Submitter : Mr. Marc Claussen **Date:** 02/20/2007

Organization : Alpharma Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1321-Attach-1.DOC

Attachment 1321

February 20, 2007

Via Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
750 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on CMS-2238-P, Medicaid Rebate Program; Prescription Drugs (Proposed Rule)

Dear Sir or Madam:

Alpharma Inc. is pleased to provide these comments on the above-referenced rule proposed by the Centers for Medicare & Medicaid Services ("CMS"), which was published in the Federal Register on December 22, 2006.[1] Alpharma's comments relate to the issue of patient coupons and their inclusion in or exclusion from the determination of best price ("BP").

The proposed rule states that "[m]anufacturer coupons redeemed by a consumer" are to be excluded from BP,[2] while "[m]anufacturer coupons redeemed by any entity other than the consumer" are to be included in BP.[3] The preamble elaborates that CMS "believe[s] that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy)."[4]

Many manufacturers, including Alpharma, offer to consumers "dollars off" coupons up to the amount of a patient's copay. Alpharma believes that a regulation that

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1 CMS, Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (Dec. 22, 2006).

2 Id. at 77,198 (proposed 42 C.F.R. § 447.505(d)(8)).

3 Id. (proposed 42 C.F.R. § 447.505(c)(12)).

4 Id. at 77,183.

would require a manufacturer to include such coupons in BP would be inconsistent with the statute and Congressional intent, regardless how the coupon is redeemed. BP is defined as "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 Unites States . . . ."[5] This list does not include patients. It is evident from this language that Congress intended BP to reflect prices from the manufacturer to commercial customers – not to individual consumers. Moreover, BP includes any prices "available from the manufacturer."[6] Manufacturers do not make available any prices to patients because manufacturers do not sell to patients. If there is no price paid by patients to the manufacturer, a manufacturer coupon cannot be a reduction in such a price.

Furthermore, contrary to CMS's statement in the preamble, a coupon redeemed through a pharmacy is not a price reduction to the pharmacy. The pharmacy is in no better position financially by virtue of having redeemed a coupon for a patient than it would have been had it collected the full copay from the patient. The pharmacy is merely administering a discount to the patient on behalf of the manufacturer. Whether the coupon is redeemed through a pharmacy or directly to the manufacturer, the patient benefits from the coupon by having a reduced copay, and the manufacturer is the entity that absorbs the cost of the coupon. The only difference when the coupon is redeemed through the pharmacy is that the patient pays a reduced copay at the time the drug is dispensed, rather than waiting until he or she redeems the coupon with the manufacturer, and the pharmacy bears the cost of the coupon until the pharmacy is reimbursed by the manufacturer. To treat these transactions differently in BP depending how the coupon is redeemed is to elevate form over substance. For these reasons, Alpharma believes that coupons redeemed by a patient through a pharmacy should be treated the same as those redeemed directly to the manufacturer – both should be excluded from BP.

If CMS nonetheless decides that a coupon redeemed by a patient through a pharmacy should be included in BP, Alpharma requests guidance from CMS regarding how a manufacturer should account for such coupons in BP. Assuming that CMS views a coupon redeemed through a pharmacy as a price reduction to the pharmacy, Alpharma requests clarification regarding the price from which the value of the coupon should be subtracted to arrive at BP. In most cases, the manufacturer does not know the price that a pharmacy has paid a wholesaler for the drug. In some cases, the manufacturer may have a pricing contract with the pharmacy, but it would be very burdensome to track every redeemed coupon back to the pharmacy contract price. One practical alternative might be

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5 42 U.S.C. § 1396r-8(c)(1)(C)(i).

6 Id.

to subtract the value of the coupon from WAC. However, pharmacies often pay a price greater than WAC, so this may not provide an accurate price. Another alternative would be for CMS to estimate what pharmacies generally pay wholesalers (e.g., WAC plus 20 percent) and require manufacturers to subtract the value of the coupon from such an estimated price. In any event, in order to avoid inequities in Medicaid Rebate liability among manufactures, CMS should provide guidance on this issue rather than leave it to each manufacturer to select its own methodology.

