13 72 Fed. Reg. 39210.

14 71 Fed. Reg. 69624, 69787 (Dec. 1, 2006) (amending 42 C.F.R § 414.804(a)) ("2006 ASP Final Rule").

concessions such as chargebacks and rebates). Because the 2006 ASP Final Rule did not mandate the use of a particular methodology for estimating lagged ineligible sales,[15] Amgen requests that CMS clarify that manufacturers may use their current estimation methodology for ASP-exempt lagged sales to estimate ineligible lagged sales for purposes of AMP. Amgen further requests that CMS confirm that the "DRA Policy Questions and Answers" issued by CMS on November 27, 2007 do not prohibit this result. In response to the question "May a manufacturer opt to smooth sales that are excluded from AMP?", CMS responded:

> No. For the purposes of Medicaid, only the discounts, rebates, and other price concessions associated with sales included in AMP should be used in the 12-month rolling average to estimate the value of lagged price concessions.[16]

Amgen understands this statement to mean that manufacturers should not include ineligible sales in the denominator of the 12-month rolling average ratio used to estimate the value of lagged price concessions, which is consistent with the ASP methodology,[17] and not to prohibit the use of a estimation methodology to estimate lagged ineligible sales. We ask that CMS confirm this understanding.

CMS should clarify the treatment of discounts to pharmacy benefit managers (PBMs) in AMP calculations.

The Final Rule directs manufacturers to include in the calculation of AMP "[s]ales including discounts, rebates or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases."[18] Discounts, rebates or other price concessions other than for the PBM's mail order purchases are excluded from AMP.[19] In the preamble to the Final Rule, CMS states that it has "clarified in the final rule at § 447.504(g)(6) that sales and discounts to mail order pharmacies operated by PBMs are included in AMP."[20] Amgen asks that CMS further clarify that rebates and administrative fees (that do not meet the definition of a bona fide service fee) that relate to PBM mail-order utilization should be included in AMP only to the extent that the manufacturer can document that (i) the mail-order pharmacy is operated by the PBM **and** (ii) the mail-order utilization is separately quantifiable. In some cases, despite reasonable efforts on the part of the manufacturer, the manufacturer may not be able to determine whether the PBM operates any or all of the mail order pharmacies that contract with the PBM, or the PBM may not be able or willing to provide separate utilization data for the mail-order utilization. Amgen asks that CMS confirm that in such circumstances, all of the PBM discounts, both mail-order and non-mail order, should be excluded from AMP.

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15 71 Fed. Reg. at 69,671.

16 CMS, DRA Policy Questions, available at http://www.cms.hhs.gov/DeficitReductionAct/39_MedicaidPrescriptionDrugs.asp#TopOfPage (11/27/2007).

17 42 C.F.R § 414.804(a)

18 72 Fed. Reg. at 39241 (42 C.F.R. § 447.504(g)(6)).

19 72 Fed. Reg. at 39242 (42 C.F.R. § 447.504(h)(22)).

20 72 Fed. Reg. 39179.

REVIEW OF RECOMMENDATIONS ON ISSUES RELATED TO CALCULATION OF AMP AND BEST PRICE AMOUNTS

For the reasons noted above, Amgen makes the following recommendations:

- ***Recommendation 1***: Clarify that manufacturers may estimate lagged price concessions and lagged ineligible sales for the monthly and quarterly AMP calculations using the estimation methodology adopted in the 2006 ASP Final Rule, and may estimate lagged ineligible sales using the methodology the manufacturer employs in its ASP calculation.

- ***Recommendation 2***: Clarify that rebates and administrative fees that relate to PBM mail-order utilization should be included in AMP only to the extent that the manufacturer can document that (i) the mail-order pharmacy is operated by the PBM **and** (ii) the mail-order utilization is separately quantifiable.

COLLECTION OF MEDICAID REBATES ON PHYSICIAN-ADMINISTERED DRUGS

CMS should issue guidance that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid.

Amgen asks that CMS change its current position and determine that manufacturer rebate liability for drugs is limited to that proportion of the rebate amount that is equal to the proportion of the payment for the drug that is paid by the state Medicaid program. In response to public comment on this issue, CMS stated that it disagreed that the rebate should be proportional to the amount of the claim paid by Medicaid:

> Neither the law nor the national rebate agreement makes provision to reduce the rebate liability based on the amount of payment made by the Medicaid Program. Rather, the law provides formulas for rebate payments for single source, innovator multiple source, and noninnovator multiple source drugs that are used when Medicaid makes payment for a drug.[21]

Amgen respectfully disagrees with this position. As Amgen explained in its February 20, 2007 comment letter on the Proposed Rule (the "February 2007 Comment Letter"), limiting the Medicaid rebates to the proportional amount paid by Medicaid would not change the rebate calculation under section 1927(c) of the Social Security Act ("SSA"). Rebates would still be calculated according to the statutory formula, and this amount would then be collected proportionally based on the ratio of the State's actual payment amount to the total amount reimbursed for the drug.

This position is supported by the language of the Medicaid statute, which provides that the Medicaid rebate is to be considered a reduction in the amount expended by

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21 72 Fed. Reg. at 39218.

the State and the legislative history of the statute, which makes clear that the Medicaid rebate was intended to be a discount to provide the State with the best price at which the manufacturer sells the drug to any other purchaser.[22] This issue was further clarified by Senator Charles Grassley, who explained in an August 2006 letter to CMS Administrator McClellan that the "language in Section 6002 [of the DRA] makes clear that the Medicaid rebate is only available for the Medicaid portion of the payment."[23] Moreover, with the recent changes to the state invoice form, CMS Form R-144, CMS has the tools to require collection of the Medicaid rebate in proportion to the payment by the state.[24]

For all of these reasons, Amgen strongly urges CMS to issue a clarification, consistent with Congressional intent, that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid.

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22 The text and legislative history of the Medicaid statute are set forth in detail in Amgen's February 2007 Comment Letter.

23 Letter from Chairman Charles E. Grassley to Administrator Mark B. McClellan, Aug. 14, 2006. Sen. Grassley was Chairman of the Senate Finance Committee during the enactment of the DRA and is now the ranking Republican on that Committee. Congress specified in section 6002 of the DRA that States must collect and submit utilization data and coding to secure Medicaid rebates "for drugs administered for which payment is made under this title." DRA § 6002, Pub. L. No. 109-171 (adding SSA § 1927(a)(7)).

24 See Medicaid Rebate Program Release for State Medicaid Directors #143, available at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp (Aug. 23, 2006).

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Amgen appreciates this opportunity to comment on the important issues raised in the Final Rule and we look forward to working with you to ensure that Medicaid beneficiaries have continued access to critical treatments. Please contact Andy Swire by phone at (202) 585-9611 or by email at aswire@amgen.com to arrange a meeting or if you have any questions regarding our letter. Thank you for your attention to this important matter.

Regards,

Joshua J. Ofman, MD, MSHS
Vice President,
Global Coverage and Reimbursement
Global Health Economics

cc: Dennis Smith, Director, Centers for Medicaid and State Operations (CMSO)
Bill Lasowski, Deputy Director, CMSO
Gale Arden, Director, Disabled and Elderly Health Program Group (DEHPG), CMSO
Deirdre Duzor, Director, Pharmacy Division, DEHPG, CMSO
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PhRMA

December 14, 2007

VIA EXPRESS MAIL AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–8012

Re: **Comments on the Medicaid Program Prescription Drugs; Final Rule with Comment**

Dear Acting Administrator Weems:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit the following comments regarding the final rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) that was published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on July 17, 2007.[1] In the final rule, CMS requested "comments from the public on the AMP and FUL outlier provisions[2] as set forth in [the final] rule to assist [CMS] in fully considering issues and developing policies."

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA appreciates the efforts of CMS to provide clear and specific guidance on the calculation of Medicaid rebates and related reporting provisions. Clear ground rules are essential

[1] Medicaid Program; Prescription Drugs, Final Rule, 72 Fed. Reg. 39142 (Jul. 17, 2007).

[2] PhRMA notes that although CMS has requested comments on the AMP and FUL outlier provisions and not specifically on the Best Price provision, in certain circumstances, the AMP provision implicates issues relevant to the determination of Best Price. Because of this fact, where applicable, PhRMA has addressed both the AMP and Best Price implications as part of these comments. We also address certain issues that are only pertinent from the Best Price perspective, which we hope that CMS will clarify in FAQ guidance or in the revised final rule.

to the smooth and efficient operation of the Medicaid Drug Rebate program. The final rule provides significant new guidance to manufacturers relating to the calculation of AMP and Best Price. However, in addition to the specific comments on the final rule that we raise below, we wish to note at the outset that we are concerned with CMS' change in approach to the definition of AMP in the final rule. As CMS considers further changes to the AMP definition, it should focus on the fact that the Medicaid rebate statute defines AMP as a price paid to a drug's manufacturer, instead of a measure of the drug's acquisition cost to pharmacies.

We are pleased to provide the following specific comments on the final rule.

I. AMP Comments

A. Bundled Sales

1. General comments

The final rule, like the proposed rule, makes substantial changes to the definition of the term "bundled sale." We note at the outset, as we did in our comments to the proposed rule, that the new definition appears to encompass a broad range of contracting practices, which under the existing Medicaid Rebate Agreement are not considered bundled sales. Currently, the Medicaid Rebate 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]

The definition in the final rule introduces several modifications to the definition of a bundled sale under the Medicaid Rebate Agreement and the purpose for these changes is unclear.[4] For example, the definition in the rule could encompass an arrangement involving "the purchase of the same drug," whereas the definition from the Medicaid Rebate Agreement requires "the packaging of drugs of different types."[5] (Emphasis added.) In addition, the Medicaid Rebate Agreement definition of a bundled sale is limited to arrangements involving the packaging of drugs of different types where the customer must purchase more than one drug type as a condition

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[3] Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050, § I(e) (Feb. 21, 1991).

[4] The Final Rule defines a bundled sale as "an 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 available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle." 72 Fed. Reg. 39240 (codified at 42 C.F.R. § 447.502).

[5] 56 Fed. Reg. 7049, 7050, § I(e) (Feb. 21, 1991).

of receiving a rebate or discount or where the resulting rebate is greater than would have been available if the drug products had been purchased separately. However, the new definition arguably would extend to arrangements where the only condition for the discount is including drugs on a formulary (or placement on a certain formulary tier), even if there is no requirement to purchase any or all of the formulary drugs. This definition is overbroad and could conceivably implicate as a "bundled sale" any contract covering more than one product. As we said in our proposed rule comments, the definition could create absurd results and, thus, we strongly disagree that a single contract that offers multiple products for sale but does not expressly require purchase of any one product in order to achieve availability of another product should be deemed a bundled sale. Such a broad definition would create confusion and substantially increase the complexity of AMP and Best Price calculations. It could well distort the economic reality of a particular transaction in such a way that the reported AMP and Best Price for the affected products would not accurately reflect the underlying transactions. In a given instance, this could greatly understate, or overstate, the price of a particular drug. CMS should reconsider the application of the bundled sale definition to contracts with multiple products but no purchase requirement.

Similarly, a plain reading of the final rule would sweep into the definition of a bundled sale any arrangement involving a "market share" requirement, even though such requirements would not necessarily require the purchase of different types of drugs and do not create a bundle under the Medicaid Rebate Agreement definition. The new definition also encompasses any arrangement, either involving the same drug or different drugs, that included any "performance requirement" - an undefined term with the potential to create confusion and interpretive difficulties. Moreover, under the final rule's definition, a bundle includes an arrangement in which the "same drug" is sold under circumstances where "the resulting discounts . . . are greater than those which would have been available had the bundled drugs been purchased . . . outside the bundled arrangement."[6] Under this language, it is difficult to understand what arrangements would not represent a "bundled sale," since almost any contract would presumably offer a discount greater than what would have been available to the purchaser outside the contract.

Thus, as detailed in this section, we have significant concerns and questions about the new definition. Moreover, the new definition cannot properly be applied retroactively to periods preceding the final rule's effective date.

2. Retroactive Effect

In connection with the final rule's preamble discussion of the definition of bundled sale, CMS stated:

> The clarification of the bundled sales definition in this final rule does not create a new definition or impose new obligations that did not already exist under the Rebate Agreement. It has always been our policy that AMP and best price must be

[6] 72 Fed. Reg. at 39240.

> adjusted to reflect discounts offered in bundled sale arrangements to those entities included in the determination of AMP and best price.[7]

With respect to the effective date of the final rule, CMS stated that "to the extent that this rule addresses previous policies already established by the Agency, those policies will remain in effect."[8] Taken together, these statements suggest that CMS intends the bundled sale definition in the final rule to have a retroactive effect.[9] That is, CMS has directed that the new definition of a bundled sale in the final rule be applied to periods predating October 1, 2007. Rather than merely clarifying the Medicaid Rebate Agreement and existing guidance from CMS, however, the definition of bundled sale in the final rule materially changes the previous definition. The new definition thus cannot be applied to periods prior to the fourth quarter of 2007, since such application would amount to retroactive rulemaking in contravention of the Administrative Procedure Act.

The Medicaid Rebate Agreement and the final rule definitions of bundled sale differ in at least four material respects. The final rule defines the term "bundled sale": (1) to provide that bundled sales can occur "regardless of physical packaging," (2) to include arrangements with price concessions contingent on either purchase requirements or "performance requirements" other than a purchase requirement (whereas the Medicaid Rebate Agreement definition extends solely to "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 discount or rebate requires the products not be "purchased separately"); (3) to include arrangements with purchase or performance requirements involving the "same" drug (as well as "drugs of different types," which is the standard required in order to have a bundle under the Medicaid Rebate Agreement); and (4) to include arrangements with purchase or performance requirements involving at least one covered outpatient drug that also include products other than a covered outpatient drug (whereas the Medicaid Rebate Agreement's definition of bundled sale only applies if there are two or more covered outpatient drugs, of different types, and would thus not be triggered by an arrangement involving a covered outpatient drug and a non-drug product).

The Medicaid Rebate 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.[10] (Emphasis added.)

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[7] 72 Fed. Reg. at 39158-59.

[8] 72 Fed. Reg. at 39157.

[9] We note that unlike the changes in the definition of bundled sale that were first in the proposed rule, to which we provided comment, CMS did not suggest in the proposed rule that it would apply the definition of bundled sale retroactively and thus PhRMA was unable to provide comment on that issue at that time.

[10] 56 Fed. Reg. 7049, 7050, § I(e) (Feb. 21, 1991).

CMS first adopted this Medicaid Rebate Agreement definition (at the Medicaid Rebate Statute's inception) and published it in the Federal Register in a notice on February 21, 1991, and repeated the definition in its 1995 proposed Medicaid Rebate regulations (which were never finalized).[11]

Given the significant differences between the definition of bundled sale in the final rule and the longstanding definition in the Medicaid Rebate Agreement, which has been reiterated in past agency guidance related to bundled sales, the final rule definition is not a simple clarification of the Medicaid Rebate Agreement's definition of a bundled sale. Accordingly, any assertion that manufacturers must apply the bundled sale definition in the final rule before October 1, 2007 would be inconsistent with the Medicaid Rebate Agreement, would not be authorized by any statute and is arbitrary and capricious, or otherwise not in accordance with law and therefore in violation of the Administrative Procedure Act. [12]

CMS should, therefore, revise its position and state that the new bundled sale definition in the final rule first came into effect on October 1, 2007.

3. Issues for Clarification

For purposes of applying this new definition of bundled sale prospectively, there are numerous questions that arise requiring further clarification or modification. To assist companies in applying the new definition of "bundled sale," PhRMA requests that CMS provide specific direction regarding the types of arrangements that do not fall within the definition. In addition, CMS should provide further guidance with respect to the allocation methodology established in the final rule.

a. Arrangements That Are Not Bundled Sales

First, CMS should confirm that different products in the same contract are not necessarily a bundled sale merely by virtue of being offered in the same contract.

PhRMA requests CMS confirm that under the final rule definition, a bundled sale does not occur if several products are included in the same contract, but each product has a discount that is not contingent on any performance or purchase requirement. For purposes of contracting efficiency, manufacturers and customers may choose to specify pricing terms for multiple products within a single agreement. Within such an agreement, a customer may realize a discount specified for a drug included in the agreement without meeting any purchase or performance

[11] 56 Fed. Reg. 7049 (Feb. 21, 1991); Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, proposed rule, 60 Fed. Reg. 48442 (Sept. 19, 1995). CMS also specifically addressed the issue of non-drug products in its Operational Training Guide discussion of bundled sales, where it made clear that arrangements involving a covered outpatient drug and a non-drug product were not bundled sales; instead, "[v]alid bundled sales only include drug products that meet the definition of a covered outpatient drug . . . ." Training Guide at F11d.

