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CMS FINAL RULE ON THE MEDICAID DRUG REBATE PROGRAM

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CMS Final Rule on the Drug Rebate Program

On July 17, 2007, the Centers for Medicare & Medicaid Services ("CMS") published a final rule with comment period to implement the Medicaid Drug Rebate Program.[1] With certain notable exceptions, which are discussed below, the final rule is largely consistent with the proposed rule published by CMS in December 2006.[2] This memorandum summarizes the final rule, noting where it differs from the proposed rule and prior policy or guidance issued by CMS. We also identify issues that would benefit from further clarification from CMS.

I. EFFECTIVE DATE AND COMMENT PERIOD

Rejecting requests that CMS delay implementation of the final rule, particularly with regard to AMP, CMS decided that the regulations will be effective October 1, 2007. This means that manufacturers will be required to comply beginning with the monthly average manufacturer price ("AMP") calculations for October 2007 and the quarterly AMP and Best Price submissions for the fourth quarter of 2007.

Although the rule addresses many aspects of the Medicaid Drug Rebate Program, CMS has solicited comments only on the AMP provisions and Federal Upper Limit ("FUL") outlier provision. Comments are due by January 17, 2008. According to the preamble, CMS will consider revising the Medicaid Drug Rebate Agreement in accordance with applicable Federal statutes and regulations.[3]

II. AMP AND BEST PRICE REPORTING

A. Definition of Manufacturer

The Manufacturer of a covered outpatient drug is responsible for reporting AMP and Best Price and for paying rebates to state Medicaid agencies. The final rule defines "Manufacturer" to mean the entity that "possesses legal title to the NDC for a covered drug or biological product" and engages in the activities described in the statutory definition (e.g., production, preparation, processing, packaging, labeling).[4] For drugs subject to private labeling arrangements, the term manufacturer also includes the entity that does not possess legal title to the NDC

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1 CMS, Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142 (July 17, 2007).

2 CMS, Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174 (Dec. 22, 2006). We distributed a memorandum summarizing the proposed rule on December 29, 2006.

3 72 Fed. Reg. at 39,157.

4 42 C.F.R. § 447.502.

number.[5] The notion of holding "legal title" to an NDC, which is taken from the current Rebate Agreement, has always been puzzling since a labeler code is not a license or other property interest, but instead is merely a number assigned by the FDA. However, CMS has eliminated any potential confusion by explaining in the preamble that, outside of the authorized generics context, it will consider the manufacturer possessing legal title simply to be the company whose NDC number appears on the label at the time the drug is dispensed.[6]

B. AMP

Tracking the statute, the final rule defines AMP as the average price paid to the manufacturer in the U.S. by wholesalers for drugs distributed to the "retail pharmacy class of trade."[7] In accordance with section 6001(c) of the Deficit Reduction Act of 2005 ("DRA"), and contrary to prior law, AMP is to be calculated without regard to customary prompt pay discounts extended to wholesalers. Pursuant to the statute, this change was effective January 1, 2007, even though the rule was not finalized at that point. AMP includes all sales and associated discounts for all drugs distributed to the retail pharmacy class of trade, unless the sale, discount, or price concession is specifically excluded by statute or regulation or to an entity excluded by statute or regulation. The rule clarifies that "AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees (except bona-fide service fees), and any other rebates, discounts or other price concessions, other than [Medicaid rebates], which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade."[8]

The rule defines the "retail pharmacy class of trade" as "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[9] The most notable difference from the proposed definition is that pharmacy benefit managers ("PBMs") have been deleted from the list of entities included in the retail pharmacy class of trade.[10] Consistent with the proposed rule, CMS has determined to include mail order pharmacies within the retail pharmacy class of

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5 42 C.F.R. § 447.502. With respect to authorized generics, discussed in more detail in Section II.D, below, the definition of manufacturer also includes the original holder of the approved new drug application ("NDA"). Id.

6 72 Fed. Reg. at 39,162.

7 42 C.F.R. § 447.504(a).

8 42 C.F.R. § 447.504(i).

9 42 C.F.R. § 447.504(e).

10 See 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § 447.504(e)).

trade, rejecting comments that the term should be defined consistently with the Medicare Part D definition of "retail pharmacy," which does not include mail order pharmacies.[11] Furthermore, CMS explains that the reference to "'other outlets' allows for the inclusion of sales to other entities, such as physician offices and outpatient clinics, that purchase drugs from the manufacturer and provide them to the general public."[12]

Consistent with this general definition, the final rule identifies specific categories of customers and transactions that should be included in or excluded from the determination of AMP. These are addressed below. A table summarizing the AMP and Best Price treatment of various customer categories and transactions is included as an attachment to this memorandum.

1. **Treatment of Certain Customer Categories**

a. *Federal prices.* Federal prices are **excluded** from AMP (both units and dollars). These include prices to the Indian Health Service, the Department of Veterans Affairs, state veterans homes, the Department of Defense, the Public Health Service, and covered entities under section 340B of the Public Health Service Act (PHS Act); other federal supply schedule (FSS) prices; and depot prices (including Tricare) and single award contract prices.[13] This is generally consistent with the current Medicaid Drug Rebate Agreement.[14]

b. *Retail pharmacies.* Sales to retail pharmacies are, of course, **included** in AMP, as are discounts or other price concessions associated with such sales.[15] This is consistent with the proposed rule and prior CMS guidance.[16]

c. *Mail order pharmacies.* Sales to mail order pharmacies, including those operated by PBMs, are **included** in AMP.[17] This is consistent with the

11 72 Fed. Reg. at 39,164.
12 72 Fed. Reg. at 39,164.
13 42 C.F.R. § 447.504(h)(1)-(3).
14 See Medicaid Drug Rebate Agreement, § I(a).
15 42 C.F.R. § 447.504(g)(5) and (g)(14).
16 See 71 Fed. Reg. 77,196 (proposed 42 C.F.R. § 447.504(g)(5)); CMS, Release No. 29 (June 5, 1997).
17 42 C.F.R. § 447.504(g)(6) and (g)(9).