* * *

Alpharma appreciates the opportunity to comment on this proposed rule. If you have any questions about these comments, please do not hesitate to contact me at 317-773-0695.

Respectfully submitted,

/s/

Marc Claussen

Submitter : Mr. George Chelland **Date:** 02/20/2007

Organization : Costa Drugs, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare Services(CMS)regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper limit(FUL) program for generic drugs. Costa Drugs, Inc. is an independent pharmacy with 3 stores, located in Scranton, PA., Dickson City, PA., and Clarks Summit, PA. We are a major provider of pharmacy services in the community, with special services such as free pick-up and delivery of prescriptions, blood pressure monitoring, bubble packing, and many other services not provided by chains and certainly not provided by mail order. Many of our patients are elderly or disabled. We truly believe that if we are forced out of business by the low re-imbursements from medicaid and PBM's, including Medicare D, it will be a great loss to these patients. They will not find the personal assistance and special services we provide if our doors are closed. We are already losing money with the current medicaid pricing. Some drugs are paid at far below our actual cost. The new proposed rule on AMP will, without a doubt, put us out of business. Your consideration of these comments is essential.
Our comments are as follows:
1. Definition of "Retail Class of Trade- Removal of PBMs and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These Organizations do not dispense to the "general public." The more extensive comments submitted by Pennsylvania Pharmacists Association have addressed differention, consistency with federal policy, and the benefits of excluding these data elements.

2.Calculation of AMP-Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

3.Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

4. Manufacturer Data Reporting for Price Determination-Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulations could create an avenue for market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, Pennsylvania Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, we ask that you consider the independent retail pharmacy when making your decision on the proposed AMP regulation.

We support the more extensive comments that are being filed by Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

George J. Chelland, R.Ph.
Corporate Secretary
Costa Drugs, Inc
Corporate Secretary

Submitter : **Ms. Mary Jo Carden** **Date: 02/20/2007**

Organization : **Transplant Pharmacy Coalition**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

See attached

Collection of Information Requirements

Collection of Information Requirements

See attached

GENERAL

GENERAL

See attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attached

CMS-2238-P-1323-Attach-1.DOC

Attach # 1323

Transplant Pharmacy Coalition

February 18, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: CMS 2238-Pn RIN 0938-AO20 Medicaid Program: Prescription Drugs; AMP Regulation

I Introduction

The Transplant Pharmacy Coalition (TPC) is pleased to provide comments on *Medicaid Program; Prescription Drugs; AMP Regulation* published on December 20, 2006. TPC is a coalition of seven specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (New Orleans, LA); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). These companies specialize in providing individuals who have received transplants with medications and the pharmacy services necessary to ensure proper treatment after an organ transplant. TPC members primarily provide these services to individuals with Medicare, although most pharmacies also serve individuals with Medicaid.

TPC members have significant experience with a retrospective payment system, the Medicare Part B average sales price (ASP) system that is similar in many ways to the proposed Medicaid AMP system. As these comments demonstrate, retrospective payment systems such as the proposed AMP and ASP do not adequately reflect current market prices for prescription drugs. This means that in many cases, pharmacies cannot acquire products at prices less than the reimbursement rate. Implementing such a system for the Medicaid population could result in increases in cost rather than decreases, particularly if the reimbursement prices do not ensure appropriate generic utilization.

TPC members support the role that pharmacists play in increasing appropriate generic utilization that leads to lower prescription drug costs. State Medicaid's system of open formularies provides the ability for pharmacists to drive dispensing of generic medications. Recent CMS data suggest that Medicare Part D generic utilization is nearly 60%.[i] CMS recognizes the value of generics and the role in reducing health care costs for patients.[ii] TPC finds that this rule would discourage generic utilization and urges CMS to work with pharmacies to establish a better payment system for generic drug products rather than implement a flawed system.