[12] *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988).

requirement. For example, CMS should clarify that an arrangement is not a bundled sale if a contract offers a discount of 10% on product A, 15% on product B, and 20% on product C, but these discounts are available regardless of whether the customer purchases any or all of the products.

Similarly, PhRMA requests CMS confirm that under the final rule definition, a contract may include both bundled and non-bundled sale arrangements. For example, a contract may offer a combined discount of 10% on products A and B, if the undiscounted sales of products A and B together reach $1 million. If that contract also provides a 20% discount on all sales of product C, which is not contingent on any purchase or performance requirement, Product C should not be treated as part of the bundled sale arrangement between Product A and B, despite its inclusion in the same contract. CMS should therefore confirm that the sales of product C should not be rolled into the product A and B bundled sale arrangement.

In addition, CMS should not consider an arrangement to be a bundled sale if a contingency applies only to the same drug (which we use here to mean the same NDC-9). As CMS recognized in the preamble to the final rule, contingent arrangements involving the same NDC-9 can be considered volume discounts.[13] CMS made this observation in response to a comment that asserted that arrangements for a single NDC-9 like "buy one, get one free" or "buy one, get the next at X% discount" "essentially represent volume discounts."[14] CMS stated, and PhRMA agrees, that in such circumstances the aggregate value of all the discounts should be allocated proportionately to all drugs in the arrangement. (In other words, if the contract allows the purchaser to buy 1 unit of a certain NDC-9 for $10 and then to get a second unit of that NDC-9 for "free," the two units would each be considered to have a net price of $5.) PhRMA, however, disagrees that contingencies involving a single NDC-9 should therefore be treated as creating a "bundled sale." Instead, CMS should recognize such arrangements as volume discounts and manufacturers should allocate the discount to account for the structure of the discount.

By defining such arrangements as "bundled sales" rather than volume discounts, CMS may have created a needlessly complicated and confusing rule. Unless CMS removes "same drug" from the definition of bundled sale, manufacturers will be forced to try and give that part of the definition meaning, searching for circumstances where a purchase or performance requirement involving a single NDC-9 could result in a reallocation of discounts. For example, the definition might apply to an arrangement where a customer can earn a $10 discount off of the wholesale acquisition cost (WAC) of a specific NDC-9 for a year, if it agrees to place that NDC-9 on formulary for that year. Such an arrangement apparently would create a bundle over time, and, if the WAC for the drug were to change over the course of that year, could create allocation challenges (i.e., the percentage discount would vary over the year and discounts on the same product might still have to be reallocated between quarters).

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[13] See 72 Fed. Reg. at 39158.

[14] Id.

It is our understanding that the purpose of the bundled sale definition is to make price reporting more accurate; in the above example, however, it is difficult to see how reallocating discounts between quarters would make the reported prices more accurate, and we doubt if CMS intended to require such reallocations. If left as is, the bundled sale definition is much more likely to create significant administrative burdens. Given CMS' assurances that it does not intend for the final rule to increase administrative burdens for manufacturers, we do not believe that CMS meant for the definition of bundled sale to lead to such a result. For this reason, CMS should remove "same drug" from the definition of bundled sale and instead clarify that volume discounts must be allocated as part of price reporting obligations.

b. Allocation when Non-Contingent Discounts Present

When a bundled sale arrangement involves both contingent discounts and some non-contingent discounts, the final rule does not clearly specify the value of the discount to be allocated and the allocation method. To illustrate this point, PhRMA makes the following observations and recommendations.

The preamble to the final rule notes that a commenter asked "how discounts should be allocated when a bundled sale arrangement includes both contingent and non-contingent discounts and rebates."[15] CMS replied that it "consider[s] all contingent and non-contingent drugs to be within the bundled sale if any drug must be purchased in order to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price. Additionally, a bundled sale exists where the discounts available are greater than those which have been received had the drug products been purchased separately and apart from the bundled arrangement."[16] CMS' response does not seem to address squarely whether non-contingent discounts should be allocated. CMS should make clear that when a product is part of a bundled sale arrangement in which only part of the discount is contingent upon a purchase or performance requirement, only the contingent discount should be allocated across the products in the bundle. For example, if a manufacturer has a contract in which a purchaser receives a 10% base discount on product A without meeting any requirement (i.e., a non-contingent discount), and the purchaser can receive an extra discount of 5% on product A if it buys product B (i.e., the contingent discount), only the 5% incremental discount that is contingent should be allocated across product A and product B.

Confusion also exists regarding the appropriate value to use as the base price for allocation purposes in an arrangement that includes both contingent and non-contingent discounts. For example, assume product A and product B are part of a bundled sale arrangement and product A and product B both have a WAC of $10. Under the agreement, if the customer achieves a certain market share for product A, it can purchase product A for $5 and product B for $7. However, regardless of whether the customer satisfies the market share requirement, it can purchase product B at a discount of $8. It is unclear whether the prices used as the base for allocating the bundled discount are the $10 WAC for each product or the $10 WAC for product A and the $8

[15] 72 Fed. Reg. at 39159.

[16] 72 Fed. Reg. at 39159.

non-contingent price for product B. It is also not clear from the rule whether this is a material issue to CMS. CMS should specify that, in determining the base price to be used for allocating the bundled discount, manufactures may choose a reasonable allocation methodology provided that they use it consistently. Thus, in this example, a manufacturer could allocate the bundled discount either using the $10 WAC for products A and B as the allocation base, or using as the allocation base the $10 WAC for product A and the $8 non-contingent price to the customer for product B.

c. Allocation Issues with Non-Covered Outpatient Drugs

The bundled sale definition and the reporting of AMP and Best Price apply in the context of covered outpatient drugs under the Medicaid Drug Rebate Program. As noted above, previously, the Operational Training Guide stated that if a manufacturer provides a discount on a product that is not a covered outpatient drug under the Medicaid rebate program (e.g., a vaccine), which is contingent on a purchase requirement on a covered outpatient drug, there is not a bundled sale. The final rule definition of a bundled sale does not clearly address how to allocate discounts in arrangements that involve sales of covered outpatient drugs with products that are not covered outpatient drugs.[17] However, the new bundled sale definition in the final rule refers to a condition upon the purchase of the same drug, drugs of different types, or another product. CMS should delete the phrase "another product" from the definition and then confirm that there is no bundled sale when one of the contingent products in the arrangement is not a covered outpatient drug. If the bundled sale is to include a non-covered outpatient drug or some other product, CMS should make clear how the discounts in such an arrangement are to be measured and allocated.

d. Allocation when Multiple Periods at Issue.

In the preamble to the final rule, CMS was asked about a situation where sales from one period are used as a basis for measuring performance in a later period. CMS stated:

> [D]ata used in the determination of [a] bundled sales arrangement should reflect and apply to the month or quarter being used in the determination, for example, in a situation where a manufacturer must achieve a certain market share of the product in one quarter to achieve a discount in the second quarter, CMS would treat the contingent discount as a bundle. The quarter for the prior purchase and current purchase would be used in the determination of the bundled sale arrangement.[18]

This response did not specifically discuss how manufacturers should use the quarter for the prior purchase and the current purchase "in the determination of the bundled sale arrangement." PhRMA recommends that CMS confirm that discounts based on market share requirements involving more than one quarter should be allocated to sales made in the quarter during which the

[17] See 42 C.F.R. § 447.502 ("For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.")

[18] 72 Fed. Reg. at 39159.

discount was realized. For example, a manufacturer may offer a customer a 10% discount off of product A in Q2 if the customer meets a 20% market share performance target for use of product A in Q1. In this case, the discount should be allocated to Q2 sales. Similarly, a manufacturer may offer a customer a 10% discount off of product A in Q2, if the customer meets a 20% market share performance target for use of product B in Q1. Under such an arrangement, the discount earned on Product A should be allocated across sales of both product A and B in Q2. In another circumstance, a manufacturer may condition the discount on the achievement of a certain percentage growth in market share. For example, the customer may be able to obtain a 10% discount off of product A in Q2 if the rate of growth in the customer's use of product A between Q1 and Q2 increases by 2%. In such a case, the discount should be allocated to sales of product A in Q2.

B. 12-Month Rolling Average

1. Maintaining Consistency with Average Sales Price (ASP) Guidance

In the 2007 Physician Fee Schedule (PFS) proposed rule, CMS announced its intention to establish a uniform approach that required manufacturers to use a 12-month rolling average ratio methodology to estimate lagged exempt sales. After reviewing the numerous comments on this proposal, however, CMS changed this position in the 2007 PFS final rule.

> The comments received in response to the proposed rule reflect a broader set of manufacturers' perspectives. Some commenters indicated that for certain types of exempted sales the proposed methodology for excluding lagged exempted sales from the ASP calculation might lead to inaccuracies in the ASP calculation in their particular circumstances. At the same time, a number of commenters supported the proposed methodology. We recognize these commenters' concerns regarding the difficulties in tracking both the exempted sale and its associated price concessions. . . . [W]e are not including the methodology in our regulations, but are allowing the manufacturers to use the methodology where applicable.[19]

PhRMA recommends that CMS consider expressly extending this policy to lagged exempt sales in the AMP calculation. Such a position would promote and maintain appropriate consistency across the calculations required for various government price reporting obligations. Consequently, CMS should adopt the same position in the AMP context as in the ASP context to estimate lagged exempt sales: use of a 12-month rolling average ratio methodology to estimate lagged exempt sales should be permitted, but not required.

2. Use of AMP Values Calculated Prior to October 1, 2007

The final rule preamble states that CMS has "decided to require manufacturers to use a 12-month rolling average to estimate the value of lagged price concessions in their calculation of monthly and quarterly AMPs. . . ."[20] Lagged price concessions are defined as "any discount or

[19] 71 Fed. Reg. 69624, 69671 (December 1, 2006).

[20] 72 Fed. Reg. at 39210.

rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts."[21] However, due to changes enacted on January 1, 2007 by the DRA and by the final rule, AMPs calculated prior to January 1, 2007, and then again prior to October 1, 2007, will be based on a somewhat different set of transactions than AMPs calculated after those dates.

PhRMA notes that it would be unduly burdensome to require manufacturers to recalculate the AMPs reported for each covered outpatient drug they produce in accordance with the new regulations to estimate lagged price concessions. Instead, PhRMA requests CMS to confirm that it is reasonable for manufacturers to utilize previously reported AMPs to calculate their 12-month rolling averages.

3. Treatment of Bundled Sales

Under 42 C.F.R. § 447.502, "lagged price concessions" are defined as "any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts." A bundled sale arrangement may involve discounts that are "realized after the sale of the drug." PhRMA notes that under the current guidance and regulations it is unclear whether it is appropriate for AMP purposes to account for a bundled discount that is a lagged price concession using the 12-month rolling average methodology. PhRMA recommends that CMS clearly state that for AMP purposes manufacturers may account for a bundled discount that is a lagged price concession using the 12-month rolling average methodology. This would avoid any need to reallocate such a bundled discount across time periods or to restate AMP, because under 42 C.F.R. § 447.510(b)(2), a manufacturer must report revisions to AMP "except when the revision would be solely as a result of data pertaining to lagged price concessions."

C. Bona Fide Service Fees[22]

1. General Comment

In the final rule preamble, CMS states: "We do not believe that for the purposes of the Medicaid drug rebate program, administrative services related to the administration of a rebate contract would qualify as bona fide service fees because these fees are not associated with the efficient distribution of drugs or our interpretation of the bona fide service fee guidance."[23] (Emphasis added.) Previously, CMS had referred to services involving the "efficient distribution of drugs" in its ASP guidance on bona fide services, though it is not clear that CMS meant to limit "bona fide" services to those involving the efficient distribution of drugs. Moreover, the definition of bona fide service fees does not reference such a limitation.

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[21] 42 C.F.R. § 447.502.

[22] We note that, except for our comment in this section below related to treatment of inpatient hospital sales for AMP purposes, our comments on Bona Fide Service Fees relate both to the treatment of bona fide service fees for both AMP and Best Price purposes.

[23] 72 Fed. Reg. at 39182.

Under 42 C.F.R. § 447.502, "bona fide service fees" are defined as

> [F]ees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Although services that involve the efficient distribution of drugs may qualify as bona fide service fees, the regulatory definition of bona fide service fees is not limited to fees for such services. There is no reason to limit the scope of bona fide service fees and to treat a service fee as a price concession on a manufacturer's drugs simply because the fee is paid for services unrelated to drug distribution. Consequently, PhRMA recommends that CMS clarify that fees do not have to be associated with services that involve "the efficient distribution of drugs" in order to qualify as bona fide service fees.

2. Treatment of Group Purchasing Organization (GPO) Administrative Fees

In PhRMA's comments on the proposed rule, we noted that GPO administrative fees are not price concessions, but rather bona fide service fees that reflect the value of facilitated contracting. PhRMA continues to endorse the approach to GPO administrative fees advanced by the trade association that represents GPOs, the Health Industry Group Purchasing Association (HIGPA). GPO fees should not be treated as price concessions "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."[24] Applying this bright line standard to GPO fees would provide a useful and justifiable benchmark. CMS should explicitly recognize that unless the agreement between a manufacturer and a GPO requires the GPO to pass through the fees paid by the manufacturer to the GPO's members or customers, the fees should not be treated as price concessions. In addition CMS confirmed in the final rule that sales to hospitals for drugs used in the inpatient setting are excluded from the AMP calculation, Thus, any administrative fees which are paid to a GPO in connection with those excluded sales, regardless of whether they would be construed as price concessions or not, should be excluded from the AMP calculation along with the associated excluded sales.

3. Administrative Fees to PBMs vs. All Other Entities

A further question was raised by the following question and answer that was included as part of the "DRA Policy Questions" released by CMS, the current version of which is dated November 27, 2007:

[24] January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

Question: Are all PBM administrative fees excluded from AMP and considered in BP or just those related to PBM mail order rebates?

Answer: In general, administrative fees are excluded from AMP and BP only if they meet the criteria for bona fide service fees. For PBMs, other than mail order, all administrative fees are excluded from AMP and best price.

This response creates a per se exclusion for PBM administrative fees (apart from administrative fees associated with PBM mail-order). Arrangements with all other contracting entities, such as GPOs, must satisfy the requirements for bona fide service fees in order for those arrangements to be excluded from AMP and Best Price. PhRMA requests that CMS explain whether it intended this outcome, and if so, explain its rationale for creating this distinction between administrative fees to PBMs and to other entities.

D. PBM Price Concessions

The final rule states that AMP does not include rebates "to PBMs, except for their mail order pharmacy's purchases."[25] Similarly, Best Price also does not include PBM rebates "except their mail order pharmacy purchases" (and in other circumstances not relevant here).[26] Throughout the preamble to the final rule, CMS makes clear that it is excluding PBM discounts from AMP and Best Price because of the burden of tracking those discounts. For example, in the preamble to the final rule, CMS stated that "[w]e understand that manufacturers may face administrative burdens regarding the collection of data to determine whether a [service] fee is passed on" and noted "we have excluded . . . price concession[s] to PBMs so there is no longer the administrative burden associated with PBM adjustments."[27] CMS added: "We believe [excluding PBM price concessions from AMP] will alleviate some of the administrative burden associated with the calculation of AMP and result in more accurate and consistent AMPs across manufacturers."[28] CMS further stated that excluding PBM price concessions from AMP "is consistent with previous guidance issued in manufacturer releases and to the extent that PBM discount rebates and price concessions did not meet these criteria, the impact on the calculation of AMP is likely to be minor."[29] Therefore, with the exception of PBM mail-order purchases, CMS wrote: "[W]e do not believe that it is appropriate to include PBM rebates, discounts, and prices in either AMP or best price. . . "[30]

Nevertheless, the "DRA Policy Questions," referenced above, now include the following question and answer:

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[25] 42 C.F.R. § 447.504(h)(22).

[26] 42 C.F.R. § 447.505(d)(13).

[27] 72 Fed. Reg. at 39184.

[28] 72 Fed. Reg. at 39193.

[29] 72 Fed. Reg. at 39192.

[30] 72 Fed. Reg. at 39198.

> Question: Rebates to PBMs, except for their mail order pharmacy purchases are now excluded from AMP. However, many PBMs do not separate their data between mail order pharmacy purchases and non-mail order purchases nor do they provide detailed data for plans under them. In these situations, may a manufacturer exclude the entire PBM rebate, consistent with the general meaning of the rule that sales may only be excluded based on actual data?
>
> Answer: The AMP final rule requires that all sales, rebates, discounts and price concessions to mail order pharmacies, including mail order sales to PBMs, be included in AMP. We expect that manufacturers will take steps to obtain the necessary data to exclude non-mail order PBM rebates. Until they obtain such data, manufacturers may make reasonable assumptions consistent with the statute, regulations, and their customary business practices.