proposed rule and prior CMS guidance.[18] CMS was not swayed by objections from pharmacists that including mail order sales will lower AMP, reducing FULs and AMP-based reimbursement to levels at which retail outlets cannot afford to purchase medications.[19] The preamble explains that mail order pharmacies are within the retail pharmacy class of trade because "they provide drugs to the general public."[20]

d. *Wholesalers*. Sales to wholesalers are **included** in AMP, except for sales that can be identified with adequate documentation as being subsequently sold to an excluded entity.[21] This is consistent with the proposed rule and prior CMS guidance.[22] CMS defines wholesaler very broadly 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."[23] One comment noted that if there is no chargeback, a manufacturer may not be able to ascertain whether the end purchaser of a sale to a wholesaler was retail. CMS responded that sales to wholesalers must be included in AMP absent such documentation.[24]

e. *Hospitals*. Consistent with prior CMS guidance,[25] direct and indirect sales to hospitals for use in inpatient pharmacies are **excluded** from AMP.[26] Sales to hospitals that can be identified with adequate documentation as being for use in outpatient pharmacies (e.g., pharmacies for a hospital outpatient department or clinic) are **included** in AMP.[27]

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18 See CMS, Release No. 29.
19 72 Fed. Reg. at 39,174.
20 72 Fed. Reg. at 39,174.
21 42 C.F.R. § 447.504(g)(1).
22 See 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(g)(1)); CMS, Release No. 29.
23 42 C.F.R. § 447.504(f).
24 72 Fed. Reg. at 39,165.
25 See CMS, Release No. 29; Medicaid Drug Rebate Agreement, § I(a).
26 42 C.F.R. § 447.504(h)(4).
27 42 C.F.R. § 447.504(g)(3).

However, absent such documentation, hospital sales must be excluded.

f. *Physicians*.[28] Sales to physicians are **included** in AMP. This provision was added in the final rule to clarify that physicians fall within the retail pharmacy class of trade to the extent that the physician provides drugs to the general public.[29]

g. *Patients*.[30] Sales directly to patients are **included** in AMP. The preamble to the proposed rule described these sales as "usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug."[31] The final rule preamble explains that the distributor is acting as a wholesaler in these situations and the sales to patients are to the retail pharmacy class of trade.[32]

h. *Third party payors*.[33] CMS has taken a uniform approach to third party payors who do not take possession of drugs, whether they are government programs or private payors. Sales by a manufacturer of units that are ultimately reimbursed by a third party payor are **included** in AMP, where the sales are made into the retail chain of distribution. However, any discounts, rebates, or other price concessions to the third party payor itself are **excluded** from AMP, because CMS has recognized that "such price concessions are essentially third party discounts and not discounts which adjust the price actually realized at the retail pharmacy." Thus, sales reimbursed by the following entities/programs are included in AMP (i.e., they are not backed out of gross sales), while rebates and other price concessions to these entities/programs

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28 42 C.F.R. § 447.504(g)(13).
29 72 Fed. Reg. at 39,172.
30 42 C.F.R. § 447.504(g)(7), (10).
31 71 Fed. Reg. at 77,180.
32 71 Fed. Reg. at 77,180-81.
33 42 C.F.R. § 447.504(g)(15).

are ignored for purposes of AMP:

- Medicaid (both Medicaid Rebates and Medicaid supplemental rebates)
- Medicare Part D, including Prescription Drug Plans ("PDPs"), Medicare Advantage PDPs ("MA-PDPs") and Medicare-subsidized retiree prescription drug plans
- State Children's Health Insurance Programs ("SCHIPs")
- State pharmaceutical assistance programs ("SPAPs")[34]
- TriCare retail pharmacy program ("TRRx"). Note that TriCare rebates are excluded from AMP whether they are voluntary or ultimately become mandatory.[35]
- Health maintenance organizations ("HMOs") and other managed care organizations ("MCOs") that do not take possession of drugs.

i. *PBMs*. In a departure from the proposed rule, rebates and other price concessions to PBMs are **excluded**, except for their mail order purchases.[36] Sales of drugs reimbursed by PBMs (other than mail order sales) are not specifically identified as included in AMP. The best interpretation of the rule is that PBMs fall within the term "third party payers" and are treated similarly to the third party payors identified above – i.e., the sales into the retail distribution channels are **included.**[37] However, because there are contradictory preamble statements,[38] this is an issue that would

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34 Note that this is a change from prior guidance indicating that SPAP sales (dollars and units) should be excluded from AMP. See CMS, Release No 29.

35 72 Fed. Reg. at 39,181.

36 42 C.F.R. § 447.504(h)(22).

37 42 C.F.R. § 447.504(h)(22).

38 See, e.g., 72 Fed. Reg. at 39,181 and 39,193.

benefit from further CMS guidance.

j. *Sales to HMOs and other MCOs that take possession*.[39] These sales are **excluded** from AMP, consistent with prior CMS guidance.[40] CMS explains that these sales are not considered the retail class of trade.[41]

k. *Long-term care facilities*. AMP excludes sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where the sales can be identified with adequate documentation, and other entities where drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.[42] In a departure from prior CMS guidance, CMS explains that these sales should be excluded from AMP because nursing home pharmacies do not dispense to the general public and therefore should not be considered the retail pharmacy class of trade.[43] The preamble also clarifies that infusion centers and rehabilitation centers that serve patients outside a nursing home would not be considered long-term care pharmacies.[44]

l. *Relabelers*. AMP **includes** sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC number, including private labeling agreements.[45] Sales to wholesalers or distributors where the drug is relabeled under the purchaser's NDC number are **excluded** from AMP.[46] These rules are consistent with prior CMS guidance.[47]