TPC's comments focus on the following areas of the proposed rule:

- An overly broad retail class of trade definition that improperly includes pharmacies that do not provide medications to the public.
- Inclusion of some rebates and discounts in the calculation of AMP.
- The 30-60 day lag time in reporting that does not provide an accurate basis for the current market price of drug products and therefore artificially lowers pharmacy reimbursement.
- No ability to account for temporary and rapid price increases that occur often in the generic market.
- CMS should ensure that any reduction in the price of pharmaceuticals is accompanied by a fair dispensing fee and other fees associated with ensuring appropriate medication utilization.

II. AMP Determination §447.504

A. Definition of Retail Pharmacy Class of Trade

The definition of retail pharmacy class of trade proposed in §447.504(e) is overly broad through its inclusion of mailorder pharmacies. In this section, CMS properly excluded sales to nursing home pharmacies because these pharmacies do not dispense to the "general public." This logic should be extended to mailorder pharmacies for the same reason. Individuals who receive medications from mailorder pharmacies through contractual arrangements through a group health plan or some other type of contractual arrangement. Absent these circumstances, the general public typically does not receive medications from mailorder establishments.

AMP is supposed to be determined based on rebates and discounts directed to retail pharmacies. Nursing home pharmacies and pharmacy benefit management (PBM) companies, often affiliated with mailorder pharmacies, receive rebates and discounts that are never received by retail pharmacies. Inclusion of rebates and discounts given to mailorder pharmacies that never reach retail pharmacies improperly lowers the AMP and would make it potentially more difficult to purchase medications at acquisition prices lower than AMP.

CMS' proposed rule analyzes the inconsistencies identified by the Department of Health and Human Services Office of Inspector General and the General Accountability Office in the definition of retail class of trade. It indicates that it must be consistent with past policy, specifically Manufacturer Releases 28 and 29. However, these releases include nursing homes as the retail class of pharmacy trade. CMS' goal in defining the retail pharmacy class of trade should be to examine the purchasing practices and contractual issues of the pharmacy in question. If the retail pharmacy class of trade benefits from rebates, discounts, and other price concessions, then these should be used for purposes of defining AMP. If the retail pharmacy class of trade does not benefit from these purchases, then rebates, discounts, and other price concessions should be excluded

from the definition. This analysis provides a more sound rationale for determining class of trade than inconsistent subregulatory guidance from the past 10 years.

TPC supports the definition proposed by the National Community Pharmacists (NCPA) of the retail pharmacy class of trade. This definition suggests that CMS use "independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations."[iii]

B. Inclusion of certain rebates, discounts, and price concessions by PBMs and others

AMP as a reimbursement measure should be defined to include only those rebates, discounts, and price concessions to the retail pharmacy class of trade. A January 2007 Congressional Budget Office study describing drug pricing in the United States recognizes that retail pharmacists are often involved with changing certain prescribed products with those on a PBM formulary.[iv] The study recognized that the pharmacist often has to call the prescriber to approve the change. This takes time for the pharmacy and the financial benefit for making the change to the preferred agent accrues to the PBM, not the pharmacy.[v]

A recent sound study by the General Accountability Office finds that inclusion of the PBM rebates and discounts in the AMP would result in acquisition prices that are, on average 36% lower than retail pharmacy acquisition costs for nearly 77% of generic drugs surveyed. This creates a financial disincentive for retail pharmacies to dispense more cost effective generic drug products. This situation plus the addition of increased government costs based on the reporting defeats the purpose of the creation of AMP. Therefore, rather than implement a flawed system, TPC encourages CMS to work with the industry to create a more effective system if it seeks to reduce Medicaid prices.

III. Manufacturer Requirements §447.510

AMP Prices Will Not Reflect Current Market Based Prices

TPC members are very familiar with the negative impact of a pricing structure is compounds the price that lags behind actual market prices for prescription drugs. Under the Medicare Part B ASP system, prices are nearly six months old when published. This creates a much worse situation than is proposed by AMP, although the 30-60 day lag period associated with AMP will make prices for generics outdated. This is particularly for problematic for generic pharmaceuticals that often result in dramatic price differences from month to month. This would create more problems if the AMP includes rebates, price concessions, and discounts that do not accrue directly to pharmacies.