While PhRMA appreciates this attempt by CMS to clarify the treatment of PBM rebates under the final rule, this posted exchange could be read to imply that manufacturers must track the different types of PBM utilization. CMS may be confusing rebates associated with sales to a PBM's owned mail order pharmacy with rebates to a PBM on utilization managed by a PBM that happens to be dispensed by the PBM's mail order pharmacy. As highlighted above, CMS has acknowledged that the administrative burden associated with gathering the latter type of information is part of the reason CMS excluded price concessions to PBMs that are not associated with their mail order business from AMP.[31] Therefore, any obligation to track rebates to PBMs associated with mail order dispensing, which is likely to create significant administrative burdens for manufacturers, runs contrary to the Agency's intent as stated in the final rule.

PhRMA requests that CMS clarify the meaning of this DRA Policy Questions exchange. CMS should state explicitly that if a manufacturer has a rebate agreement with a PBM that has a mail order pharmacy and does not have a separate agreement with the PBM for its mail order purchases, then the manufacturer is not required to implement steps to track utilization that happens to be prescriptions dispensed by the PBM's mail order pharmacy. At the same time, CMS could confirm that where a manufacturer has contracted to receive specific mail order utilization and corresponding rebate information, the manufacturer should treat the rebates paid to the PBM that are associated with prescriptions dispensed by the PBM's mail order pharmacy as rebates for "their mail order pharmacy's purchases" for purposes of 42 C.F.R. §§ 447.504 (h)(22) and 407.505 (d)(13). Such an interpretation of the regulation is consistent with CMS' stated intent in the final rule and does not impose an undue burden on manufacturers.

With regard to Best Price, under 42 C.F.R. § 447.505(d)(13), the definition of Best Price was revised to exclude "PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level." (Emphasis added.) For Best Price purposes, "provider" is defined as a "hospital, HMO, including an MCO or entity that treats or provides

[31] See 72 Fed. Reg. at 39192.

coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care."[32]

These provisions suggest that PBM rebates affect Best Price if they are "designed" to adjust prices to PBM clients such as health plans that provide coverage. It is not clear what "designed" is intended to mean. PhRMA notes that it would be inconsistent to require exclusion of PBM price concessions from AMP so that manufacturers avoid tracking, while requiring such a burden of tracking for Best Price purposes.

Thus, CMS should confirm that in the context of Best Price, like AMP, manufacturers are not expected to undertake the task of determining whether fees or rebates are passed on by a PBM to a customer. CMS should confirm that manufacturers can make reasonable assumptions about the circumstances in which a PBM rebate is "designed" to adjust prices at the retail or provider level. For example, CMS should clarify that it is reasonable for a manufacturer to exclude PBM rebates from Best Price unless the manufacturer's contract with a PBM requires pass-through of PBM rebates to Best Price-eligible clients of the PBM.

E. Base Date AMP

1. Recalculating Base Date AMP Using Reasonable Methodologies

We appreciate that the final rule permits manufacturers to adjust base date AMP in order to account for changes in the law that occurred subsequent to a product launch and the original calculation of base date AMP. The ability to restate base date is critical to ensure that manufacturers do not have a liability for additional rebate amounts solely because of the change in law and CMS' interpretations of the law in the final rule. Nevertheless, we have a number of concerns about the potential limited availability of the restatement.

First, the final rule requires that "[a] manufacturer must use actual and verifiable pricing records in recalculating base date AMP."[33] For products launched in the early years after the Medicaid rebate statute was enacted, manufacturers would have had to retain all records for 10 to 15 years or more, way beyond any recordkeeping requirement imposed by law. Manufacturers may not have documentation that extends for that period.

Second, we have applauded CMS for issuing a rule which is very specific about what sales and transactions are included and excluded from AMP. That level of guidance did not previously exist and is greatly appreciated. Therefore, manufacturers previously may not have maintained data in a way that categorizes sales in the same way that they are categorized in the final rule. Thus, it may be difficult or impossible for manufacturers to restate base date AMP to specifically reflect the revisions in Section 447.504 as required by the rule. For example, the final rule provides several useful refinements to the definition of retail pharmacy class of trade. As a result, there are

[32] 42 C.F.R. § 447.505(b).

[33] 42 C.F.R. § 447.510(c)(2)(iii).

a number of types of transactions for which, prior to October 1, 2007, the effective date of the final rule, manufacturers may not have been breaking out sales data in a way that corresponds to the final rule categories. For instance, as noted in our previous comments, sales to physician offices was a category of sales for which there previously was a lack of guidance and thus prior to the publication of the final rule, manufacturers may not have been tracking sales of covered outpatient drugs to physicians offices specifically. Consequently, it may not be possible for a manufacturer to restate its base date AMP in accordance with the new classifications (like sales to physicians offices), because it will lack the necessary data to do so. PhRMA, therefore, requests that CMS allow manufacturers to make reasonable assumptions in their recalculation of base date AMP. [34] Manufacturers should not be obligated to pay an additional rebate amount in excess of the amount that would have been paid in the absence of the change.

2. Allowing Multiple Recalculations of Base Date AMP

As the law changed January 1, 2007 to exclude customary prompt pay discounts to wholesalers from AMP calculations, but the rule with its changes was not effective until October 1, 2007, there are changes made to AMP twice in 2007. CMS should allow manufacturers to make adjustments to base date AMP to address the varying points in time during which AMP calculations will have changed due to both statutory and regulatory changes.

We believe that a manufacturer should have the ability to restate base date AMP for any changes in the AMP calculation adopted by CMS compared to the methodology the manufacturer used at the time base date AMP was calculated. Manufacturers also should have the flexibility to use a reasonable methodology to approximate the impact of the final rule on their base date AMPs.

Moreover, PhRMA recommends that the recalculated base date AMPs should be applied retroactively to the first three quarters 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 to the proposed rule on the recalculation issue, stated, "[w]e propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP."[35] Further on, CMS states, "[h]owever, 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".[36] The only way to alleviate that additional financial burden is to apply the recalculated base date AMP retroactively to the first three quarters of 2007 when provisions of the DRA that changed the AMP definition were effective. PhRMA 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.

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[34] We note that CMS posted a new DRA Policy Question dated December 5, 2007, on this issue: "Can a manufacturer elect to recalculate a base date AMP to reflect the customary prompt pay discount only and not the other revisions to AMP?" The response was "No." For the reasons, we state above, we request that CMS reconsider this position.

[35] 71 Fed. Reg. at 77185.

[36] 71 Fed. Reg. at 77194.

CMS should therefore allow manufacturers to recalculate base date AMP for the first three quarters of 2007, to account for the statutory change excluding prompt pay discounts that was effective January 1, 2007, and then to allow manufacturers to recalculate base date AMP a second time for the fourth quarter 2007. A recently posted DRA Policy Question (December 5, 2007 posting) asked whether the effective date of all recalculated base date AMPs be denoted as October 1, 2007 or the quarter submitted. CMS responded that "[I]n light of the effective date of the regulation, a recalculated base date AMP should be denoted as October 1, 2007 (3rd Quarter 2007) regardless of the date submitted to CMS within the four calendar quarter deadline. Prior quarter adjustments (PQAs) will be generated back to the October-December 2007 quarter when the submission is later than that quarter." Thus, CMS clearly demonstrates that an effective date of a recalculated base date AMP can be retroactive to a date before the submission and so should allow manufacturers to make these calculations twice for 2007.

3. Treatment of Lagged Price Concessions

According to the regulations, "[a] manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart."[37] Because the new regulations that require manufacturers to estimate lagged price concessions are located in § 447.510(d)(2), and not § 447.504, lagged price concessions should not be included in base date AMP calculations. We appreciate CMS' confirmation in the December 5, 2007 posted DRA Policy Questions that that in recalculating the base date AMP manufacturers are not required to estimate lagged price concessions.

F. Vouchers

We appreciate the substantial changes to the final rule that CMS made with respect to coupons and vouchers, so as to ensure that these items are excluded from AMP, whether the coupons or vouchers are redeemed directly by the consumer or by an entity such as a pharmacy on the consumer's behalf as long as certain conditions are met. These changes respond to concerns raised by PhRMA and others that the approach in the proposed rule could have unintended consequences for patients, particularly low income patients.

There are a number of issues, however, that still require clarification in connection with vouchers. First, in the preamble to the final rule, CMS stated "we believe that vouchers for free samples should be excluded from AMP in instances that the pharmacy receives a replacement product and collects no payment greater than the cost of the sample and a bona fide service fee."[38] In administering a voucher program, a manufacturer is unlikely to know a pharmacy's product acquisition cost and may use a set, market-based formula that is consistently applied to all participants in the program, in order to provide appropriate payment to a pharmacy that dispenses the product to a customer who presents a free sample voucher. For example, such a formula might be WAC plus X%. CMS should clarify that if a manufacturer, in administering a free sample

[37] 42 C.F.R. § 447.510(c)(2).

[38] 72 Fed. Reg. at 39190 (emphasis added).

voucher program, utilizes a set formula to pay the pharmacy, then CMS will not require the manufacturer to include such a transaction in its AMP and Best Price.

G. Patient Assistance Programs

There are a number of differences between the section of the final rule on AMP and the section on Best Price regarding the related treatment of patient assistance programs (PAPs) that do not seem to have a basis in the statute. For example in the DRA Policy Questions posted on the CMS website (the current version of which is dated November 27, 2007), CMS acknowledged that the criteria in the preamble to the final rule regarding the treatment of PAPs is different than the criteria used with respect to the best price exclusion and that CMS intended for the criteria to be the same for best price and AMP. Although the solicitation for comments is directed at comments on the calculation of AMP, we urge CMS to confirm in its rulemaking that the criteria for treatment of PAPs, including with respect to free goods, and Medicare coverage is the same for both AMP and Best Price.

H. Authorized Generics

In the proposed rule, CMS proposed that a "manufacturer holding title to the original NDA of the authorized generic drug must include the direct and indirect sales of this drug in its AMP."[39]

While PhRMA raised concerns about how an innovator manufacturer would capture the prices from the secondary manufacturer to its own customers, so as to include those prices in the innovator drug's AMP and Best Price, none of those concerns were insurmountable. These issues could have been addressed in a number of ways suggested in our comments.

Therefore, we were surprised and concerned with CMS' complete reversal in the final rule on the treatment of authorized generics with respect to AMP. Instead of the proposed rule's approach, CMS now requires a manufacturer holding title to the original NDA to include "the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler."[40] CMS' grounds for reversal lack a basis in the statute and should be reversed.

First, CMS states in the preamble that "unlike the Best Price amendment, the DRA did not amend the definition of AMP. . . ."[41] That is an inaccurate statement and particularly surprising given that CMS interpreted the statute differently in the proposed rule. The DRA amended the Medicaid Rebate statute's definition of AMP to add the following:

> In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section

[39] 71 Fed. Reg. at 77198.

[40] 42 C.F.R. § 447.506(b).

[41] 72 Fed. Reg. at 39200.

> 505(c) of the Federal Food, Drug and Cosmetic Act, such term [AMP] shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.[42]

This statutory provision requires that the innovator drug manufacturer reflect the prices of the authorized generics in its AMP. The final rule appears to ignore the statute, and, as a result, it is not consistent with this statutory requirement. The regulations require that the AMP for an innovator drug include sales of the authorized generic "when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler."[43] A "wholesaler" is defined as "any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug."[44] It is not clear that an authorized generic manufacturer would meet that requirement.

CMS should revise the final rule to reflect the statutory language or should specify that it would be reasonable for a primary manufacturer to treat the secondary (authorized generic) manufacturer as a "wholesaler" for purposes of this provision. PhRMA believes this would be one way to account for the statutory requirement that the innovator AMP include the AMP for the authorized generic.

I. Returns

The regulations provide that Best Price:

> [S]hall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer."[45]

Returns are not enumerated in the Medicaid rebate statute's definition of Best Price as an item that should be included in Best Price. Product may be returned for a variety of reasons, some of which do not serve as price reductions, e.g., expiration, restocking, etc. As Best Price is to be net of returns, CMS should clarify that the term "returns" is included in Section 447.505 to confirm that a return of product whose specific previous sale had triggered the Best Price reverses that specific previous sale and the Best Price trigger. Thus, Best Price does not include that return.

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[42] 42 U.S.C. § 1396r-8(k)(1)(C).

[43] 42 C.F.R. § 447.506(b).

[44] 42 C.F.R. § 447.504(f).

[45] 42 C.F.R. § 447.505(e)(1) (emphasis added).

A different interpretation which might treat all returns regardless of their purpose as discounts, would not be consistent with the statutory language or with CMS' treatment of returns in the context of AMP.

Returns involve the reversal of a sale and do not constitute a price available from the manufacturer for purchase of a drug. For this reason alone, they should not be taken into account in the determination of Best Price (except as noted above to the extent that a return cancels a sale that previously set Best Price). Consistent with this position, CMS did not include returns as part of the list of transactions for which manufacturers must account in ascertaining Best Price in its discussion of Best Price in the preamble to the proposed rule. The preamble to the proposed rule also notes that with this proposed regulation CMS intends to codify the policy embodied in the Medicaid Rebate Agreement with respect to the definition of Best Price. Under the Best Price definition in the Medicaid Rebate Agreement, returns are notably absent.[46]

In connection with the calculation of AMP, the rule excludes from AMP calculations "[r]eturned or replaced goods when accepted or replaced in good faith."[47] Therefore, CMS should specify that returns should affect Best Price only if they are used as price reductions (on products the customer keeps, not on the returned products). In addition, if the returns are made pursuant to a manufacturer policy that was not adopted to distort AMP or Best Price, then the returns should not affect Best Price.

J. TRICARE

We appreciate that CMS responded to comments on the proposed rule regarding the treatment of rebates and price concessions in connection with the TRICARE retail pharmacy program. In the final rule, CMS indicated that TRICARE prices are excluded from Best Price "to the extent section 1927(c)(1)(C)(i)(I) of the [Social Security] Act includes the DoD as an exclusion from Best Price."[48] SSA § 1927(c)(1)(C)(i)(I) does exclude from Best Price any prices charged to DoD on or after October 1, 1992. Therefore, it is unclear what purpose is served by the limiting language "to the extent" prices to DoD are exempt from Best Price. CMS should therefore clarify that it did not intend to limit the application of this exclusion with the phrase "to the extent" and that TRICARE prices and rebates, available on or after October 1, 1992, whether pursuant to a voluntary rebate agreement or otherwise with DoD or another agency on DoD's behalf, are excluded from Best Price.

K. Aggregating Discounts to Different Customers for Best Price Purposes

The Medicaid rebate statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance

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[46] See 56 Fed. Reg. 7049, 7050, § I(d) (Feb. 21, 1991).

[47] 42 C.F.R. § 447.504(h)(21).

[48] 72 Fed. Reg. at 39199.

organization, nonprofit entity, or governmental entity within the United States."[49] There are a number of statements in the preamble to the final rule that raise questions regarding CMS' treatment of discounts to different entities for Best Price purposes. If the Medicaid rebate statute required manufacturers to aggregate discounts to different customers, Best Price would be the lowest net price realized by the manufacturer, as opposed to the lowest price available to one of the specific customers named in the statute. However, the statute does not say Best Price is the "lowest net price realized by the manufacturer." Thus, CMS should confirm that manufacturers should not aggregate discounts to different customers in determining Best Price.

Thus, for example, where a manufacturer provides a $2 prompt pay discount to a wholesaler and a $10 rebate to an end-user on a product for which the WAC is $100, the $90 price to the end-user customer and the $98 price to the wholesaler would be the prices relevant to the determination of Best Price. Assuming that no other prices are relevant for Best Price determination purposes, the $90 price to the end-user customer would be the Best Price (not an $88 aggregated price that was not actually available to any customer).

PhRMA recommends that CMS confirm that, while all non-exempt price concessions to a Best Price-eligible entity must be accounted for in determining the lowest price to the relevant entity (and thus in determining Best Price), this does not mean that manufacturers should combine price concessions to different entities to determine Best Price. Such an aggregated price would not satisfy the statutory definition of Best Price, because it is not a price available to a Best Price-eligible entity. Instead, manufacturers should determine the lowest prices available to each Best Price-eligible customer for a particular drug, compare those prices, and then report the lowest price paid by a single Best Price-eligible customer.

There are a number of statements on this issue included in the final rule that necessitate this clarification.

First, CMS stated that it did not agree with commenters who asserted that the proposed rule could be misconstrued as requiring manufacturers "to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price."[50] PhRMA requests that CMS confirm that its disagreement with the commenters is based on the fact that aggregating price concessions to different customers' results in a net price that is not actually available to any Best Price-eligible purchaser. As a result, a price constructed by aggregating price concessions to different entities fails to meet the requirements of the statutory definition of Best Price: "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."[51]

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[49] 42 U.S.C. 1396r-8(c)(1)(C)(i).

[50] 72 Fed. Reg. at 39198.

[51] 42 U.S.C. § 1396r-8(c)(1)(C)(i).