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39 42 C.F.R. § 447.504(h)(5).
40 See CMS, Release No. 29; Medicaid Drug Rebate Agreement, § I(a).
41 72 Fed. Reg. at 39,181.
42 42 C.F.R. § 447.504(h)(6).
43 72 Fed. Reg. at 39,172.
44 72 Fed. Reg. at 39,172.
45 42 C.F.R. § 447.504(g)(2).
46 42 C.F.R. § 447.504(h)(14).
47 See CMS, Release No. 29.

m. *Other customer categories **included** in AMP*:

- *Sales to specialty pharmacies.*[48]
- *Sales to home infusion therapy pharmacies.*[49]
- *Sales to outpatient facilities*, including clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers.[50]
- *Sales to home health care providers,* unless dispensed through nursing facilities.[51]

n. *Other customer categories **excluded** from AMP*:

- *Sales to hospices* (inpatient and outpatient).[52] CMS explains that sales to hospice pharmacies are outside of the retail marketplace because the drugs are not available to the general public.[53]
- *Sales to prisons.*[54]

2. **Treatment of Certain Transactions**

a. *Nominal prices*. Nominal prices are **excluded** if they are to a covered entity described in section 340B(a)(4) of the PHS Act, an intermediate care facility for the mentally retarded ("ICF/MR"), or a state-owned or operated nursing facility.[55] Nominal prices to all other entities are **included** in AMP. "Nominal price" is defined as a price that is less than 10 percent of AMP in the same quarter for which the AMP is computed.[56]

b. *Customary prompt pay discounts*. The DRA amended the statutory definition of AMP to exclude customary

48 42 C.F.R. § 447.504(g)(11); 72 Fed. Reg. at 39,176.
49 42 C.F.R. § 447.504(g)(10); 72 Fed. Reg. at 39,176.
50 42 C.F.R. § 447.504(g)(8)).
51 42 C.F.R. § 447.504(g)(12); 72 Fed. Reg. at 39,172.
52 42 C.F.R. § 447.504(h)(7).
53 72 Fed. Reg. at 39,172.
54 42 C.F.R. § 447.504(h)(9).
55 42 C.F.R. § 447.504(g)(4).
56 42 C.F.R. § 447.502.

prompt pay discounts to wholesalers, effective January 1, 2007. Accordingly, the final rule **excludes** customary prompt pay discounts extended to wholesalers from the calculation of AMP.[57] This change went into effect on January 1, 2007, even though the rule had not been finalized at that time. The rule defines a prompt pay discount as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment."[58] CMS declined to define "prompt," but explains in the preamble that "the length of time in which the purchaser can receive the discount should be consistent across purchasers for that manufacturer as well as consistent with customary business practice."[59]

c. *Bona fide service fees*.[60] All bona fide service fees are **excluded** from the calculation of AMP. CMS defines "bona fide service fees" as "fees 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."[61] This is the same definition used in CMS's regulation governing the ASP[62] definition. In light of this fact, and responding to numerous comments, CMS expressly adopts for AMP purposes the helpful guidance related to this definition that was contained in the preamble to CMS's 2007 final Physician Fee Schedule Rule.[63] CMS also clarifies that "distribution fees" which are ordinarily included

57 42 C.F.R. § 447.504(h)(20).
58 42 C.F.R. § 447.504(c).
59 72 Fed. Reg. at 39,167.
60 42 C.F.R. § 447.504(h)(19).
61 42 C.F.R. § 447.502.
62 42 C.F.R. § 414.802.
63 72 Fed. Reg. at 39,182. See 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006).

in AMP, are excluded if they otherwise qualify as a bona fide service fee.[64]

d. *Administrative fees to group purchasing organizations ("GPOs")*. The preamble clarifies that administrative fees and other fees to GPOs are **excluded** from AMP and are not considered price concessions if they are bona fide service fees, so long as the fees are not passed on to the GPO's members or customers.[65] Notably, however, "there must be no evidence or arrangement that the fee is passed on to the member pharmacy, client or customer of any entity" that would otherwise be included in AMP.[66]

e. *Manufacturer coupons*. The final rule **excludes** all manufacturer coupons from AMP where full value of the coupon is passed on to the consumer, and no pharmacy or other entity receives any price concessions.[67] This is more flexible than the proposed rule, which would have permitted exclusion of coupons from AMP only when redeemed directly to the manufacturer, and not when redeemed through a pharmacy. The final rule preamble elaborates that if the following four conditions are met, the coupon need not be included: (1) the coupon is not contingent upon any purchase requirement to individuals (presumably, other than on the units that are the subject of the coupon); (2) the benefit is established by the manufacturer without any negotiation with a third party (such as an insurer or PBM); (3) the entire amount of the free product or coupon amount goes to the individual with no portion going to a third party (such as an insurer or PBM); and (4) the pharmacy does not receive any additional amount, other than the benefit amount and a bona fide service fee for processing the coupon.[68] The final rule also provides

64 42 C.F.R. § 447.504(i)(1).
65 72 Fed. Reg. at 39,183.
66 72 Fed. Reg. at 39,183.
67 42 C.F.R. § 447.504(h)(15); 72 Fed. Reg. at 39,187.
68 72 Fed. Reg. at 39,187.

that vouchers for free samples received from a pharmacy are **excluded** from AMP.[69]

f. *Manufacturer Patient Assistance Programs*.[70] Patient assistance programs ("PAPs") that provide free product to consumers without purchase requirements and which provide no price concessions to the pharmacy are **excluded** from AMP. The four requirements described above for coupons are also applicable here, except that the first requirement also specifies that the program must be intended to benefit low-income individuals and families.[71]

g. *Free goods*. Consistent with the Medicaid Rebate Agreement, free goods not contingent upon any purchase requirement are **excluded** from AMP.[72]

h. *Returned goods*.[73] Like the proposed rule, the final rule **excludes** returned goods from the calculation of AMP when the returns are made in good faith (i.e., not intended to inflate or deflate AMP).[74] This is a departure from prior policy, which required returned goods to be credited back to the manufacturer.[75]