The CMS proposal also does not provide any mechanism to account for severe price shifts that occur between the time data are collected and publication. CMS should provide a mechanism to allow the Office of Inspector General to alert it to changes in

prices that will substantially impact the ability of pharmacies to acquire generics at costs below AMP. CMS should work with the pharmacy industry to develop guidelines on how to identify severe price shifts and the mechanism to properly alert states, the public, and pharmacies to the situation.

III. CMS Should Ensure State Dispensing Fees and Other Fees Adequately Compensate Pharmacies for Services Provided

The Deficit Reduction Act (DRA) required states to implement minimum dispensing fees for pharmacies that dispense generic drug products. The provisions of the DRA were intended to be implemented by January 1, 2007 and state plan amendments updated by this date. Currently, most states have not implemented changes to state plan amendments partially because of uncertainty associated with the provisions of the DRA. TPC urges CMS to ensure that if the AMP provisions are enacted by July 2007, states adopt the changes necessary to ensure that pharmacies are properly compensated for providing generic drugs. If this cannot be accomplished in 2007, then TPC supports delaying implementation until states these provisions are in place.

IV. Conclusion

TPC believes that the current AMP system as proposed by CMS will not meet the goal of reducing Medicaid program costs but will actually add to the burdens for the government, manufacturers, and pharmacies. TPC recommends that CMS reconsider the proposal until it develops a more appropriate solution to reduce Medicaid prescription drug costs.

If you have questions regarding these comments, please contact Mary Jo Carden, TPC's Washington counsel, at 202-904-2482 or email: mcarden@cardenassociates.net.

Sincerely,

Mary Jo Carden, RPh, JD
On behalf of the Transplant Pharmacy Coalition

[i] Generic Drug Utilization on the Rise: Consumers and Payers Benefit More as Americans Turn to Generics to Save Money and Improve Their Health. Press Release. Ctrs for Medicare & Medicaid Svcs. February 8, 2007. Available at http://www.cms.hhs.gov/apps/media/press/release.asp. Accessed February 18, 2007.
[ii] *Ibid.*
[iii] Information available at www.ncpanet.org. Accessed February 18, 2007.
[iv] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[v] *Ibid.*

Submitter : Ms. Michelle Butler **Date:** 02/20/2007

Organization : Hyman, Phelps & McNamara, P.C.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1324-Attach-1.PDF

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February 20, 2007

Via Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
750 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on CMS-2238-P, Medicaid Rebate Program; Prescription Drugs (Proposed Rule) – Upsher Smith Laboratories, Inc.

Dear Sir or Madam:

On behalf of Upsher Smith Laboratories, Inc. ("Upsher Smith"), we are pleased to submit the following comments on the rule proposed by the Centers for Medicare & Medicaid Services ("CMS") regarding the Medicaid Drug Rebate Program on December 22, 2006.[1]

I. Calculation and Reporting of Average Manufacturer Price ("AMP"), Best Price ("BP"), and Customary Prompt Pay Discount

A. Authorized Generics

Upsher Smith seeks clarification from CMS regarding the calculation of AMP and BP for branded products for which there are authorized generic products. Under the proposed rule, a manufacturer holding title to a new drug application ("NDA") would be

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1 CMS, Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (Dec. 22, 2006).

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required to include in its AMP calculations its "direct" and "indirect" sales of the authorized generic and would also be required to include in its BP prices to certain specified types of purchasers.[2] The preamble elaborates that the NDA holder would include in AMP and BP sales of the authorized generic marketed by the secondary manufacturer or by the NDA holder's subsidiary.[3] Upsher Smith seeks guidance from CMS in three areas.