Second, CMS stated that "[b]oth the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price."[52] CMS should clarify that it did not intend to require manufacturers to aggregate prompt pay discounts to wholesalers with price concessions to an end-user generally but only when the discount to the wholesaler is designated in the contract to be passed onto the end use customer. PhRMA recommends this result because the end user customer is the intended recipient of the discount and adding this discount to the other discounts provided to that customer is not aggregating discounts to different entities. These price concessions, added together, result in a price paid by a single Best Price-eligible customer, not an artificial price derived from adding price concessions to different entities.

PhRMA would appreciate CMS clarifying how to handle, for Best Price purposes, a contract that designates that a rebate, or portion thereof, that is paid to a PBM must be passed on to the PBM's customer. We believe the designated portion of the rebate is designed to adjust prices at the level of that customer. Consequently, the amount of the rebate that is contractually required to be passed on to an end-user customer should be aggregated with any other price concessions available to that end-user customer for the purposes of determining Best Price (assuming the end-user customer is a Best Price-eligible entity). Therefore, the portion of the rebate that is passed on to the end-user customer should not be treated as having been retained by the PBM (and thus should not be treated as a rebate on purchases by the PBM's mail order pharmacy, where such a purchase is involved).

Finally, CMS stated in the final rule that "[a]s we have previously stated, there is no basis to exclude these discounts [prompt pay discounts to wholesalers, and price concessions to an end-customer under a contract administered through a wholesaler chargeback arrangement]."[53] CMS guidance is that all eligible price concessions must be taken into account in determining the lowest price available to each individual Best Price-eligible customer. However, it is the price available to a specific Best Price-eligible customer that sets Best Price and not the aggregation of price concessions to different customers.

L. Nominal Price

In the final rule, CMS requires manufacturers to report on a quarterly basis, "[p]rices that fall within the nominal price exclusion."[54] The requirement specifically refers to the list of entities that are listed in Section 447.508(a). However, in the DRA Policy Questions, currently dated November 27, 2007, CMS provided the following question and answer:

> Question: Should manufacturers who sell drugs at less than 10 percent of AMP to 340B covered entities, state owned or operated nursing facilities or ICF/MR

[52] 72 Fed. Reg. at 39199.

[53] 72 Fed. Reg. at 39199.

[54] 42 C.F.R. § 447.510.

facilities through a federal supply schedule (FSS) contract include these sales in their nominal price reporting?

Answer: No. Manufacturers are not required to submit reports concerning prices charged under the FSS. Therefore, manufacturers should include only those sales in nominal price that would otherwise be included in best price.

The FAQ is confusing because on one hand it could be interpreted to mean that the nominal price reporting is for sales included in Best Price. On the other hand, it could be read to mean that CMS is requiring that the quarterly report on nominal sales be made for those sales that would otherwise be included in best price but for the nominal sales exclusion under Section 447.508. The latter interpretation seems the better reading, but CMS should clarify that if a sale were otherwise excluded from best price, the fact that it is to one of the enumerated entities in Section 447.508 would not matter and no reporting of the sale for nominal price reporting would be required. CMS should revise Section 510(a)(4) to add "and are not otherwise excluded under section 447.505(b)" after "Prices that fall within the nominal price exclusion."

H. Guidance Process Practices

PhRMA greatly appreciates CMS' willingness and efforts to provide additional guidance to manufacturers regarding the interpretation and implementation of the final rule. Many PhRMA members have utilized tools such as the DRA Policy Questions, which are posted on the CMS website, to seek guidance on questions relevant to the Final Rule. Based on our members' experiences, PhRMA offers the following observations, which we hope will help CMS continue to refine its guidance process practices.

CMS should publicly announce, perhaps via blast email or notice on its website, when it updates or modifies existing guidance. For example, at least four separate versions of the DRA Policy Questions have been posted on the CMS website. Although PhRMA appreciates the ongoing efforts of the Agency to address questions through this tool, CMS should alert stakeholders when it posts a new or modified document. Furthermore, it would be useful for CMS to highlight in some manner how a new version differs from a previous version and to add a "date issued" or "date last revised" to each entry.

CMS should also consider that when it issues an FAQ or alters or modifies a previous statement, manufacturers begin taking actions to respond appropriately to such changes. Therefore, it is critical that each FAQ be written in a manner that avoids ambiguity. Second, if CMS intends merely to refine a position, it should avoid deleting the FAQ from one version of its guidance only to repost it in slightly modified form in a later version. (For example, recently CMS deleted an FAQ on "smoothing of AMP" from the DRA Policy Questions and then, after an intervening period, put up a new FAQ substantially similar to the deleted FAQ on smoothing; but taking down the old FAQ had confused manufacturers by leading them to think that CMS was making a substantive change in its smoothing guidance.) If the timing of a change necessitates a withdrawal before a subsequent posting, CMS should alert manufacturers of an impending change to prevent them from taking premature or unwarranted actions.

Finally, it takes time for systems to be changed to reflect additional guidance and CMS should consider the extent to which such changes may be necessary and the period in the reporting cycle during which CMS is issuing such guidance for whether a manufacturer may be able to take the latest guidance into account in its monthly or quarterly reports.

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PhRMA appreciates the opportunity to provide these additional comments to CMS regarding the final rule. We look forward to further fruitful interactions with CMS on these and other important issues related to the Medicaid Drug Rebate Program. It is our hope that these comments will be of assistance to CMS as it seeks to provide clear and specific guidance to all the parties participating in the Medicaid Drug Rebate Program. Please do not hesitate to contact us with questions or requests for further information.

Sincerely,

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NOVARTIS

December 20, 2007

BY OVERNIGHT MAIL

Kerry N. 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 Administrator Weems:

I am pleased to submit the following comments on behalf of Novartis Pharmaceuticals Corporation ("Novartis"), regarding the above-referenced rule (the "Final Rule").[1] We provide a broad portfolio of innovative, effective, and safe products in diversified treatment areas, including oncology, primary care, transplantation, and ophthalmics. In addition, Novartis aims to harness the latest advances in biomedical research and technology to develop new therapies with the potential to benefit millions of patients throughout the world.

We thank the Centers for Medicare & Medicaid Services for providing guidance in the Final Rule regarding the calculation of average manufacturer price ("AMP") and Best Price, and we support many of CMS' proposals. We write, however, to highlight areas where we believe manufacturers would benefit from additional clarification of the Final Rule.

I. CMS Should Provide Additional Guidance on "Bundled Sales"

A. CMS Should Clarify the Scope of the Definition of Bundled Sales

Novartis requests CMS to provide additional guidance as to the types of arrangements that should be considered to be bundled sales. The scope of the revised definition of bundled sale included in the Final Rule still is unclear in many respects. CMS should further confirm the precise boundaries of the definition so that manufacturers can properly and consistently classify their contracts under the Final Rule's definition. In particular, Novartis believes that CMS should confirm and/or clarify the following issues:

[1] 72 Fed. Reg. 39,142 (July 17, 2007).

Inclusion of non-contingent drugs in discount reallocation: Novartis urges CMS to confirm that products that are merely included in the same contract as other products that are "bundled" or linked are not part of the bundle and need not be included in the discount reallocation calculation. Manufacturers and customers that enter into discount contracts often include the entire portfolio of a given manufacturer's products in such contracts rather than separately contracting for individual products or groups of products. This practice is simply more efficient from a contracting point of view and should not result in the designation of all of the manufacturer's products as being "bundled". Novartis believes CMS intended the bundled sale definition to apply solely to those products in a contract or arrangement that are linked by purchase or performance requirements, but is concerned that the preamble discussion of the definition could be read to suggest that all products in a contract containing a bundle become part of that bundle. Novartis requests that CMS confirm that the bundled sale definition is limited to contingent or linked products and that other products that are included in the same contract are not included in the bundle.

Products included in market share measurements: In the case of an arrangement that satisfies the bundled sales definition because it involves a performance requirement in the form of a market share requirement, Novartis requests that CMS confirm the treatment of products included in the denominator of the market share measurement. Such performance requirements typically require that the customer's purchases of the contracted product be no less than a specified percentage of the customer's overall purchases of products in the applicable therapeutic category (or market basket). To calculate the market share, the customer's purchases of the contracted product (the numerator) are divided by the customer's purchases of all products in the therapeutic category (the denominator). Where a manufacturer sells multiple products in that therapeutic category, it is possible that the contract will offer a discount on only one of those products, but other of the manufacturer's products in that same category may be included in the denominator because they are part of the total universe of products in the therapeutic category. Novartis requests CMS to confirm that the presence of the manufacturer's non-contracted products in the denominator of the market share calculation does not cause those other products to be part of the contracted product's "bundled sale." This approach is appropriate because the other products' presence in the denominator is actually a disincentive to the customer to purchase those products, because doing so will lower the relative market share of the contracted product.

Temporal bundles: In the preamble to the Final Rule, CMS indicates that it considers contracts involving discounts based on prior period performance to require application of the reallocation calculation "to all drugs for all quarters including prior purchases used in the calculation of the discount."[2] Over successive quarters, this approach would become complex and increase the risk of error in the case of Best Price because for each quarter the manufacturer would need to determine the discount earned and retained in the reporting quarter as well as the discount attributable to the quarter from the immediately subsequent quarter. In addition to being difficult to apply, Novartis believes that this interpretation is inconsistent with the goals of the Medicaid drug rebate program.

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[2] 72 Fed. Reg. at 39,159.

For example, consider an arrangement that measures market share on Product A in Q1, and based on that market share in Q1, provides a discount on Product A in Q2. The arrangement continues with each successive quarter, such that the market share on Product A in Q2 determines the discount on Product A in Q3, and so on. If the Final Rule requires the discount in Q2 to be reallocated across sales in Q2 and Q1, and the discount in Q3 to be reallocated across sales in Q3 and Q2, the Best Price calculation for Q2 would require the manufacturer to calculate the amount of discount in Q2 that is NOT reallocated back to Q1, and then add to that amount the amount of discount in Q3 that is reallocated back to Q2. Such a requirement significantly increases the complexity and risk of error in the calculation, and without necessarily serving the goals of the Rebate program. Specifically, the reallocation of a single quarter's discounts across two quarters of sales has the effect of lessening the discount amount per unit and therefore the likelihood that the discount will set a lower Best Price. CMS's interest in ensuring a lower Best Price will be better served by requiring manufacturers to attribute such "temporal bundle" discounts solely to the quarter in which the sales occurred on which the discounts were applied.

B. The Bundled Sales Provisions Should Not Be Applied Retroactively

CMS has stated that the regulations published in the Final Rule are effective starting October 1, 2007 unless CMS otherwise indicates an alternative effective date.[3] However, CMS also has stated that the Final Rule "is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect."[4] We understand these directions to mean that existing polices regarding price reporting that are consistent with the Final Rule remain in effect but that any new polices are effective as of October 1 unless CMS indicates an alternative effective date for such new policies.

The Medicaid Rebate Agreement and the Final Rule define bundled sales differently. Under the Medicaid Rebate Agreement, a bundled sale is defined 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."[5] The Final Rule, however, defines a bundled sale as:

> an 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 72 Fed. Reg. at 39,142, 39,157.

4 72 Fed. Reg. at 39,157.

5 Medicaid Rebate Agreement, § 1(e).

available had the bundled drugs been purchased separately or outside the bundled arrangement.[6]

As made evident by the italicized language, the Final Rule definition of bundled sales differs significantly from that of the Medicaid Rebate Agreement. The Final Rule definition, for example, now includes arrangements involving "the purchase of the same drug." The Final Rule definition also, for the first time, defines drugs of different types as products that have different nine-digit NDCs.

Despite these clear differences between the Agreement and Final Rule definitions, the Preamble states that the Final Rule "do[es] not create a new definition for bundled sales, but merely clarif[ies] the existing definition."[7] This statement suggests that CMS intends to apply the new bundled sale definition to reporting periods prior to the October 1, 2007 effective date. The definition of "bundled sale" in the Final Rule is not a simple clarification of the language in the definition of "bundled sale" in the Medicaid Agreement, however. Rather, as discussed above, the Final Rule definition and the related allocation methodology are new substantive requirements that should apply only as of October 1, 2007. We request that CMS confirm that the Final Rule requirements for bundled sales are new polices that are effective as of October 1, 2007 and need not be applied to AMP and BP calculations for quarters prior to that date.

II. The Final Rule's Authorized Generic Provisions Should Be Consistent with the Statutory Requirements

CMS is obligated to issue regulations that are consistent with the provisions of the applicable authorizing statute. In our view, the Final Rule's provision regarding the treatment of authorized generics in the calculation of AMP is not consistent with the Deficit Reduction Act of 2005 ("DRA"). In particular, Novartis urges CMS to clarify that the primary manufacturer may include the sales of the secondary manufacturer in the calculation of the branded product AMP, which would be consistent with the DRA.

The DRA requires that calculations of AMP "be inclusive of the average price paid" for authorized generic drugs "by wholesalers for drugs distributed to the retail pharmacy class of trade."[8] In addition, the DRA requires the inclusion of authorized generics in the calculation of Best Price.[9]

Novartis believes that CMS has issued regulations that are inconsistent with the DRA's revisions to the statutory definition of AMP. On December 22, 2006, CMS issued a proposed rule (the "Proposed Rule") to implement the DRA in which it "propose[d] to interpret . . . the DRA to include in the best price and AMP calculations of the branded drugs, the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand

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6 72 Fed. Reg. at 39,240 (42 C.F.R. § 447.502) (emphasis added).

7 72 Fed. Reg. at 39,159.

8 42 U.S.C. § 1396r-8(k)(1)(C).

9 Id. at § 1396r-8(c)(1)(C)(ii)(IV).

manufacturer (or NDA holder)."[10] Under the Proposed Rule, CMS required the inclusion of secondary manufacturer sales in the primary manufacturer's AMP calculation. Thus, CMS originally interpreted the DRA as requiring the primary manufacturer to include authorized generics in the brand product AMP even when all commercial sales were made by the secondary manufacturer.

In contrast, the Final Rule does not require blending. The Final Rule provides:

> (b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP *only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.*[11]

Under this provision, CMS limits the scope of authorized generic sales that are included in AMP to those of the primary manufacturer. Although the statute requires the inclusion of "the average price paid . . . by wholesalers," the Final Rule limits the authorized generic drugs to be included in the calculation to only those authorized generics "sold by the manufacturer holding title to the original NDA directly to a wholesaler." The effect of the Final Rule is to exclude the sales of the secondary manufacturer from the calculation of AMP, rather than having AMP reflect the sales of both the primary and secondary manufacturer. CMS specifically states in the Final Rule that "the primary manufacturer should not include within its AMP calculation any pricing data concerning the sale by the secondary manufacturer regarding the authorized generic product."[12] Rather, CMS directs primary and secondary manufacturers to separately report their calculations of AMP based on sales of the branded and generic drugs respectively.[13]

The authorized generic provision described above is inconsistent with the DRA itself. As amended by the DRA, the revised statutory definition of AMP requires that sales of authorized generic drugs be included in a manufacturer's calculation of AMP for purposes of the Medicaid Drug Rebate Program. Specifically, the new subsection (C) to the definition of AMP contained at (k)(1) provides:

> In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application ... [AMP] shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.[14]

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10 71 Fed. Reg. 77,174, 77,183 (Dec. 22, 2006).

11 42 C.F.R. § 447.506(b); 72 Fed. Reg. at 39,243 (emphasis added).

12 72 Fed. Reg. at 39,201 (emphasis added). CMS explained that the primary manufacturer is "the manufacturer that holds the NDA," and the secondary manufacturer is "the manufacturer that markets and sells the authorized generic drug." *See id.* at 39,199.

13 72 Fed. Reg. at 39,200.

14 42 U.S.C. § 1396r-8(k)(1)(C).

This language includes sales by parties other than "the manufacturer" itself in the calculation of AMP. Statutory construction requires that all statutory terms be given meaning.[15] By restricting AMP to the sales of the primary manufacturer, CMS is not giving meaning to the DRA's requirement that AMP is to be calculated based on prices paid "by wholesalers."

In addition, CMS's new interpretation of the authorized generics provisions conflict with the DRA's additional amendment to the statute's subsection relating to AMP reporting. That amendment directs that "[e]ach manufacturer with [a rebate agreement] shall report to the Secretary ... on the average manufacturer price (as defined in subsection (k)(1)) ... for covered outpatient drugs ... including for all such drugs that are sold under a new drug application."[16] By including this broad provision in addition to the language in the AMP definition in subsection (k), Congress clearly indicated that *all* sales of authorized generics sharing an NDA should be part of the AMP calculation.