3. Reasonable Assumptions

In the preamble, CMS makes clear that, in the absence of specific guidance, manufacturers may make reasonable assumptions in their calculations, consistent with the intent of the Medicaid Rebate statute, the regulations, and their customary business practices.[76] Manufacturers would be well advised to document their assumptions and maintain such documentation in accordance with the record-keeping requirement of the regulation (see Section III.F, below).[77]

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69 72 Fed. Reg. at 39,188.
70 42 C.F.R. § 447.504(h)(12).
71 72 Fed. Reg. at 39,188-89.
72 42 C.F.R. § 447.504(h)(10).
73 42 C.F.R. § 447.504(h)(21).
74 72 Fed. Reg. at 39,186.
75 This change is consistent with CMS's current policy regarding the calculation of ASP.
76 See, e.g., 72 Fed. Reg. at 39,164.
77 42 C.F.R. § 447.510(f)(1).

C. Best Price

CMS has defined Best Price as:

> with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA 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 entity in the United States in any pricing structure (included capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates; discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.[78]

This definition, while consistent with the definition in the Medicaid Drug Rebate Agreement, is an expansion of the definition in the statute, which identifies certain entities included in Best Price rather than using the blanket term "purchaser." The final rule identifies prices included in and excluded from Best Price. Following is a partial list of included and excluded items:

1. **Included in Best Price:**

- *Prices to wholesalers.*[79]
- *Prices to retailers (including mail order pharmacies).*[80]
- *Prices to providers such as hospitals, HMOs/MCOs, physicians, nursing facilities, outpatient clinics, and home health agencies.*[81]
- *Prices to nonprofit entities.*[82]

78 42 C.F.R. § 447.505(a).
79 42 C.F.R. § 447.505(c)(1) and (8).
80 42 C.F.R. § 447.505(c)(2).
81 42 C.F.R. § 447.5050(c)(3).
82 42 C.F.R. § 447.505(c)(4).

- *Prices to governmental entities within the United States (unless specifically excluded).*[83]

- *Prices of authorized generics*.[84] Section 6001(b) of the DRA amended the definition of Best Price to cover authorized generics. See Section II.D, below, for a more detailed discussion of authorized generics.

- *Prices directly to patients.*[85] Consistent with the AMP rule, Best Price includes sales directly to patients (except as specifically excluded by statute) because "this is an alternate channel for sales that normally flow through included entities."[86]

- *Prices to manufacturers* who act as wholesalers and do not repackage/relabel under the purchaser's NDC number, including private arrangements.[87]

- *Prices to entities that repackage/relabel under the purchaser's NDC number,* including private labeling arrangements, if the entity is a non-excluded entity.[88]

- *Customary prompt pay discounts*. Although the DRA revised the definition of AMP to exclude customary prompt pay discounts to wholesalers, CMS explains that it could find no evidence of Congressional intent to revise the definition of Best Price to exclude such discounts.[89]

2. **Excluded from Best Price:**

- *"Federal" prices*, including prices to the Indian Health Service, the Department of Veterans Affairs, state veterans homes, the Department of Defense, the Public Health Service, and covered entities under section

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83 42 C.F.R. § 447.505(c)(5).
84 42 C.F.R. § 447.505(c)(6).
85 42 C.F.R. § 447.504(c)(7).
86 72 Fed. Reg. at 39,199.
87 42 C.F.R. s`447.504(c)(10).
88 42 C.F.R. § 447.504(c)(11).
89 72 Fed. Reg. at 39,199.

340B of the PHS Act;[90] other FSS prices;[91] and depot prices (including Tricare) and single award contract prices.[92] This is in accordance with the statutory exclusion for such prices. Voluntary rebates paid under the TRRx remain excluded from Best Price.[93]

- *Prices paid by a "designated" SPAP*.[94] CMS appears to have narrowed the application of this statutory exclusion. CMS previously provided guidance on the requirements for an SPAP,[95] and compliance with these requirements was sufficient to exclude rebates or discounts to such SPAPs from Best Price. In the final rule, CMS appears to have limited the application of the exclusion to "designated SPAPs" which are listed on the CMS website. The term "designated" seems to indicate that CMS will now require an SPAP to submit an application to CMS and be designated to be excluded from Best Price.[96]

- *Sales at nominal prices* to a covered entity described in section 340B(a)(4) of the PHS Act, an ICF/MR, or a state-owned or operated nursing facility.[97] Prior to enactment of the DRA, neither the statute nor the Rebate Agreement contained any restrictions regarding the kinds of purchasers that may receive excludable nominal prices. Section 6001(d)(2) of the DRA amended the statute to limit the nominal price exclusion from Best Price to sales to certain entities and safety net providers. Nominal Price continues to be defined as "a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed."[98] CMS declined to add a fourth category of safety net provider despite suggestions by

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90 42 C.F.R. § 447.505(d)(1).
91 42 C.F.R. § 447.505(d)(2).
92 42 C.F.R. § 447.505(d)(4).
93 72 Fed. Reg. at 39,199.
94 42 C.F.R. § 447.505(d)(3).
95 See CMS, Release No. 68 (Apr. 1, 2005).
96 72 Fed. Reg. at 39,197.
97 42 C.F.R. § 447.504(g)(4).
98 42 C.F.R. § 447.502.

commenters that CMS do so.[99]

- *Returns*. The final rule indicates that Best Price should be net of returns.[100] However, there is no guidance on how returns should be deducted in determining Best Price.

- *Manufacturer coupons.*[101] Coupons are excluded from Best Price if the conditions for exclusion from AMP are met (see Section II.B.2, above).