First, Upsher Smith asks CMS to clarify whether an NDA holder's sales of an authorized generic to a secondary manufacturer are to be included in the NDA holder's AMP. On one hand, the term "direct" sales would appear to encompass such sales. However, this interpretation would lead to the double-counting in AMP of every authorized generic unit – once when the unit is sold by the NDA holder to the secondary manufacturer, and again when the unit is sold by the secondary manufacturer to its customers – an obvious distortion of AMP. Because manufacturer-to-manufacturer sales should be excludable as non-retail,[4] Upsher Smith urges CMS to clarify that such sales are excluded from AMP in the authorized generic context.

Second, Upsher Smith asks CMS to clarify whether an NDA holder's sales of an authorized generic to a secondary manufacturer are to be included in BP. The proposed rule specifies types of purchasers the prices to which are to be included in the computation of BP.[5] This list includes "any manufacturer," which could include the secondary manufacturer. As noted above, the preamble makes it clear that the NDA holder is required to include in its BP all sales of authorized generic drugs by the secondary manufacturer to the specified types of purchasers.[6] However, the preamble does not address the sales of the authorized generic by the NDA holder to the secondary manufacturer. Because sales to a manufacturer that repackages/relabels under the purchaser's NDC number are only included in BP if the entity is a health maintenance organization or other non-excluded entity,[7] sales to the secondary manufacturer in the authorized generic context should be

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2 Id. at 77,198 (proposed 42 C.F.R. § 447.506(b), (c)).

3 Id. at 77,184.

4 Id. at 77,196-97 (proposed 42 C.F.R. § 447.504(g)(2)).

5 Id. at 77,198 (proposed 42 C.F.R. § 447.506(c)).

6 Id. at 77,184.

excluded from BP. Therefore, Upsher Smith urges CMS to clarify that such sales are excluded from BP.

Third, Upsher Smith seeks clarification regarding how an NDA holder is to take into account the AMP and BP of the secondary manufacturer in its own calculations of AMP and BP. This is of particular concern given potential anti-trust concerns pertaining to the sharing of AMP and BP information among manufacturers. One alternative would be to require the NDA holder to obtain the secondary manufacturer's raw sales, chargeback, and rebate data and perform its own calculations of AMP and BP. However, this would be unduly burdensome, and would, in many cases, be hampered by differences in automated data systems and data fields. For example, the secondary manufacturer's classes of trade might be incompatible with those of the NDA holder (e.g., the secondary manufacturer might sell to chain pharmacies whereas the NDA holder does not). Furthermore, every automated price calculation system has certain data formatting requirements. Raw data from the secondary manufacturer's systems may not be formatted in the correct way for the NDA holder's systems. To modify the latter's systems so that they can accommodate differently formatted data will often be an enormous IT project.

Upsher Smith believes these problems could be avoided by permitting the NDA holder to obtain the AMP, total number of units sold, and BP for each authorized generic from the secondary manufacturer and to feed those numbers into its own calculations.[8] In doing so, the NDA holder should be permitted to rely on the secondary manufacturer's certification of the accuracy of its information and calculations and of its compliance with CMS regulations and policy.

B. Bona Fide Service Fees

Upsher Smith urges CMS to clarify the proposed definition of "bona fide service fees."[9] Specifically, Upsher Smith asks that CMS provide guidance regarding how a

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7 Id. at 77,197 (proposed 42 C.F.R. § 447.505(c)(11)).

8 For AMP, the product of the secondary manufacturer's AMP times the total units sold would be added to the NDA holder's net retail sales dollars to arrive at total net retail sales dollars, and the total units sold by the secondary manufacturer would be added to the NDA holder's AMP-eligible units to arrive at total AMP-eligible units.

9 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. § 447.502).

company should determine the fair market value for a service. CMS has provided guidance regarding fair market value in the Medicare Part B average sales price ("ASP") context.[10] For ASP, CMS stated that fair market value "means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities."[11] CMS also clarified that, depending on the nature of the drug distribution services, it may be appropriate to calculate fair market value for a set of itemized services rather than for each individual itemized service. While CMS did not mandate any specific method for determining fair market value, it acknowledged a manufacturers' ability to determine the most appropriate, industry accepted method. Upsher Smith requests that similar guidance be provided for purposes of the Medicaid Drug Rebate Program.