Novartis also disagrees with CMS's concern that inclusion of secondary manufacturer sales in the branded product AMP would present antitrust concerns and administrative difficulties. Such concerns are allayed by the fact that the primary manufacturer could include the secondary manufacturer's sales in the branded product AMP by deriving a weighted average of the AMPs for the branded and authorized generic products. This approach would be no more burdensome than the weighted averaging that the Final Rule already requires manufacturers to perform when deriving a quarterly AMP from monthly AMPs.[17] In addition, the primary manufacturer would not need to be privy to any market sensitive information because the weighted average AMP for the two products can be derived using the numerator and denominator of the AMP for the secondary manufacturer, which is no more market sensitive than the secondary manufacturer's resulting AMP figure. That AMP figure will be made public under the DRA, and the primary manufacturer certainly should be able to rely on the same AMP data, which the secondary manufacturer itself will be obligated to certify, to derive the weighted average AMP.[18] Thus, we do not believe CMS has a legitimate policy basis for preventing the blending of AMP data with respect to authorized generics.

In order to properly implement the statutory requirements of the DRA, Novartis strongly urges CMS to revise the Final Rule provision regarding the treatment of authorized generics in AMP to permit manufacturers to include secondary manufacturer sales in the branded product's AMP calculation.

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15 *Nat'l Insulation Transp. Ctte. v. ICC*, 683 F.2d 533, 537 (D.C. Cir. 1982) (holding that Court must give effect to every phrase of statute so that no part is rendered superfluous); *Wilderness Soc. v. Morton*, 479 F.2d 842, 857 (D.C. Cir. 1973) ("It is a well-known maxim of statutory construction that all words and provisions of statutes are intended to have meaning and are to be given effect, and words of a statute are not to be construed as surplusage").

16 42 U.S.C. § 1396r-8(b)(3)(A)(i)(I) (emphasis added).

17 See 42 C.F.R. § 447.504(i)(2).

18 The sharing of the secondary manufacturer's Best Price data with the primary manufacturer would have presented such a concern, but the Final Rule's requirement that the primary manufacturer reports its sale price to the secondary manufacturer as the Best Price for the branded product eliminated the need to share this type of sensitive information.

III. CMS Should Clarify the Calculation of Best Price

Novartis believes that some of the discussion contained in the preamble is inconsistent with the Final Rule itself and therefore raises questions regarding the meaning of those regulatory provisions. For the reasons stated below, Novartis requests that CMS confirm that discounts provided to separate customers do not need to be aggregated when calculating Best Price, and that administrative fees paid to Group Purchasing Organizations ("GPOs") that are not purchasers themselves need not be counted in Best Price unless those fees are passed back to a GPO member.

A. Discounts Should Only be Aggregated for Best Price Where Realized by a Single Purchaser

The statutory definition of Best Price directs a manufacturer to report as its BP the manufacturer's lowest price to a given qualifying entity:

> 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.*[19] (emphasis added).

The Agreement and Final Rule definitions similarly define Best Price as a price realized by a particular entity.[20] These definitions' consistent focus on the price received by a particular purchaser or provider indicates that manufacturers need not aggregate discounts provided to different purchasers or providers when determining Best Price. The statute's use of the term "any" before the list of entities reinforces this conclusion, because it requires a determination of the price received by each entity individually.

This conclusion is also supported by the different language CMS uses to define AMP. The definition of AMP focuses on the average price received by the manufacturer,[21] and because of that manufacturer focus, appropriately requires inclusion of discounts across all retail purchasers when calculating AMP. The language in the definition of Best Price instead focuses on the individual purchaser or provider, and that difference in language and focus further supports the conclusion that manufacturers are obligated to aggregate discounts when calculating Best Price only when those discounts are provided by the manufacturer directly or indirectly to the same purchaser or provider.

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19 42 U.S.C. §1396r-8(c)(1)(C)(i)(2007).

20 Agreement at § I(d); 42 C.F.R. § 447.505(a).

21 42 C.F.R. § 447.504(a).

The preamble to the Final Rule contains several responses to comments, on pages 39,198 to 39,199, that could be read to suggest, notwithstanding these definitions and prior silence by CMS on this issue, that such aggregation now may be required in the BP calculation. 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, Novartis interprets those definitions to provide, and urges CMS to confirm, 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.

B. GPO Fees Should Only Be Included in Best Price If They are Passed On to the Final Purchaser

In light of the Final Rule's definition of Best Price and that definition's focus on the price received by a particular purchaser or provider, Novartis urges CMS to clarify that any administrative fees paid to a GPO that is not a purchaser itself are included in the calculation of Best Price only when they affect the price realized by a purchaser or provider, i.e. the GPO, passes back the fee to its members. Where such fees are paid to a GPO that is not a purchaser and the fees are not passed back to a GPO member that is a purchaser, the fees simply do not affect the manufacturer's price to the member and should not be included in the calculation of Best Price.

This position is consistent with the Final Rule's existing guidance regarding the treatment of Pharmacy Benefit Managers ("PBMs") in Best Price. The Final Rule notes that PBMs are not directly involved in the supply chain and therefore specifies that price concessions to PBMs are not included in Best Price except where rebates provided to PBMs adjust prices received by purchasers or providers.[22] The same logic applies to GPOs, which also are not typically purchasers themselves or involved in the supply chain. Where fees paid to those GPOs are passed back, however, and therefore affect price at the purchaser or provider level, those fees, like PBM discounts, should be included in Best Price. Novartis urges CMS to clarify this point.

[22] 72 Fed. Reg. at 39,198.

IV. CMS Should Confirm that All Discounts to Pharmacy Benefit Manager ("PBM") Mail Order Pharmacies Should Be Included in the Calculation of AMP

Under the Final Rule, sales and discounts to mail order pharmacies operated by PBMs are included in the calculation of AMP. [23] Novartis interprets this direction to require inclusion of price concessions provided to PBMs in relation to their mail order pharmacy operations purchases in all circumstances. Specifically, Novartis believes this requirement applies both where the mail order pharmacy purchases product directly from the manufacturer as well as where the mail order pharmacy purchases indirectly through a wholesaler. Similarly, Novartis believes that this requirement applies regardless of the form that the price concession takes – whether through an on-invoice price reduction, a chargeback, or a rebate based on PBM-furnished utilization data. Novartis believes that there is confusion in the industry regarding these factors, however, and so requests that CMS confirm that all discounts paid by the manufacturer on PBM-operated mail pharmacy purchases should be included in the calculation of AMP.

V. CMS Should Confirm that Health Management Organization ("HMO") and Managed Care Organization ("MCO") Closed-Door Mail Order Pharmacies Are Not in the Retail Class of Trade

The Final Rule provides that sales reimbursed by a HMO or MCO that does not take possession of product should remain in AMP, but sales directly to such entities should be excluded from AMP.[24] In the preamble to the Final Rule, CMS specifies that "HMO-operated pharmacies that purchase drugs and provide these drugs only to their enrollees are excluded from AMP."[25] This is confirmed by the text of the Final Rule, which excludes "Sales to HMOs (including MCOs and HMO/MCO-operated pharmacies) that purchase or take possession of drugs."[26]

Novartis requests that CMS clarify that this requirement to exclude from AMP sales to HMO/MCO pharmacies applies not only where the pharmacy is on-site at the HMO or MCO facility but also where it is a mail order pharmacy operated by the HMO or MCO and dispenses product solely to the HMO/MCO's enrollees. Where the manufacturer can confirm that the mail order pharmacy is operated by the HMO/MCO and dispenses only to enrollees of the HMO/MCO, Novartis believes there is no basis for distinguishing such a mail order pharmacy from a captive bricks-and-mortar pharmacy that is on-site at the HMO/MCO facility. We therefore ask CMS to confirm that manufacturer sales to an HMO/MCO-operated mail order pharmacy that dispenses product solely to enrollees also should be excluded from the calculation of AMP.

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23 Id. at 39,241 (42 C.F.R. § 447.504(g)(6)).

24 Id. at 39,241 (42 C.F.R. §§ 447.504(g)(15) & 447.504(h)(5)).

25 72 Fed. Reg. at 39,181.

26 72 Fed. Reg. at 39,241 (42 C.F.R. § 447.504(h)(5)) (emphasis added).

VI. CMS Should Confirm That Manufacturers May Apply Lagged Price Concessions on an Actual Basis in Restatements of Base Date AMP

Under the Final Rule, manufacturers may restate base date AMPs to account for changes to the definition of AMP, including changes to the definition of retail class of trade.[27] Manufacturers must use actual data in any recalculations, not estimates or reasonable assumptions, and must also use the definition of AMP provided in the new 42 C.F.R. §447.504.[28] Manufacturers have four quarters from the publication of the Final Rule to submit the recalculated base date AMPs.[29]

In its most recently posted DRA Policy Questions document, CMS indicates that manufacturers can calculate a single quarterly AMP and need not calculate a monthly AMP for each of the months in the base date quarter and then calculate a weighted average of those AMPs to determine the revised base date AMP. Novartis requests that CMS also clarify that manufacturers need not use a 12-month rolling average estimation methodology for lagged price concessions when calculating the revised quarterly base date AMP. Given that base date AMPs will be calculated based on historical data, it is unnecessary to estimate lagged price concessions for that calculation. Manufacturers will know all lagged price concessions relating to a past base date quarter and be able to account for those transactions on an actual basis in the recalculation. This approach is consistent with the Final Rule itself, as section 447.510, which govern such recalculations, specifies only that the recalculation comply with section 447.504, and the requirement to use the 12-month rolling average exists in section 447.510(d)(2). Novartis therefore requests clarification from CMS that recalculations of base date AMP can apply lagged price concessions on an actual, non-estimated, basis.

VII. CMS Should Clarify that Non-customary Prompt Pay Discounts May Be Treated as Non-lagged

Customary prompt pay discounts are excluded from AMP under the Final Rule.[30] Although Novartis understands that prompt pay discounts that are not customary must be included in the calculation of AMP, we seek clarification regarding the treatment of such discounts. In particular, we note that it may be difficult to quantify the exact date when a particular non-customary prompt pay discount is taken where such data are only available through accounts receivable transactions and thus are not easily accessible. In order to ensure a more accurate calculation of AMP, Novartis believes manufacturers should be able to account for non-customary prompt pay discounts on the date that they are offered (i.e., the invoice date) and requests CMS to confirm the acceptability of such an approach.

VIII. CMS Should Clarify That Manufacturers May Use a 12-month Rolling Average Methodology to Estimate Lagged Ineligible Sales

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27 Id. at 39,243 (42 C.F.R. § 447.510(c)).

28 Id.

29 Id.

30 72 Fed. Reg. at 39,242 (42 C.F.R. § 447.504(h)(20)).

Novartis requests that CMS confirm the permissibility of using a 12-month rolling average methodology to estimate lagged ineligible sales in the Medicaid context. CMS currently permits use of the 12-month estimation methodology for lagged ineligible sales in the context of the Medicare average sales price calculation,[31] and Novartis requests that CMS expressly permit manufacturers to use such a methodology in their calculation of AMP.

Such a clarification is particularly important because one of the questions and answers included in the most recently posted DRA Policy Questions could be read (incorrectly we believe) to suggest that use of such a methodology is not permitted. In response to the question "May a manufacturer opt to smooth sales that are excluded from AMP?", CMS responds:

> No. For the purposes of Medicaid, only the discounts, rebates, and other price concessions associated with sales included in AMP should be used in the 12-month rolling average to estimate the value of lagged price concessions.

Novartis agrees with the answer's statement that AMP-ineligible sales should not be included in the denominator of the lagged eligible price concessions estimation ratio, in accordance with the ASP methodology defined at 42 C.F.R. §414.804. However, Novartis is concerned that this answer could be read to prohibit use of a 12-month rolling average methodology to estimate the lagged ineligible sales themselves.

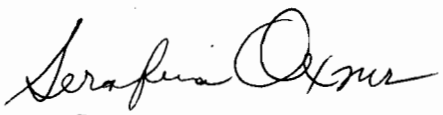
As CMS knows, manufacturers use lagged price concession data, such as chargebacks and rebates, to identify ineligible sales that must be removed from the AMP calculation. Thus, manufacturers will need to develop an estimation methodology for these lagged ineligible sales because, as is the case with lagged price concessions generally, manufacturers do not have all the necessary data available within the 30 day AMP reporting period to accurately quantify these sales. Novartis therefore requests that CMS confirm that a 12-month rolling average methodology may be used to estimate lagged ineligible sales.

* * *

[31] See 71 Fed. Reg. 69,624, 69,670 (Dec. 1, 2006).

Novartis thanks CMS in advance for its serious consideration of these comments and we look forward to working together to ensure accurate Medicaid price reporting. Please contact me at 862-778-8300 or serafina.oxner@novartis.com if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Serafina Oxner
Executive Director
Healthcare Contract Administration
Novartis Pharmaceutical Corporation

Bayer HealthCare

December 17, 2007

Hand-Delivery

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2238-FC: Medicaid Program; Prescription Drugs

Bayer HealthCare LLC

400 Morgan Lane
West Haven, CT 06516

Phone: 203-812-2000

Dear Administrator Weems:

Bayer Healthcare LLC ("Bayer") thanks the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") for its continued efforts to ensure that beneficiaries have access to high-quality drugs and biologics under the Medicaid Program. For over 100 years, Bayer has dedicated itself to the development and production of such high-quality drugs and biologics.

We appreciate this opportunity to comment on the final rule with comment period that implements the provisions of the Deficit Reduction Act of 2005 ("DRA") pertaining to prescription drugs under the Medicaid Program (the "Final Rule").[1] We have previously raised questions regarding the restatement of base date average manufacturer price ("AMP"), the treatment of pharmacy benefit manager ("PBM") concessions for best price determinations, the degree of consistency required when selecting dates used for lagged items, and the consideration of previous purchases in determining whether a "bundled sale" exists. Our comments below focus primarily on these issues and select other areas where additional guidance or clarification would be particularly helpful to manufacturers.

[1] Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., Medicaid Program; Prescription Drugs; Final Rule ("Final Rule"), 72 Fed. Reg. 39,142 et. seq. (Jul. 17, 2007).

Bayer presents the following issues, in summary, for your consideration:

- **AMP Calculation**

  - *Application of the Final Rule:* We ask CMS to acknowledge explicitly that the new regulations and guidance issued within the Final Rule represent substantive rules that must be applied prospectively only.

  - *Bundled Sales:* Bayer believes that CMS, at least temporarily, should permit manufacturers to continue making such reasonable assumptions consistent with the Medicaid Rebate Agreement treatment of bundled sales. A delay in implementing the new bundling rule will permit CMS to reconsider the regulatory definition of "bundled sale" concurrently in both the Medicaid and Medicare contexts, and to address the difficult bundling questions that will have arisen under the Final Rule.

  - *Bona Fide Service Fees:* We request that CMS clarify that all fees for service that meet the regulatory definition in § 447.502 may be considered bona fide service fees. In addition, we believe that manufacturers would benefit from more detailed guidance as to some possible methods for evaluating whether a fee reflects fair market value.

  - *Patient Assistance Programs ("PAPs"):* Bayer requests that the Agency confirm that it has distinguished PAPs that offer free goods assistance from those that only offer parties financial assistance.

  - *Manufacturer Coupons:* We are troubled that the preamble discussion differs substantively from the regulation, and request clarification as to which test applies. Additionally, we question the scope of the preamble discussion requiring that a manufacturer establish a benefit amount of the coupon absent "negotiation" with a third party. As such, we urge CMS to acknowledge explicitly that "negotiation" does not include market research or other attempts to gather information from third parties that fall short of creating an agreement regarding the benefit design.

- **Best Price Calculation**

  - *PBM Price Concessions:* We encourage CMS to state explicitly that, when determining whether it may permissibly exclude a PBM concession pursuant to § 447.505(d)(13), a manufacturer should examine its own intent in designing the concession.

- **Manufacturer Reporting Requirements**

  - *Restatement of Base Date AMP for Older Products:* Bayer respectfully requests that CMS clarify that, although § 447.510(c)(2) requires the use of actual data, it does not mandate the use of actual data exclusively. As such, manufacturers may rely, in part, on estimates and reasonable assumptions.

  - *Restatement of Base Date AMP for Divested Products:* We urge CMS to state plainly that the statute and regulations do not create an affirmative obligation for the original manufacturer to assist the current manufacturer in its base date AMP recalculation.

  - *Prompt Pay Discount:* We ask CMS to confirm that manufacturers may permissibly use reasonable assumptions in connection with § 447.510(a)(3).

  - *Lagged Price Concessions:* Bayer encourages CMS to confirm that the consistency noted in the preamble refers to the calculation of AMP and best price separately and not both together. So long as there is an appropriate reason for using different methodologies in addressing lagged items, such inconsistency between the AMP and best price calculations is not problematic.

  - *Lagged Ineligible Sales:* We urge CMS to permit more explicitly manufacturers to employ smoothing methodologies for lagged ineligible sales.

We appreciate very much your willingness to consider these issues further in developing Medicaid policy. To that end, we are including draft questions and answers ("Q&As") on many of these topics. We hope that you will consider our suggestions carefully as you issue additional guidance on these important issues.