- *PAPs*.[102] Manufacturer-sponsored PAPs are also exempt from Best Price if the conditions for exclusion from AMP are met (see Section II.B.2, above).

- *PBMs.* PBM rebates, discounts, and price concessions are excluded from Best Price unless they are intended to adjust prices recognized by providers or retailers.[103]

D. Authorized Generics

In order to implement section 6003 of the DRA, the rule includes provisions related to authorized generics. CMS defines an authorized generic as "any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the [Federal Food, Drug, and Cosmetic Act]; and marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug."[104] Because an authorized generic is not generally marketed under the labeler code of the NDA holder and the NDA holder would therefore not meet the general definition of manufacturer of the authorized generic, CMS has further defined the term manufacturer for the purpose of an authorized generic to include the original holder of the NDA.[105]

In the proposed rule, CMS stated that a manufacturer holding title to an NDA would be required to include in its AMP calculations its "direct" and

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99 72 Fed. Reg. at 39,205.
100 42 C.F.R. § 447.505(e).
101 42 C.F.R. § 447.505(d)(8).
102 42 C.F.R. § 447.505(d)(9).
103 42 C.F.R. § 447.505(d)(13).
104 42 C.F.R. § 447.506(a).
105 42 C.F.R. § 447.502.

"indirect" sales of the authorized generic and would also be required to include in its Best Price sales of the drug to purchasers.[106] The preamble to the proposed rule elaborated that the primary manufacturer (i.e., the NDA holder) would include in AMP and Best Price sales of the authorized generic marketed by the secondary manufacturer (i.e., the manufacturer that markets and sells the authorized generic drug) or by the NDA holder's subsidiary.[107] However, it was unclear whether a primary manufacturer's sales of an authorized generic to a secondary manufacturer are to be included in the NDA holder's AMP. Although manufacturer-to-manufacturer sales arguably are excludable as non-retail,[108] commenters urged CMS to specifically exclude such sales from AMP in the authorized generic context.

Departing from the proposed rule, the final rule requires only the price of an authorized generic product from the primary manufacturer to the secondary manufacturer to be included in Best Price.[109] Subsequent sales by the secondary manufacturer to its customers are not included in Best Price. This change eliminates the need for the primary manufacturer to obtain sales data from the secondary manufacturer in order to determine the former's Best Price. The preamble clarifies that the inter-company sale should be adjusted to account for profit sharing, licensing, and royalty fees.[110]

With regard to AMP, as with Best Price, CMS makes clear that the sales of the secondary manufacturer to its customers are not included in the primary manufacturer's AMP. However, it is unclear whether the sales from the primary to the secondary manufacturer are included in the former's AMP, as they are in Best Price. The rule requires AMP to include sales from the primary manufacturer "directly to a wholesaler,"[111] and wholesaler is defined broadly enough to include a manufacturer.[112] However, the transfer price is not specifically identified among the items to be included in AMP as it is in Best Price. Preamble statements are contradictory.[113] Pending further guidance, we believe it likely that CMS intends the inter-company sale to be treated under the general rule for sales to another entity that relabels under its own labeler code – i.e., the sale is excluded.[114] This would avoid the same unit of drug being counted in two different AMPs.

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106 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. § 447.506(b), (c)).

107 71 Fed. Reg. at 77,184.

108 See 71 Fed. Reg. at 77,196-97 (proposed 42 C.F.R. § 447.504(g)(2)).

109 72 Fed. Reg. at 39,199.

110 72 Fed. Reg. at 39,202.

111 42 C.F.R. § 447.506(b)

112 42 C.F.R. § 447.504(f).

113 Compare 72 Fed. Reg. at 39,204 ("The primary manufacturer would be responsible for including prices to the secondary manufacturer…") with id. at 39,200 ("The DRA did not amend the AMP definition to include prices paid to the manufacturer by other manufacturers.").

114 42 C.F.R. § 447.504(h)(14).

E. Bundled Sales

Unlike the current Medicaid Drug Rebate Agreement definition, which refers only to combinations of one drug with a different drug, the final rule has defined a "bundled sale" to explicitly include a contingent arrangement involving drugs (of different package sizes) that share the same NDC-9, or drugs with different NDC-9s, or drugs with other products.[115] In addition, a bundle exists where a discount is conditioned, not only on the purchase of another drug or product, but on the achievement of some other performance requirement for another drug, such as achievement of market share or placement on a formulary tier.[116] As is currently the case, the total discount must be proportionally allocated among all of the items in the bundle.[117]

III. REPORTING AND RECORDKEEPING REQUIREMENTS

A. Monthly Reporting

In accordance with section 6001(b) of the DRA, the final rule requires manufacturers to report AMP calculated on a monthly basis. A manufacturer must submit monthly AMP data to CMS no later than 30 days after the last day of the reporting month.[118] In a change from the proposed rule, which would not have permitted revisions to monthly AMPs, the final rule allows manufacturers to report revisions to monthly AMP data for up to 36 months from the month in which the data were due.[119] CMS expects that this extended timeframe for reporting revised monthly AMP data will decrease disparities between monthly and quarterly AMPs.[120]

Monthly AMP will be calculated in the same manner as quarterly AMP, but using a timeframe of one calendar month.[121] Monthly AMP should be calculated based on the weighted average of prices for all manufacturer package sizes of each covered outpatient drug (i.e., at the NDC-9 level) sold by the manufacturer during a month, excluding ineligible sales and subtracting price reductions in accordance with the AMP determination rules described above.

After considering public comments, CMS has decided to require a manufacturer to estimate the value of its lagged price concessions in monthly

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115 42 C.F.R. § 447.502.
116 42 C.F.R. § 447.502.
117 42 C.F.R. § 447.502.
118 42 C.F.R. §§ 447.510(d) and 447.504.
119 42 C.F.R. § 447.510(d)(3).
120 72 Fed. Reg. at 39,208-09.
121 42 C.F.R. § 447.504.