I. AMP Calculation

We offer comments on the AMP calculation regarding the following: application of the Final Rule, bundled sales, bona fide service fees, PAPs, and manufacturer coupons.

A. Application of the Final Rule

The Final Rule established an effective date of October 1, 2007 for most sections, with the exception of those sections which the statutory provisions of the DRA mandated to take effect at an earlier date. CMS unnecessarily introduced ambiguity as to the effective date of numerous provisions, however, by characterizing certain changes in regulatory policies as mere "clarifications" of existing guidance. We ask CMS to acknowledge that the new regulations and guidance issued within the Final Rule represent substantive rules that, pursuant to the Administrative Procedures Act ("APA"), must be applied prospectively only.

The APA defines a substantive rule as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."[2] There can be no doubt that the Final Rule represents a substantive rule. As such, the Final Rule can have only a future effect – for, as Justice Scalia explained, "rules have legal consequences only for the future."[3]

Indeed, the Supreme Court has held that "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."[4] Because Congress has not expressly granted CMS the ability to implement retroactive regulations pursuant to the DRA, CMS cannot give retroactive effect to the regulations and guidance within the Final Rule. Thus, CMS should acknowledge that, with the exception of those sections made effective earlier by the statutorily requirements of the DRA, the regulations and guidance within the Final Rule are effective no earlier than October 1, 2007.

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[2] 5 U.S.C. § 551(4) (2007) (emphasis added).
[3] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring).
[4] *Id.* at 208.

B. Bundled Sales

Bayer strongly supports the harmonization of bundling rules across the Medicare and Medicaid programs, as a consistent body of rules will help reduce calculation errors with respect to the calculation and reporting of average sales price ("ASP") and AMP. However, the definition of "bundled sale" that CMS has provisionally adopted in § 447.502 extends far beyond the Medicaid Rebate Agreement ("MRA") definition to which CMS remains legally bound. Bayer strongly believes that CMS should adopt the MRA definition of bundling in both the Medicaid and Medicare contexts. In the event that CMS does not adopt the MRA definition, however, we suggest that CMS delay the implementation of its bundling rule and guidance, as it has done for ASP, to permit further consideration of this important issue and to ensure consistency.

CMS' regulatory definition of "bundled sale" significantly broadens the agency's policy with respect to what will be considered a bundle. For example, the MRA definition of "bundled sale" refers to *purchases* of *different drugs*, whereas the regulatory definition drastically expands the MRA definition to include performance requirements that fall short of a purchase requirement, including achievement of market share or formulary conditions, and arrangements involving the same drug, for example.[5]

The fact that the new regulatory definition of "bundled sale" represents a significant change in CMS policy is evidenced by the fact that CMS' bundling rules have been the subject of three different sets of rulemaking within one year—the CY 2007 physician fee schedule (Dec. 2006),[6] the AMP Final Rule (July 2007),[7] and the CY 2008 physician fee schedule (Nov. 2007).[8] A mere "clarification" of existing policy would not call for or justify such considerable discussion.

As discussed above regarding the application of the Final Rule, the APA requires prospective-only application of substantive changes in regulatory policies after notice-and-comment rulemaking. Therefore, retroactive application of the "bundled sale" definition in § 447.502 would plainly violate the APA.[9] Furthermore, even if retrospective application of CMS' new bundling rule were permitted by the APA, to do so here would penalize manufacturers for their compliance to date with the MRA and Medicaid rebate guidance.

For years CMS has directed manufacturers to make "reasonable assumptions ... consistent with the general requirements and intent of section 1927 of the Act, Federal regulations and the Medicaid Drug Rebate Agreement" when no

[5] Medicaid Rebate Agreement at section I(e).
[6] 71 Fed. Reg. 69,624, 69,673-69,675 (Dec. 1, 2006).
[7] Final Rule, 72 Fed. Reg. at 39,158-39,160.
[8] 72 Fed. Reg. 66,222 et. seq. (Nov. 27, 2007).
[9] *Bowen*, 488 U.S. at 225 (Scalia, J., concurring).

specific guidance is available on a particular issue.[10] Accordingly, manufacturers have been making reasonable assumptions for bundled sales, consistent with the MRA definition of that term. Moreover, pursuant to the CY 2008 Medicare physician fee schedule, manufacturers will be making such reasonable bundling assumptions for the calculation of ASP.[11]

Therefore, we believe that CMS, at least temporarily, should permit manufacturers to continue making such reasonable assumptions for purposes of Medicaid price reporting consistent with the MRA. Specifically, we request that CMS adopt the MRA definition of bundled sale in its final regulations, and codify current practice. Alternatively, we ask CMS to delay implementation of any new bundling regulations or guidance as it has done for ASP.

A delay will permit CMS to reconsider the regulatory definition of "bundled sale" concurrently in both the Medicaid and Medicare contexts, and to address the difficult bundling questions that arise from that definition. For example, we have asked whether a bundled sale could exist when there is not a performance requirement that could have affected the prior period, because there was no agreement requiring performance over the two periods. We believe that a bundled sale cannot exist under such circumstances.

Although § 447.502 sets out the term "bundled sale" broadly, it must have some boundaries in order to have any real meaning. If the definition is read too broadly it would result in the aggregation of all sales to a customer over the lifetime of their dealings into one enormous bundle. Below, we include a Q&A that will help to create a reasonable definition of "bundled sale":

> *Q: Manufacturers often use the basis of performance for a prior period to determine price in a future period. Sometimes, this is done after the reference period is complete, when the customer can no longer have an impact on the reference period. If the manufacturer makes its assessment of performance for a prior period only after that period has ended, a "bundled sale" is not created. For example, if, during Q3, a manufacturer decides to drop price by 5 percent in Q4 because a customer increased market share during Q2 by 2 percent, must the Q2 sales be used in the determination of a bundled sale and allocated accordingly?*
>
> A: No. A "bundled sale" does not exist unless there was a performance requirement that could have affected Q2 purchases and there was an agreement or understanding requiring performance during that quarter.

[10] Medicaid Drug Rebate Program Manufacturer Release No. 78 (Jun. 26, 2007).
[11] 72 Fed. Reg. at 66,258.

> In this example, there was no performance requirement, obligation, or agreement. In fact, the manufacturer did not make a decision to drop its Q4 price until after Q2 had ended. Accordingly, there was no opportunity for the customer to perform based on Q2 purchases. Here the manufacturer acted unilaterally; there was no arrangement between the manufacturer and the customer.
>
> If, however, the manufacturer and the customer had agreed during Q2 that a 2 percent increase in Q2 sales would result in a lower Q3 price, then a "bundled sale" would have been created and would need to be allocated accordingly over Q2 and Q3.

We appreciate CMS' efforts to bring clarity to the treatment of bundled sales for Medicare and Medicaid price reporting purposes. To the extent that clear, administrable guidance can be promulgated consistent with CMS' legal obligations under the MRA, we support the prospective application enactment of such guidance. To the extent that CMS cannot yet offer such clear guidance, we respectfully request that CMS delay the implementation of its bundling guidance and, instead, continue to permit manufacturers to make reasonable assumptions consistent with the MRA and federal law.

C. Bona Fide Service Fees

We thank CMS for its decision to adopt the same definition of bona fide service fee as used in the final ASP regulations and to harmonize, to the extent possible, the price reporting calculations under the Medicare and Medicaid programs. We think that the definition of bona fide service fee appropriately distinguishes between those manufacturer payments that constitute price concessions or reductions in price, and those payments that represent bona fide fees for service. We respectfully request that CMS take this opportunity to clarify its guidance with respect to the bona fide service fee definition.

Specifically, we request that CMS explicitly acknowledge that all fees for service that meet the regulatory definition in § 447.502 may be considered bona fide service fees. That is, we ask CMS to clarify that all fees for services—whether the services are "core" distribution services, rebate administrative services, or other services—may be excluded from AMP and best price if they (1) are not passed on, and (2) represent fair market value (3) for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement.

We are concerned that the Final Rule may be misread to suggest that services related to the administration of a rebate contract can *never* satisfy the bona fide

service fee definition.[12] To the contrary, PBMs, group purchasing organizations ("GPOs"), and other middlemen often perform substantial rebate administrative services on behalf of manufacturers that the manufacturers would otherwise have to perform themselves—for example, collecting and analyzing utilization data from PBM and GPO customers, validating the reported utilization data, and allocating and distributing rebates based on these validations. If the fees paid for such services are not passed on and represent fair market value, then such fees satisfy the definition of bona fide service fees.

Moreover, blanket assertions that entire categories of fees may or may not meet the definition of bona fide service fee provide little useful guidance to manufacturers. Whether a service fee is bona fide depends upon facts unique to each manufacturer's arrangement with the service provider. For this reason, CMS has repeatedly declined to identify specific categories of services that qualify as bona fide service. For example, in the ASP context, CMS stated that "to avoid inadvertently limiting the scope of what could constitute a bona fide service, we will not establish a list of 'bona fide services' at this time."[13]

CMS' bona fide service fee guidance necessarily asks manufacturers to determine when fees for service meet the definition of bona fide service fee, and we think such a policy is wise given the myriad service fee arrangements in the market and the evolving nature of the market. Manufacturers would benefit from more detailed guidance on topics regarding some proper methods for evaluating whether a fee reflects fair market value. For example, many manufacturers have looked to the GPO safe harbor to the federal Anti-Kickback Statute as a standard for determining fair market value for PBM administrative fees,[14] given that the Office of the Inspector General ("OIG") has instructed manufacturers to analyze such PBM fees by applying the GPO safe harbor. Accordingly, these manufacturers treat an administrative fee of 3 percent of the purchase price as a bona fide service fee, and any fees exceeding 3 percent as price concessions. Thus, we respectfully request that CMS take the opportunity to provide this guidance in response to the comments submitted on the Final Rule.

D. PAPs

We thank the Agency for its clarification of the criteria necessary for manufacturers to exclude sales to PAPs from the calculation of AMP.[15] However, CMS should state explicitly that (1) the Agency's criteria for exclusion distinguish between PAPs that offer free goods assistance and those that offer financial assistance short of

[12] *See* Final Rule, 72 Fed. Reg. at 39,182 (responding to comment regarding recommendation that CMS eliminate the condition that the services would be required "in the absence of the service arrangement").
[13] 71 Fed. Reg. at 69,668.
[14] 42 C.F.R. § 1001.952(j) (2007).
[15] 42 C.F.R. § 447.504(h)(12).

providing free goods, and (2) it will make a determination as to financial need only as to the latter.

The preamble sets forth four criteria for the exclusion of sales to PAPs from the calculation of AMP.[16] The first requires that "the program is focused on extending free products not contingent upon any purchase requirement or extending financial assistance to low income families, as determined by CMS."[17] The placement of the conjunction "or" creates a distinction between PAPs that offer free goods assistance and PAPs that offer financial assistance. Accordingly, CMS may only apply the low income criteria to programs that do not involve free goods.

The Agency's confirmation of how the "or" operates in the first criterion for purposes of excluding sales to PAPs from the calculation of AMP is critically important to manufacturers. It impacts how manufacturers structure their PAPs. It is imperative that manufacturers understand how to structure their programs appropriately to ensure that there is no disruption in assisting patients. Manufacturers create these programs to ensure continuity of care. On behalf of the affected patients, we urge the Agency to provide the confirmation we seek here.

E. Manufacturer Coupons

Bayer appreciates the Agency's additional guidance on the treatment of manufacturer coupons for purposes of calculating AMP. We are troubled, however, that the preamble differs substantively from the regulation. Additionally, we question the scope of the preamble discussion requiring that a manufacturer establish a benefit amount of the coupon absent "negotiation" with a third party. We respectfully request further clarification on both issues.

1. Test for Exclusion

Section 447.504(h)(15) excludes from AMP "[m]anufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession." We understand the exclusion from AMP to turn on two factors—whether the full value is passed on to the consumer and whether any other entity receives any price concession—regardless of who, except the consumer, redeems the coupon.

But the preamble suggests that CMS may be looking to other factors. In response to comments, CMS details a four-part test for excluding manufacturer coupons from AMP:

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[16] Final Rule, 72 Fed. Reg. at 39,188-39,189. *See also* CMS, *Deficit Reduction Act Policy Questions* (Sept. 28, 2007).

[17] Final Rule, 72 Fed. Reg. at 39,188-39,189 (emphasis added).

1. The manufacturer coupon is not contingent upon any purchase requirement to individuals.

2. The manufacturer establishes a benefit amount of the coupon to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the free product or coupon amount is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce the benefit amount, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the coupon.[18]

Because the four-part preamble test above attempts to expand on the codified regulatory text at § 447.504(h)(15), Bayer asks for further clarification as to which set of provisions should govern our determination of whether coupons may be permissibly excluded from AMP.[19] Namely, we request that CMS address clearly whether a manufacturer must assess the existence of contingent purchase requirements and the manner for establishing the benefit amount in determining if it may exclude a coupon from AMP.

If the Agency intends to apply these two criteria for the purpose of determining which coupons may be excluded from AMP, then we strongly urge it to codify the additional criteria in the regulation.[20] Another clarification in the preamble of a future rulemaking would only further complicate the discrepancy between the regulatory text and the preamble. Until such time that CMS codifies a clarification, manufacturers will be permitted, under the regulation, to continue to rely on the two-part test set out at § 447.504(h)(15).

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[18] *Id.* at 39,187.

[19] *Compare* 42 C.F.R. § 447.504(h)(15) (including two requirements for exclusion from AMP calculation) *and* Final Rule, 72 Fed. Reg. at 39,187 (discussing four requirements for exclusion from AMP calculation).

[20] Because of the importance of parity between AMP and best price, we encourage CMS to remain consistent in its treatment of coupons. If it elects to change the AMP regulation with respect to manufacturer coupons, we urge it to make a parallel change in the best price regulation.

2. "Negotiation" With A Third Party

If CMS decides to codify the four-part coupon test from the preamble, we ask it to clarify the second requirement, which would require that a manufacturer establish a benefit amount of the coupon absent "negotiation" with a third party.[21] It appears that CMS is attempting to limit the AMP exclusion to coupons whose value has been determined by the manufacturer. We agree with this policy generally, but ask CMS to clarify that discussions with third parties to collect information on which to base decisions regarding the benefit amount are not implicated by the "negotiation" standard. Manufacturers often engage in market research to help them determine and design their coupon programs. We do not believe that this type of information gathering constitutes a "negotiation" with a third party. It is not part of any negotiation.

II. Best Price Calculation

Bayer appreciates that CMS understands that certain data are difficult for manufacturers to capture and cites PBM pricing data as an example of those challenges.[22] We are pleased that CMS recognizes that "manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs".[23] We are pleased that CMS recognizes that manufacturers wrestle with the issue because of questions about "what part of these discounts, price concessions, or rebates are kept by the PBM for the cost of their activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part that entity passes on to pharmacies."[24] Despite the additional guidance provided in the Final Rule, however, we continue to struggle with the treatment of PBM concessions in the best price context.

When asked to confirm whether or not manufacturers are obligated to aggregate concessions paid to PBMs and those paid to a PBM's customers, CMS states: "there are instances where some PBM rebates and discounts may be designed to adjust prices at the retail or provider level."[25] CMS acknowledges with this statement that there are some PBM rebates and discounts that a manufacturer designs to adjust prices at the retail or provider level and some concessions it does not. We read this to mean that not all the concessions paid to PBMs must be aggregated with those concessions paid to a PBM's customers. It is our understanding that this is a purpose-based test which turns on the manufacturer's intent. Accordingly, only those PBM concessions that a manufacturer designs to adjust price at the retail or provider level must be included in best price.

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[21] Final Rule, 72 Fed. Reg. at 39,187.
[22] *See id.* at 39,146
[23] *Id.* at 39,150; *See also* Manufacturer Releases 28 and 29.
[24] Final Rule, 72 Fed. Reg. at 39,150.
[25] *Id.* at 39,198.

We are troubled, however, by a later assertion in the preamble that: "[w]here PBM rebates, discounts, or price concessions do not operate to adjust prices, they should not be included in the best price calculation."[26] We read §§ 447.505(c)(2) and (d)(13) together with the preamble to mean that a manufacturer must only include non-mail order pharmacy concessions that it designed for a PBM to pass through to the retail or provider level. It is the manufacturer's intent, not the PBM's actions, that should govern the manufacturer's best price calculations.

To help us better understand how to operationalize the regulations, we seek additional guidance as to what it means to be "designed to" adjust prices.

> *Q. Manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs. Manufacturers often do not know what part of these discounts, price concessions, or rebates, if any, may not be kept by the PBM. Section 447.505(d)(13) excludes from best price: "PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level." What does it mean to be "designed to" adjust prices for the purposes of § 447.505(d)(13)?*
>
> A. In calculating best price, consistent with § 447.505(d)(13), a manufacturer may exclude non-mail order pharmacy PBM price concessions unless it intended the PBM to pass through those concessions to the retail or provider level. Unless a manufacturer designed a concession to adjust prices at the retail or provider level, then that concession may be excluded from best price.
>
> A manufacturer may receive assurances through contract terms, or otherwise, that nothing is passed through to the retail or provider level. But, it is not necessary to do so. The determination as to whether or not to exclude a non-mail order pharmacy PBM concession from best price turns on the manufacturer's intent in designing and negotiating the concession.
>
> If a manufacturer designs a concession to be passed through, where, for instance, a price given to a PBM is, by contract, also made available to the PBM's mail order pharmacy, then the manufacturer should consider the

[26] *Id.* (emphasis added).

concession in determining best price. Conversely, if a manufacturer did not design or intend a concession to be passed through, then it should be excluded from best price, regardless of whether or not it is actually being passed through by the PBM.

In sum, when determining whether it may permissibly exclude a non-mail order pharmacy PBM concession pursuant to § 447.505(d)(13), a manufacturer should rely on its own intent in designing the concession.

III. Manufacturer Reporting Requirements

Bayer respectfully offers the following comments regarding manufacturer reporting requirements. Below, we request additional guidance regarding the restatement of base date AMP, calculation of the prompt pay discount, lagged price concessions, and lagged ineligible items.

A. Restatement of Base Date AMP

Bayer applauds CMS for allowing manufacturers to recalculate base date AMP.[27] We believe that this will equitably account for the new treatment of customary prompt pay discounts. Yet, we continue to have some technical concerns related to the restatement. Our questions focus on two areas—(1) older products with missing data or data that is difficult to ascertain and (2) manufacturer obligations where products have been divested.

1. Older Products

We appreciate that it is CMS' intent in permitting manufacturers to report a revised base date AMP to allow all manufacturers the opportunity to recalculate their base date AMPs.[28] Bayer commends the Agency for wanting this requirement to be "minimally burdensome to manufacturers."[29] We applaud CMS for many aspects of this provision, including allowing restatement on a product-by-product basis and extending the restatement period to 4 full quarters.[30] Unfortunately, we think these positives will be undermined if there is not a reasonable interpretation of what it means to "use" actual and verifiable pricing records.

Bayer, like many other manufacturers, currently manufactures many older products. In total, we are currently manufacturing or were the original manufacturer for about 75 NDCs whose base date AMP was stated more than a decade

[27] 42 C.F.R. § 447.510(c)(2).
[28] Final Rule, 72 Fed. Reg. at 39,211.
[29] *Id.*
[30] 42 C.F.R. §§ 447.510(c)(2)(ii) and (c).

ago.[31] Since these products were launched, we have upgraded our computer systems multiple times. In order for us to recalculate a new baseline, considerable administrative burden and costs would be involved due to significant systems limitations affecting data availability. We are currently determining what data we have and how it is formatted. But, for example, we already know that we did not previously have a separate transaction code for the prompt pay discount. As such, that data is not tagged and impossible for us to isolate retrospectively.

We understand the need to require that "a manufacturer must use actual and verifiable pricing records in recalculating base date AMP."[32] We agree that the use of actual data is a necessary and appropriate component of a restatement. But, while the regulation requires the use of actual data, it does not appear to mandate the use of actual data exclusively. We understand that CMS did not rule out the use of reasonable assumptions in support of actual data. As CMS itself said: "because the base date AMPs will be used to determine all future rebate calculations, we are not permitting manufacturers to rely solely on estimates or reasonable assumptions for calculating a revised base data AMP. Manufacturers must use actual data to calculate revised base date AMPs."[33] While we appreciate that CMS will not permit manufacturers to rely *solely* on estimates or reasonable assumptions, some use appears permissible. In fact, Bayer believes that reliance on estimates and reasonable assumptions, along with actual data, is critical for older products.

We encourage CMS to confirm our understanding about the data points that may be used to recalculate base date AMP. Permitting manufacturers to use actual data as augmented by estimates and reasonable assumptions, particularly for older products, would "allow all manufacturers the opportunity to recalculate their base date AMPs" and impose the minimum burden the Final Rule contemplates. This approach strikes a balance that prevents some manufacturers from unduly taking advantage of the restatement opportunity, while allowing others, particularly those with older products, to avoid unjust penalties resulting from the change in law. We fear that a more narrow reading would only disadvantage those manufacturers with the longest histories of participating in the Medicaid program.

Below is a sample Q&A, which we encourage CMS to consider issuing:

Q. Because some manufacturers have older products, their base date AMPs were set long ago. Since these and other older products were launched, manufacturers may have upgraded their computer systems multiple times. In order for them to recalculate a new baseline, considerable administrative burden and costs would be involved due to significant systems

[31] Bayer is concerned that one possible reading of the CMS guidance is actually inconsistent with the 10 year data retention rule as applied in this context.
[32] 42 C.F.R. § 447.510(c)(2)(iii).
[33] *Id.* (emphasis added)

limitations for obtaining data. In some cases, there was not a separate transaction code for the prompt pay discount historically, thus actual data at the NDC-9 level is not available. While § 447.510(c)(2)(iii) requires the use of actual data, it does not appear to mandate the use of actual data exclusively. Given that, may manufacturers rely on estimates and reasonable assumptions, along with actual data, in restating its base date AMP for older products?

A. Yes. Consistent with § 447.510(c)(2)(iii), manufacturers may use actual data as augmented by estimates and reasonable assumptions to recalculate base date AMP. Actual data need not be used exclusively, although it certainly may be, and we encourage manufacturers to use whatever actual data they do have to the greatest extent reasonably possible. Where actual data is unavailable, however, at the NDC-9 level a manufacturer may build off of the aggregated actual data it does have, supplementing its calculations with estimates and reasonable assumptions consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices, in order to allocate the aggregate data to the NDC-9 level.

Alternatively, a manufacturer could begin with its original base date AMP calculation, if those calculations were based on actual data, then the manufacturer could make an appropriate adjustment to the original value based on the fact that customary prompt pay discounts now do not act to reduce AMP.

2. Divested Products

Section 447.510(c) and the preamble do not address product divestitures. However, it should be clear, as a legal matter, that the regulation and the statute cannot and do not impose any obligation on former manufacturers in reissuing base date AMPs. Because this is a fundamental point, we believe CMS should address it.

Q. Subsequent to the establishment of base date AMP, when the original NDC holder has divested a product to another manufacturer, what, if any, responsibilities does the original manufacturer have regarding recalculation of the baseline under the statute or regulations?

A. The statute and regulations do not create an affirmative obligation for the original manufacturer to assist the current manufacturer in its base date AMP recalculation.

B. Prompt Pay Discount

Bayer thanks CMS for wanting the quarterly reporting of the customary prompt pay discount to be "as simple as possible."[34] As discussed in the base date AMP restatement context, the available data related to the customary prompt pay discount will vary by manufacturer. This issue is not limited to baseline AMP determinations. It also affects quarterly reporting of customary prompt pay discounts. We believe that the existing guidance regarding the quarterly reporting of customary prompt pay discounts permits a manufacturer to proceed as we described above in the baseline AMP section of our comments. We ask CMS to confirm this point for restatement purposes as well as for the reporting of the prompt pay discount going forward on a quarterly basis.

C. Lagged Price Concessions

In the preamble, CMS states: "We believe that we have developed requirements in this final regulation that are clear and concise and that can provide a basis for consistent calculations and fair reimbursement rates."[35] Bayer commends CMS for its efforts in this regard. As we noted in our comments on the proposed rule, we believe that consistency is an important element to strive for in price reporting. Because of the inherent differences between AMP and best price, however, we believe that there are times when consistency between the two metrics is not required or even desirable. Lagged price concessions is one example of where different treatment may be important.

Section 447.510(d)(2) requires that manufacturers calculate monthly AMP "based on the best data available" at the time of the submission. Thus, if the realization of a price concession is unknown to the manufacturer at the time it reports its monthly AMP, the manufacturer must consider the concession a lagged item. This approach inherently relies on data related to the date the rebate is paid and includes estimating the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.[36] Interestingly, however, CMS expressly prohibits revisions to monthly AMP resulting solely from data pertaining to lagged price concessions.[37] It is the smoothly methodology that eliminates the need to revise. We very much agree with the decision to require manufacturers to use a smoothing methodology and believe it will lead to greater stability in AMP.[38]

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[34] Final Rule, 72 Fed. Reg. at 39,207.
[35] *Id.* at 39,170.
[36] 42 C.F.R. § 447.510(d)(2).
[37] *Id.* at § 447.510(d)(4).
[38] *See* Final Rule, 72 Fed. Reg. at 39,210.

In contrast, similar requirements are not in place for best price calculations.[39] There is no obligation to lag price concessions. Because of the inherent difference between AMP and best price, no smoothing is called for. Moreover, there is no parallel prohibition against revising quarterly best prices when a lagged price concession would set a new best price. Together, these differences are the basis for our decision to use the date a rebate is earned in determining best price, even though the date of payment is used for AMP purposes.

We are hopeful that the use of the date a rebate is earned—as opposed to the date a rebate is paid—in our best price calculations will assist us in avoiding the need to restate solely based on lagged items. We are striving to minimize our need to revise best price and believe that this will assist us in doing so. As such, Bayer encourages CMS to further clarify that the consistency noted in the preamble refers to the calculation of AMP and best price individually—not the method of calculating lagged price concessions between AMP and best price.[40]

Accordingly, we respectfully request additional guidance stating that the desired uniformity is achieved so long as the methodologies used in AMP and best price calculations are internally consistent, even if a manufacturer's methodology differs between the two. The data points a manufacturer uses to calculate the two prices may differ.

We urge CMS to issue guidance noting that this divergent treatment is permissible so long as a manufacturer's methodology is uniform within its AMP calculation and within its best price calculation. Below is a draft Q&A on this point for CMS' consideration:

> *Q. Section 447.510(d)(2) requires that manufacturers calculate monthly AMP "based on the best data available" at the time of the submission. Thus, if the realization of a price concession is unknown to the manufacturer at the time it reports its monthly AMP, the manufacturer must consider the concession a lagged item. This approach inherently requires the use of the date a rebate is paid and not earned in calculating AMP. It leads to the use of an estimate of the value of lagged price concessions based on a 12-month rolling average. Significantly, CMS expressly prohibits revisions to monthly AMP resulting solely from data pertaining to lagged price concessions.*
>
> *Due to the inherent differences between AMP and best price, and the absence of parallel smoothing requirements and revision*

[39] *See* 42 C.F.R. § 447.510(d).

[40] Final Rule, 72 Fed. Reg. at 39,170 ("We believe that we have developed requirements in this final regulation that are clear and concise and that can provide a basis for consistent calculations and fair reimbursement rates.") (emphasis added).

prohibitions in the best price context, may a manufacturer permissibly use the date a rebate is earned—as opposed to the date a rebate is paid—in calculating best price?

A. The consistency noted in the preamble to our final rule with comment period refers to the calculation of AMP and best price respectively and not the methods of calculation of both prices together. A manufacturer should calculate lagged items as part of AMP consistently from month-to-month and quarter-to-quarter. It should also calculate its best price consistently from quarter-to-quarter. At times, however, the data points a manufacturer uses to calculate the two prices may differ. For example, although a manufacturer must use the date a concession is paid to determine whether or not the concession is lagged in calculating AMP, the manufacturer may use the date a concession is earned to calculate best price, if that would yield a more accurate calculation of best price. So long as there is an appropriate basis for using different methodologies as part of the treatment of lagged items, such a difference between AMP and best price calculations is not problematic.

D. Lagged Ineligible Sales

Somewhat related to our comments above regarding the treatment of lagged price concessions is our question on lagged ineligible sales. We appreciate that: "[t]he purpose of requiring manufacturers to report revised quarterly AMPs in § 447.510(b) is to ensure the Medicaid rebate amounts are as accurate as possible."[41] Bayer commends CMS for the steps it is taking to balance the need for accurate AMPs against concerns regarding AMP volatility. To that end, we agree with CMS' use of a smoothing methodology and the § 447.510(b)(2) prohibition preventing manufacturers from reporting revised AMPs "when the revision would be solely as a result of data pertaining to lagged price concessions."

It is the use of smoothing and this revision prohibition which begs the question of how manufacturers should account for lagged ineligible sales. Much like lagged price concessions, manufacturers will frequently lack the information required to assess which sales are ineligible when they calculate prices. At the close of each month, this information simply will not be available for all sales and will need to be estimated.

Because the Final Rule does not speak to the issue of lagged ineligible sales, we urge CMS to issue additional guidance in this regard. One option would be to

[41] *Id.* at 39,210.

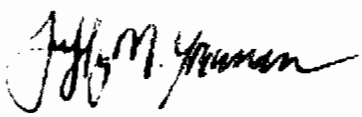
clarify that the § 447.510(b)(2) revision prohibition should be read narrowly, allowing manufacturers to report revised AMPs even when the revision would be solely as a result of data pertaining to lagged ineligible sales. We fear, however, that this would lead to perpetual revisions, which is not in the best interest of manufacturers or the Medicaid Program. Alternatively, we ask CMS to allow manufacturers to rely on estimates and use a smoothing methodology for lagged ineligible sales.

We urge CMS to permit manufacturers to employ smoothing methodologies for lagged ineligible sales. We fear that failure to address this issue promptly could have significant consequences, and we encourage CMS to issue guidance as quickly as possible to avoid AMP revisions solely as a result of lagged ineligible sales.

IV. Conclusion

Bayer thanks CMS again for its consideration of the above comments on the Final Rule regarding AMP, best price, and manufacturer reporting requirements. We look forward to continuing to work with you to improve the health of Medicaid beneficiaries and thank you in advance for your time.

Sincerely,



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December 10, 2007

By Hand Delivery

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: AMP Final Rule Implications for Bundled Sales

Dear Acting Administrator Weems:

We are very grateful for this opportunity to provide comments on the Final Rule With Comment Period ("Final Rule")[1] implementing certain provisions of the Deficit Reduction Act of 2005 ("DRA")[2] concerning the Medicaid Drug Rebate Program. Sidley Austin LLP is a law firm consisting of over 1,700 attorneys across 16 domestic and international offices. We appreciate and value the opportunity to work closely and collaboratively with the Centers for Medicare & Medicaid Services ("the Agency") and its dedicated personnel on a host of issues affecting the Medicaid program.

We thank the Agency for its significant and important efforts to articulate clearer guidance on the calculation of average manufacturer price ("AMP") and best price ("BP"), and in particular, the definition of "bundled sale" for purposes of those calculations. While we agree that the Agency has authority to revise the definition of "bundled sale" under the new regulations consistent with the Medicaid Rebate Agreement ("MRA"), we are concerned that the Agency intends the revisions to have a retroactive affect and does not intend to modify the MRA. We respectfully submit that such retroactive application would be subject to challenge under the Tucker Act and would expose the Agency to liability under the Administrative Procedure Act ("APA").

[1] Dep't of Health and Human Servs, Ctrs for Medicare and Medicaid Services; Medicaid Program; Prescription Drugs; Final Rule With Comment Period, 72 Fed. Reg. 39142 (July 17, 2007) [hereinafter Final Rule].
[2] Deficit Reduction Act of 2005, Pub. L. No. 109-171, §§ 6001-6203 (2006).

In this comment letter, we submit the following issues for consideration:

- The definition of "bundled sale" in the Final Rule is fundamentally different from the definition of these sales in the MRA.
- We are concerned that CMS may intend for the new definition of "bundled sale" to be applied retroactively and that CMS does not intend to modify the MRA.
- Retrospective application of the new definition and prospective application of the definition in the absence of changes to the MRA would constitute clear breaches of the MRA. The Agency faces claims under the Tucker Act under these circumstances. The Final Rule should not be read in a manner that contravenes the plain language of the MRA.
- The MRA does not require compliance with regulations related to the calculation of AMP and BP that were not in effect at the time that the MRA was agreed to by the parties.
- Finally, retrospective application of the new definition would violate the Administrative Procedures Act. To the extent that CMS does intend a retrospective application of its new definition of a bundled sale, the Final Rule violates the Administrative Procedure Act ("APA").

We encourage the Agency to clarify that it intends to apply the Final Rule's definition of bundled sale in only a prospective manner and that it will do so by amending the MRA. We are grateful for your consideration of our comments on these issues, which are discussed in detail below.

I. The Final Rule provides an expanded and, therefore, fundamentally new definition of "Bundled Sale."

The Medicaid drug rebate statute does not provide a definition of "bundled sale;" and so prior to issuance of the Final Rule, the only applicable definition of "bundled sale" was found in the MRA. The MRA provides that:

> "Bundled Sale" refers to 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]

The plain language of this definition requires that a bundled sale may be triggered only by the existence of a contingent purchase requirement.