AMP using a 12-month rolling average.[122] Lagged price concessions are defined as any discounts or rebates (offered to wholesalers and others) that are realized after the sale of a drug, except for customary prompt pay discounts.[123] The preamble states that manufacturers should include the current reporting month in the 12-month rolling period.[124] The preamble also indicates that manufacturers may count chargebacks in AMP either on an earned or paid basis based on their GAAPs, provided they use one method uniformly.[125] Presumably, the same flexibility is permitted for rebates.

B. Quarterly Reporting

AMP, Best Price, customary prompt pay discounts, and nominal sales will be reported on a quarterly basis. Quarterly reports are due to CMS no later than 30 days after the end of the rebate period.[126] Quarterly AMP is no longer calculated based on quarterly sales and quarterly units. Instead, it is the weighted average of the monthly AMPs in the quarter.[127] Neither the rule nor the preamble indicates whether the weighting should be done based on sales (gross or net) or units (gross or net). This is left for the manufacturer to determine, absent further CMS guidance.

A revision to a monthly AMP will require a revision to the corresponding quarterly AMP. Manufacturers must report revisions to quarterly AMP, Best Price, customary prompt pay discounts, or nominal sales for a period not to exceed 12 quarters after the quarter in which the data were due, and must report revisions to monthly AMP within 36 months after the month when the data were due.[128] There is an exception under which manufacturers "must report revisions to [monthly and quarterly] AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions."[129] Under a literal reading of this provision, manufacturers need not, but may, report revisions when they result from lagged price concessions. However, the preamble indicates that the exception is not intended to be permissive, but instead to prohibit manufacturers from reporting revisions resulting from lagged price concessions.[130]

With regard to quarterly reporting of prompt pay discounts, CMS clarifies that manufacturers must report the actual amount of the discounts for the period

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122 42 C.F.R. § 447.510(d)(2); 72 Fed. Reg. at 39,210.
123 42 C.F.R. § 447.502.
124 72 Fed. Reg. at 39,210.
125 72 Fed. Reg. at 39,209.
126 42 C.F.R. § 447.510(a).
127 42 C.F.R. § 447.504(i)(2).
128 42 C.F.R. § 447.510(b) and (d).
129 42 C.F.R. § 447.510(b)(2) and (d)(4).
130 72 Fed. Reg. at 39, 227.

rather than estimating them by applying the available prompt pay discount percentage to total direct sales.[131]

C. Base Date AMP Reporting

Manufacturers may optionally report a revised base date AMP to CMS through the third quarter of 2008.[132] This is intended to permit manufacturers to reduce disparities between base date and current quarter AMP that are due to newly required changes in AMP methodology – most notably the exclusion of prompt pay discounts. Such disparities could otherwise penalize manufacturers by increasing the additional rebate that is imposed where price increases are greater than the rate of inflation.[133] Base date AMP may be recalculated on a product-by-product basis. A recalculated base date AMP will apply in calculating the unit rebate amount beginning with the quarter in which the recalculation is submitted and will not affect prior period rebates.[134] Manufacturers must use actual and verifiable pricing data for recalculation of the base date AMP – recalculation based solely on estimates or reasonable assumptions will not suffice.[135] The rule provides that the revised base date AMP "must only reflect the revisions to AMP as provided for in section 447.504 of this subpart [on determination of AMP]."[136] Absent a future correction by CMS, this provision appears to preclude the base date AMP calculation from using 12-month averaging of lagged price concessions, since the 12-month averaging requirement appears in section 447.510 rather than section 447.504 of the rule. This may benefit manufacturers who offered deep launch discounts which preceded the initial baseline quarter, but which would be swept into a recalculated base date AMP if 12-month averaging were used. When reporting base date AMP for launches after the effective date of the rule, however, it is clear that 12-month averaging should be used, which will incorporate launch discounts.

When restating base date AMP to disregard customary prompt pay discounts, manufacturers must have data on actual prompt pay discounts provided during the period for which the base date AMP applies in order to recalculate their AMPs. CMS rejected a comment that manufacturers should be permitted to use the discount that was typically offered by the manufacturer at the time of the initial report, rather than data on actual discounts paid.[137]

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131 72 Fed. Reg. at 39,167.
132 42 C.F.R. § 447.510(c)(1).
133 See 42 U.S.C. § 1396r-8(c)(2).
134 72 Fed. Reg. 39,211.
135 42 C.F.R. § 447.510(c)(2); 72 Fed. Reg. at 39,211.
136 42 C.F.R. § 447.510(c)(2).
137 72 Fed. Reg. at 39,166.

D. Recalculations

The preamble contains new guidance on recalculations. Although manufacturers may recalculate AMP on both a retrospective and prospective basis, for retrospective recalculations or statements, manufacturers must send a written request to CMS and wait for agency approval prior to submitting restatements, as before. For prospective revisions, manufacturers should also send a written request to CMS but may make the revisions prospectively without CMS approval.[138]

E. Certification

Consistent with the proposed rule, CMS requires that each price report submitted to CMS be certified by the manufacturer's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), or an individual who has the same authority as the CEO or CFO.[139] Price reports may also be certified by an individual who has been delegated authority by one of the above individuals to perform the certification.[140]

F. Recordkeeping

CMS has updated the recordkeeping requirement that was promulgated in November 2004.[141] The revised recordkeeping requirement requires manufacturers to retain written or electronic records for 10 years from the date that the manufacturer reports data to CMS for a rebate period. The records must include data and any materials used to calculate AMP (quarterly and monthly), Best Price, customary prompt pay discounts, and nominal prices, including a record of any assumptions made in the calculations.[142]

Manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or government investigation related to pricing data used in AMP, Best Price, customary prompt pay discounts, or nominal prices and the audit findings or investigation have not been resolved.[143]

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138 72 Fed. Reg. at 39,212.
139 42 C.F.R. § 447.510(e)(1)-(3).
140 42 C.F.R. § 447.510(e)(4).
141 See 69 Fed. Reg. 68,815 (Nov. 26, 2004).
142 42 C.F.R. § 447.510(f).
143 42 C.F.R. § 447.510(f)(2).