The Medicaid Drug Rebate Operational Training Guide ("the Guide"), which was issued without notice and comment, contains an identical definition of "bundled sale." The Guide goes into greater detail with respect to bundled sales and supports the basic, fundamental notion that a bundled sale requires a purchase requirement. The Guide explains: "The key to identifying a bundled sale is that the sale is contingent upon an additional purchase requirement(s) of the retail purchaser (e.g., pharmacies, beneficiaries, etc.)."[4] The Guide provides examples of bundled sale arrangements, all of which involve a purchase requirement.[5] The Guide additionally excludes "non-drug products" from the definition of "bundled sales":

> Valid bundled sales only include drug products that meet the definition of a covered outpatient drug as defined in the drug rebate agreement and statute. If a non-drug product (e.g., lip balm, tissues, etc.) is included in the bundled sale it is not eligible for inclusion in the Medicaid Drug Rebate Program.[6]

In contrast, the Final Rule expands the definition of "bundled sale" significantly. The Final Rule provides that "bundled sale" means:

> [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

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[3] Medicaid Rebate Agreement § I(e) [hereinafter MRA] (first emphasis in original, remaining emphases added).
[4] CMS Center for Medicaid and State Operations, Finance, Systems and Quality Group – Division of State Systems, Medicaid Drug Rebate Operational Training Guide, at F11a (emphasis in original).
[5] *E.g.*, "Buy one bottle of pills and get the second bottle for 50% off. Buy one tablet and get a bottle of cream free. A labeler provides all pharmacies that purchase their drug product with 250 units of extra drug product for free. Patients get prescriptions from their doctors to redeem at pharmacies for the free drug samples." *Id.* at F11a (emphasis added).
[6] *Id.* at F11d.

> available had the bundled drugs been purchased separately or outside the bundled arrangement. . . .[7]

This definition differs from the Agency's previous definition in at least three significant, even fundamental respects.[8] First, the addition of the phrase, "or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary)" drastically and fundamentally expands the types and numbers of bundled sale arrangements by expanding the types of contingencies that can trigger a bundled sale. Significantly, the MRA provides no notice that performance requirements may trigger a bundled sale as this phrase appears nowhere in the MRA. Under this new definition, arrangements that involve performance and formulary placement contingencies, even though they do not themselves require a purchase, nevertheless trigger the definition of a bundled sale. Thus, a pricing contract with a hospital that requires the hospital to place the product on the formulary may be considered a bundled arrangement under the Final Rule even though formulary placement falls short of requiring any purchase of any product.

Second, the new definition states, contrary to the MRA, that a bundle is not limited to the "packaging of drugs of different types" but supposedly may include "the same drug" as well as "different types." It is common practice for manufacturers and their customers to contract for a single discount on a drug product. Under such contracts, that single discount is applied to all strengths and forms of the drug product, even though the drug product's individual strengths and forms are not uniquely identified in the contract. If such "drug product" –based contracting triggers a "same drug" bundle under the new definition, then virtually every pricing contract would constitute a bundle and would, therefore, trigger the requirements for apportioning the resulting discounts. The MRA provides no notice that contracting for different strengths of the same drug could constitute a bundled sale. If this new distinction is applied retroactively, manufacturers would have to "unbundle" the individual products under virtually every product-based contract and apportion the contractual discount back to each individual item based on when the item was available for sale and actually purchased by the customer. Such an exercise would be burdensome for manufacturers and pointless, in most cases. This would be the case whenever the same percentage discount is applied evenly across all strengths and forms of the same product. Apportioning the contractual discount in such situations would have no effect on the final, apportioned, individual discounts. In these situations, the mathematical result of bundling or unbundling is the same. We have appended an example to illustrate this point.

Third, the revised language does not preclude the involvement of a non-drug product or a non-covered outpatient drug from triggering a bundled sale. The MRA definition of

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[7] 42 C.F.R. § 447.502.

[8] While we are asserting that the definition of "bundled sale" differs from past definitions, we are not questioning in any way the requirement that price concessions from bundled sales be apportioned to all of the products under the bundle, where a bundle exists as provided for under the MRA.

bundled sale applies only to arrangements where "drugs of different types" were purchased. In contrast, the revised definition includes "an arrangement... under which the rebate, discount, or other price concession is conditioned upon the purchase of ... another product."[9] Here as well, the MRA provides no notice to manufacturers that non-drug items could trigger a bundled sale. In fact, as mentioned above, the Guide affirmatively states that non-covered outpatient drugs cannot trigger a bundled sale. If inclusion of a non-covered outpatient drug in a contract triggers a bundled sale, it is unclear how the value of the non-covered outpatient drug should be calculated and apportioned across the covered outpatient drug bundle.

II. We are concerned CMS may intend to apply the new definition of "bundled sale" retroactively.

In the Final Rule, CMS states that this definition of "bundled sale" is a clarification of the existing definition and may not create new obligations or administrative burdens under the MRA.[10] CMS stated generally in the Final Rule's Preamble that "[t]hose existing requirements that remain unchanged in this final rule will continue in force. In addition, to the extent that this rule addresses previous policies already established by the Agency, those policies will remain in effect."[11] In any event, we are deeply concerned that any retrospective application of the Final Rule's definition of "bundled sale" would flatly violate the MRA, the Tucker Act, and the APA.

III. Retrospective application of the new definition would breach the MRA.

To the extent that the Final Rule might be construed as conflicting with the MRA's definition of "bundled sale," pharmaceutical manufacturers party to those agreements may hold the Agency liable for breach of contract pursuant to the Tucker Act or the APA. The Agency must apply the new definition prospectively only.

By way of background, the "bundled sale" definition that presently appears in the national rebate agreement was established in 1991 after formalized rulemaking. The "bundled sale" definition contained in the MRA is identical to the definition that was published in the Federal Register in 1991. More recently, in 2001, the Agency issued written guidance to state agencies and manufacturers in the form of a Medicaid Drug Rebate Operational Training Guide. The guidance advanced the same definition of "bundled sale" as appears in the MRA.

Accordingly, the issue presented is whether the Agency intends to apply its new definition retroactively. This could clearly violate the MRA. Such a breach of contract would be

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[9] 42 C.F.R. § 447.502.
[10] Final Rule, *supra* note 1, at 39157-60.
[11] *Id.* at 39157.

actionable under the Tucker Act[12] or the Little Tucker Act[13] and would expose the Agency to liability under each operative MRA.[14,15]

The MRA reflects the parties' agreement and legal obligations under the Medicaid Rebate Program, and until the Final Rule was published on July 17, 2007, it reflected CMS' consistent position on the definition of "bundled sale." While we do not dispute the Agency's authority to revise its policy on bundled sales, and promulgate regulations that express that revised policy, we submit that it cannot unilaterally revise MRAs to reflect this changed policy and, further, cannot impose such unilateral modifications to prior time periods. Courts have noted that "[t]he purpose of contracts is precisely to fix obligations and entitlements so that they will not be affected by subsequent background changes."[16] We are confident that the Agency could not intend the AMP regulation to change its contracts with private parties as to past activities, and we request that the Agency clarify this important point.

IV. The MRA does not require compliance with regulations related to the calculation of AMP and BP that were not in effect at the time that the MRA was agreed to by the parties.

The MRA does not incorporate subsequent changes in the regulatory calculation of AMP and BP, as CMS has suggested. The MRA's general prefatory language indicates that the MRA is predicated on "the Omnibus Budget Reconciliation Act of 1990, Public Law No. 101-508, and section 1927 of the Social Security Act. . . 42 U.S.C. 1396s. . . ."[17] Notably, neither the MRA's preface nor its provisions include any reference to the MRA automatically

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[12] 28 U.S.C. § 1491(a).
[13] 28 U.S.C. § 1346(a)(2).
[14] *See* United States v. Winstar Corp., 518 U.S. 839, 865 (1996) (favoring language in a contract because a contract "lock[s] in the then-current regulatory treatment"); *see also* Holland v. United States, 57 Fed. Cl. 540, 565 (Cl. Ct. 2003) (determining that the federal government breached its contract with a private party when it issued subsequent regulations); Granite Mgmt. Corp. v. United States, 53 Fed. Cl. 228, 241 (Cl. Ct. 2002) (holding that contract language "would prevail over any conflicting regulations" where the "plaintiff did not assume the risk of regulatory change"). Embodying the commitments made by the contracting parties, the MRAs do not "unmistakably warn[]" the pharmaceutical manufacturers that a subsequent regulation may increase their contractual obligations. *Cf.* Franklin Fed, Sav. Bank v. United States, 928 F.2d 994, 999 (Fed. Cir. 2005) (reasoning that contractually defined terms may be changed by subsequent regulation where the contract "unmistakably warned [the private party] that its obligations under the contract may be increased by subsequent regulation" (internal quotation marks omitted)).
[15] In addition, the Agency may face constitutional claims brought under the Takings Clause of the Fifth Amendment. *Independence Park Apts. v. United States*, 449 F.3d 1235, 1237 (Fed. Cir. 2006) (describing generally regulatory takings claims brought against the government in conjunction with breach-of-contract claims); *Anaheim Gardens v. United States*, 444 F.3d 1309, 1315 (Fed. Cir. 2006) (explaining that a "'regulatory taking' may occur when Government action, although not encroaching upon or occupying private property, 'goes too far' and still amounts to a taking (quoting *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001)).
[16] *Cienega Gardens v. United States*, 331 F.3d 1319, 1334 (Fed. Cir. 2003).
[17] MRA, *supra* note 3.

incorporating any future regulations the Secretary may issue regarding the Medicaid Rebate Program or the AMP and BP calculations.

Significantly, the MRA does require compliance with changes to one section of the Social Security Act. The MRA requires compliance with "changes. . . to and implementing regulations. . ." for section 1928 of the Social Security Act.[18] The existence of this specific language clearly shows the intention not to require compliance with other regulatory changes. Basic principles of contract interpretation provide that an explicit reference to one circumstance necessarily establishes an exclusion of all other circumstances. The doctrine of *expressio unius est exclusio alterius* provides that when a contract affirmatively designates certain things, omissions constitute exclusions.[19]

Thus, the express reference to compliance with changes to regulations associated with section 1928 precludes any requirement to comply with changes to regulations associated with section 1927. The MRA is not affected by a change in regulatory policy.

V. Retroactive application of the new definition would violate the Administrative Procedures Act.

The APA independently confirms the illegitimacy of a retroactive application of the Final Rule as the APA defines the term "rule" as necessarily having a prospective effect.[20] The APA's definition of "rule" is the "whole or a part of an agency statement of general or particular applicability *and future effect*. . . ."[21]

Courts will determine that a regulation operates retroactively where the "new provision attaches new legal consequences to events completed before its enactment,"[22] such as by "impair[ing] rights a party possessed when he acted, increas[ing] a party's liability for past

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[18] *Id.* at § II(c).

[19] The translation of this phrase is "the express mention of one thing implies the exclusion of another." *See* Asbestos Settlement Trust v. City of New York (In re Celotex Corp.), 487 F.3d 1320, 1334 (11th Cir. 2007) (citing Plumbers and Steamfitters Local 150 v. Vertex Const. Co., 932 F.2d 1443, 1449 (11th Cir.1991) ("The doctrine of expressio unius est exclusio alterius instructs that when certain matters are mentioned in a contract, other similar matters not mentioned were intended to be excluded.")).

[20] The APA authorizes a reviewing court to hold unlawful and set aside agency action, findings, and conclusions found to be, *inter alia*, arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in excess of statutory authority or short of statutory right, or without observance of procedure required by law. 5 U.S.C. § 706.

[21] 5 U.S.C. § 551(4) (emphasis added). *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988), at 216 (Scalia, J., concurring). "The only plausible reading of . . . [the definition of a 'rule' under the APA] is that rules have legal consequences only for the future. . . . In short, there is really no alternative except the obvious meaning, that a rule is a statement that has legal consequences only for the future." *Id.*

[22] *Landgraf v. USI Film Prods.*, 511 U.S. 244, 269-70 (1994).

conduct, or impos[ing] new duties with respect to transactions already completed."[23] In making this determination, courts take "sound guidance" from "familiar considerations of fair notice, reasonable reliance, and settled expectations."[24]

The Supreme Court has struck down Agency efforts to promulgate retroactive rules holding:

> It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress. In determining the validity of the Secretary's retroactive [ ] rule, the threshold question is whether the [enabling statute] authorizes retroactive rulemaking. Retroactivity is not favored in the law. Thus ... administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. *See Brimstone R. Co. v. United States*, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic. It . . . ought not to be extended so as to permit unreasonably harsh action without very plain words"). Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.[25]

With respect to the issue of "bundled sale," there is no question that the particular statutory scheme at issue (Title XIX of the Social Security Act and the DRA) does not in any way provide the Agency with the authority to promulgate retroactive regulations. Absent such

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[23] *Id.* at 280.
[24] *Id.* at 270.
[25] *Georgetown Univ. Hosp.*, 488 U.S. at 208-09 (citations omitted). The Supreme Court's decision in Bowen v. Georgetown University Hospital serves as a useful example in the present context, illustrating that the Agency may not promulgate the Final Rule with retrospective application. In that case, the Secretary of Health and Human Services issued a Medicare cost-limit schedule that altered the way the underlying hospital "wage index" was calculated by excluding federally-run hospitals from consideration. In light of the Secretary's failure to give required notice or solicit public comment on the potential rule change, the new cost-limit schedule was invalidated. The Secretary proceeded to promulgate the rule anew, with retrospective application, by following the necessary procedures. *Id.* at 206-7.

express Congressional authority, the Agency may only apply the Final Rule prospectively because the Agency is obligated to avoid impairing vested rights acquired under the MRA, or creating a new obligation or imposing a new duty. The critical question of whether the challenged rule establishes an interpretation that changes the legal landscape must be answered in the affirmative because the Final Rule (1) abandons the notion that a bundled sale can only occur based on a "purchase" requirement; (2) suggests that bundled sales can be based on the "same" product and not simply "different types" of products; and (3) makes other changes in the new definition. Since it is undisputed that the Agency lacks the authority to promulgate a retroactive rule governing and impinging upon the contractually-defined term of "bundled sale," we urge the Agency to clarify that it is not attempting to retrospectively apply the new definition of a bundle. The Agency likely already appreciates the limits of its authority, which would explain why the express language of the final rule makes no mention of requiring a retroactive effect.

Only a prospective application of the new definition would be appropriate and consistent with the APA. In the past, manufactures have repeatedly been required to avail themselves of the reasonable-assumption mechanism provided under the MRA because of the absence of clear guidance on a variety of issues, including some bundling-related issues. Retrospective application of the Final Rule would be inconsistent with the prior guidance specifically permitting reasonable assumptions.

The plain language of the APA and the cases thereunder has required only prospective application of substantive changes in regulatory policy. We respectfully urge the Agency to confirm its intent to apply the provision prospectively as required by the notice and comment requirements of the APA and pursuant to court precedent.

* * *

In conclusion, we applaud the Agency for its much appreciated work in seeking to address more clearly some of the many complex issues raised by the Medicaid price reporting system. For the reasons articulated, however, we strongly urge the Agency to state unambiguously that it will hold true to its agreement under the MRA and its "bundled sale" definition and only give a prospective application to the new definition contained in the Final Rule. We thank the Agency again for the opportunity to comment on these important issues.

Sincerely,

William A. Sarraille

WAS: attachment

Contract Terms: *All forms and strengths of drug A receive a 10% rebate*

Example 1 (using sales volume-weighted allocation)

							Sales Volume-Weighted Allocation			
	Form/Strength	Price Per Unit	Total Units Purchased	Initial Purchase Total	Rebate Percentage	Total Rebate $	Sales as % of Total Sales	Unbundled Rebate $	Final Purchase Total $	**Net Purchase Price Per Unit**
Drug A	15mg cap	$1.00	600	$600.00	-10%	($295.00)	20.3%	($60.00)	$540.00	**$0.90**
Drug A	30mg cap	$1.50	500	$750.00			25.4%	($75.00)	$675.00	**$1.35**
Drug A	2ml injection	$2.00	800	$1,600.00			54.2%	($160.00)	$1,440.00	**$1.80**
TOTALS			**1900**	**$2,950.00**			**100.0%**	**($295.00)**	**$2,655.00**	

Example 2 (without allocation)

							Straight Discount Application			
	Form/Strength	Price Per Unit			Rebate Percentage	Total Rebate Per Unit				**Net Purchase Price Per Unit**
Drug A	15mg cap	$1.00			-10%	($0.10)				**$0.90**
Drug A	30mg cap	$1.50			-10%	($0.15)				**$1.35**
Drug A	2ml injection	$2.00			-10%	($0.20)				**$1.80**

Net purchase price per unit is the same under the contract whether the discount is allocated based on sales weighted volume or applied individually to the price per unit.