G. Reporting Format

All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format using CMS's Drug Data Reporting System ("DDR").[144] CMS issued instructions to manufacturers to provide additional guidance on the new DDR requirements in December 2006. In this final rule, CMS explains that the DDR system does not permit manufacturers to submit a text document at this time. If manufacturers wish to submit documentation about their AMP and Best Price reports, they may do so outside the DDR system. CMS will explain how manufacturers should report pricing corrections in future instructions.[145]

IV. DISCLOSURE OF AMP TO STATES

Since July 1, 2006, pursuant to section 6001(b)(1)(B) of the DRA, CMS has reported AMP to the states, and will continue to do so monthly. States will be permitted to use monthly AMPs to establish drug payment rates under Medicaid, but are not required to do so.[146] Monthly AMP data will also be updated and posted on a publicly accessible website as required under section 6001(b)(2)C) of the DRA.[147]

V. REIMBURSEMENT ISSUES

A. Federal Upper Limits

Section 6001(a) of the DRA amended the statute so that, effective January 1, 2007, a FUL must be established for each multiple source drug for which FDA has rated two or more products to be therapeutically and pharmaceutically equivalent (or "A-rated") according to the current edition of FDA's Orange Book. CMS will establish and issue FULs for multiple source drugs when at least two suppliers (e.g., manufacturers, wholesalers, repackagers, or relabelers) sell a drug listed as therapeutically and pharmaceutically equivalent in FDA's Orange Book.[148]

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144 42 C.F.R. § 447.510(g); 72 Fed. Reg. at 39,208.

145 72 Fed. Reg. at 39,208.

146 72 Fed. Reg. at 39,206.

147 72 Fed. Reg. at 39,222.

148 42 C.F.R. § 447.514(a); 72 Fed. Reg. at 39,216. As explained in the proposed rule, CMS will only use drugs that are A-rated to establish the FUL, but will continue its current practice of applying the FUL to all drug formulations. 72 Fed. Reg. at 39,215. CMS explains that applying the FUL to drugs that have not been proven to be therapeutically equivalent (e.g., "B-rated" drugs) is appropriate so that pharmacies will not be encouraged to substitute B-rated drugs to avoid the FUL. Id.

Section 6001(a)(2) of the DRA changed the formula used to establish the FUL for multiple source drugs so that the FUL will be 250 percent of AMP for the least costly therapeutic equivalent. CMS will use the monthly AMP data submitted by manufacturers to establish the FULs and will update the FULs monthly and post them on the CMS website.[149] CMS will determine if a drug is eligible for FUL pricing within seven days of notification from its contractor.[150] Terminated NDCs will not be used in setting FULs.[151]

CMS has expanded its outlier policy for determining FULs in the final rule. The AMP of the lowest priced therapeutically and pharmaceutically equivalent drug will be excluded if it is less than 40 percent of the next highest AMP.[152] In other words, if the lowest AMP is more than 60 percent below the second lowest AMP, the second lowest AMP will be used in setting the FUL.[153] CMS believes this expanded outlier policy will ensure that at least two drugs are widely available at or below FUL prices. This provision of the rule is open for further comment until January 17, 2008.

B. Dispensing Fee

The final definition of "dispensing fee" is essentially the same as that in the proposed rule.[154] CMS has revised the definition to include, in addition to fees incurred at "the point of sale," fees incurred at the point of "service" in order to recognize different service settings.[155] The definition specifically includes pharmacy costs such as time spent in drug utilization review, measurement or mixing, delivery, special packaging, and overhead. CMS states that it provided a definition in order to assist states in their evaluation of factors to be used in establishing a reasonable dispensing fee.[156] CMS has chosen not to mandate a specific formula or methodology for establishing dispensing fees because CMS wants to provide the States with flexibility to set reasonable dispensing fees. CMS does not separately identify profit as a component of the dispensing fee because CMS believes that the components in the definition provide for a reasonable profit.[157]

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149 72 Fed. Reg. at 39,213-214.
150 72 Fed. Reg. at 39,213.
151 42 C.F.R. § 447.514(c)(1).
152 42 C.F.R. § 447.514(c)(2); 72 Fed. Reg. at 39,142.
153 72 Fed. Reg. at 39,216.
154 42 C.F.R. § 447.502; 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.502).
155 72 Fed. Reg. at 39,160.
156 72 Fed. Reg. at 39,160.
157 72 Fed. Reg. at 39,161.

VI. STATE COLLECTION OF REBATES ON PHYSICIAN-ADMINISTERED DRUGS

Section 6002 of the DRA amended the statute to encourage states to capture physician-administered drugs under the Medicaid Drug Rebate Program. In light of the definition of covered outpatient drug under section 1927(k)(2) of the Act, CMS has chosen not to separately define what is meant by a covered outpatient drug that is administered by a physician. CMS believes that the DRA amendments to section 1927 were intended to emphasize that where covered outpatient drugs are administered by a physician and separately billed to Medicaid, states are required to collect rebates from manufacturers for those drugs.[158]

In order to obtain federal financial participation ("FFP") for physician-administered drugs, states must require that providers submit claims for single source physician-administered drugs and the top 20 multiple source physician-administered drugs, and states must invoice manufacturers for rebates on those drugs.[159] For single source physician-administered drugs administered after January 1, 2006, states were required to collect and submit utilization data using HCPCS codes or NDC numbers.[160] Beginning January 1, 2007, states must require providers to submit claims for physician-administered single source drugs and the top 20 multiple source physician-administered drugs using NDC numbers only.[161] CMS will publish a list of the top 20 multiple source physician-administered drugs on its website.[162] CMS will annually review this list and update it as necessary.[163]

VII. CONCLUSION

This long-awaited regulation contains welcome guidance on many issues that have perplexed the industry over the years, such as the treatment of sales and rebates to PBMs, SPAPs and other third party payors; sales to Medicaid; service fees, and GPO fees. However, uncertainties remain in certain areas, in some cases because of drafting ambiguities or inconsistent preamble statements. For example:

- How should monthly AMPs be weighted in order to derive the quarterly AMP (see p. 18)?
- Are sales that are reimbursed by PBMs included in AMP (see p. 6)?

158 72 Fed. Reg. at 39,218; 42 C.F.R. § 447.520.
159 42 C.F.R. § 447,520.
160 42 C.F.R. § 447.520(a)(1); 72 Fed. Reg. at 39,218.
161 42 C.F.R. § 447.520(b).
162 72 Fed. Reg. at 39,218.
163 72 Fed. Reg. at 39,221.

- Are intercompany sales of an authorized generic included in the NDA-holder's AMP (see p.16)?

- How should manufacturers take into account returns in Best Price (see p. 15)?

- Is 12-month averaging used in recalculating base date AMP (see p. 19)?

Further CMS guidance would be helpful in these and other areas. As noted above, the Agency is soliciting comments on the AMP provisions of the rule. CMS has also undertaken to issue further sub-regulatory guidance,[164] and one CMS official has informed us that CMS intends to post answers to "Frequently Asked Questions" on its web site. Manufacturers are encouraged to seek guidance from CMS on remaining unanswered questions.

If you have any questions concerning the final Medicaid Drug Rebate rule, please contact Alan Kirschenbaum (202-737-4283; amk@hpm.com), Jeff Wasserstein (202-737-9627; jnw@hpm.com), or Michelle Butler (202-737-7551; mlb@hpm.com).

[164] See, e.g., 72 Fed. Reg. at 39,198.

ATTACHMENT

SALES INCLUDED IN AMP AND BEST PRICE

Customer Categories

Category of Customer	Included in AMP	Included in Best Price
Sales[1] to wholesalers	Yes[2]	Yes
Sales to the Federal government[3]	No	No
Sales to state, county, or municipal governmental entities in US	No	Yes
Sales (direct and indirect) to hospitals for inpatient use	No	Yes
Sales (direct and indirect) to hospital outpatient pharmacies	Yes[4]	Yes
Sales to retail pharmacies	Yes	Yes
Sales to mail order pharmacies[5]	Yes	Yes
Sales to long term care pharmacies	No	Yes
Sales to physicians	Yes	Yes
Sales directly to patients	Yes	Yes
Sales to outpatient facilities (e.g., clinics, ASCs, dialysis centers)	Yes	Yes
Sales to specialty pharmacies	Yes	Yes
Sales to home infusion therapy centers	Yes	Yes
Sales to home health care providers	Yes	Yes
Sales to hospices	No	Yes
Sales to prisons	No	Yes

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1 For AMP, the term "sales" includes dollars, units, and associated price concessions and chargebacks, except where otherwise indicated. For Best Price, "sales" means "prices."

2 But exclude sales that can be adequately documented as being subsequently sold to an excluded entity or the non-retail pharmacy class of trade.

3 "Federal government" means the Indian Health Service, DVA, a state veterans home, DOD, PHS, a 340B covered entity, an FSS purchaser, or a federal agency purchasing under a single award contract or depot purchasing system.

4 Include only if there is adequate documentation of use in hospital outpatient pharmacy, otherwise exclude.

5 Including mail order pharmacies operated by PBMs.

Category of Customer	Included in AMP	Included in Best Price
Sales to HMO or MCO that takes possession	No	Yes
Sales reimbursed by an HMO or other MCO that does not take possession	Yes	Yes
Rebates to an HMO or other MCO that does not take possession	No	No[6]
Sales reimbursed by PBMs	Yes	Yes
Rebates to PBMs (non-mail order)	No	No[7]
Sales reimbursed by Medicaid	Yes	Yes
Medicaid Rebates and supplemental rebates	No	No
Sales reimbursed by Medicare Part D[8]	Yes	Yes
Rebates to Part D plans	No	No
Sales reimbursed by SCHIP	Yes	Yes
Rebates to SCHIP	No	No
Sales reimbursed by SPAP	Yes	Yes
Rebates to SPAP	No	No[9]
Sales reimbursed by TriCare TRRx	Yes	Yes
Rebates to TriCare TRRx	No	No
Sales to manufacturers that do not repackage/relabel under purchaser's labeler code	Yes	Yes
Sales to wholesalers or distributors where drug is relabeled under purchaser's labeler code	No	Yes[10]
Sales at nominal prices to 340B covered entity, ICF/MR, or state nursing facility	No	No
Other sales at nominal prices	Yes	Yes
Sales of authorized generic ("AG") by NDA-holder to AG distributor[11]	No[12]	Yes

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6 This assumes that treatment is the same as PBM rebates. Treatment not specified in the rule. See note 7, below.

7 Exclude unless rebates are designed to adjust prices at the retail or provider level.

8 Includes a PDP, MA-PD, or qualified retiree prescription drug plan.

9 Exclude if SPAP is "designated."

10 Include if purchaser is a non-excluded entity.

11 Sales by AG distributor to its customers are not included in AMP or Best Price of NDA-holder.

12 These sales are probably excluded, but rule and preamble are ambiguous.

Transactions

Type of Transaction	Included in AMP	Included in Best Price
Customary prompt pay discounts to wholesalers	No	Yes
Bona fide service fees	No	No
Coupons, where full value is received by patient	No	No
Vouchers	No	No
Drugs provided under patient assistance program	No	No
Drug discount card programs	No	No
Free goods not contingent on purchases	No	No
Returned goods	No	Yes