C. Combination Facilities

Upsher Smith seeks clarification from CMS regarding the treatment of sales to facilities that may operate both a closed-door long-term care pharmacy (excludable from AMP in the proposal)[12] and a retail pharmacy (includible in AMP).[13] For such a facility, it is impossible for the manufacturer to identify which units were sold through the long-term care pharmacy and which units were sold through the retail pharmacy, since their orders do not distinguish between the two. It might be possible (though we are not certain) to separate the purchases by means of data purchased from IMS Health. However, this would be costly and would involve substantial manual data manipulation. Small and midsize manufacturers have limited resources to purchase such additional data. Upsher Smith therefore seeks clarification from CMS regarding whether all sales to such a combination facility should be included in or excluded from AMP.

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10 CMS, Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule, 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006).

11 Id.

12 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § 447.504(h)(6)).

13 Id. (proposed 42 C.F.R. § 447.504(g)(5)).

D. TriCare Rebates

Upsher Smith seeks clarification from CMS regarding the proposed treatment of prices to TriCare in the calculation of AMP and BP. The proposed regulations state that "depot prices (including TriCare)" are excluded from the determination of AMP and BP.[14] In accordance with the recent decision by the U.S. Court of Appeals for the Federal Circuit in The Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs,[15] the TriCare retail pharmacy refund program was suspended and voluntary manufacturer refunds that had been paid are being returned by the government. The court invalidated on procedural grounds a determination by the Department of Veterans Affairs that retail drug sales reimbursed by the TriCare Retail Pharmacy Program constitute a depot contracting system. Accordingly, it is our understanding that, at the current time, there is no authority for considering the TriCare retail pharmacy network prices to be depot prices. If that is the case, Upsher Smith requests clarification regarding which TriCare prices, if any, are considered depot prices and are thus excludable from AMP and BP.

E. Customary Prompt Pay Discount

Upsher Smith seeks clarification from CMS with regard to the proposed definition of "customary prompt pay discount."[16] Upsher Smith requests that CMS clarify that "prompt" is defined by the manufacturer regardless of the length of time in which the purchaser can receive the discount. Upsher Smith also proposes that CMS clarify that, in accordance with current industry practice, it is appropriate for manufacturers to calculate prompt pay discounts reportable under 42 C.F.R. § 447.510(a)(3) by applying the available prompt pay discount percentage (e.g., two percent) to total direct sales. This procedure, which is based on the valid assumption that virtually all customers qualify for the prompt pay discount, is currently prevalent among manufacturers in the calculation of AMP. The alternative, which is to track down the prompt pay discount actually paid on each order, would be very burdensome. For example, Upsher Smith does not process the prompt pay discount at an NDC number level, but rather at an order or invoice level, and would find it difficult, if not impossible, to reconcile the prompt pay discount to the NDC number level.

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14 Id. (proposed 42 C.F.R. §§ 447.504(h)(3), 447.505(d)(4)).

15 464 F.3d 1306 (Fed. Cir. 2006).

16 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(c)).

Upsher Smith also notes that the customary prompt pay discount will receive inconsistent treatment in different price calculations – i.e., not deducted from AMP; deducted in determining BP; deducted from AMP in determining 340B ceiling price. This inconsistent treatment would result in complex system requirements that would be difficult to implement for small manufacturers, such as Upsher Smith. We recognize that prompt pay discounts must be excluded from AMP under the statute. However, Upsher Smith urges CMS to consider and implement an approach to the prompt pay discount that is consistent between AMP and BP, and also to coordinate with the Health Resources and Services Administration to implement a consistent treatment of prompt pay discounts under the 340B Drug Pricing Program.

F. Smoothing of Monthly and Quarterly AMP

With regard to the monthly AMP calculation, CMS has proposed a 3-month smoothing methodology to estimate the impact of end-of-quarter discounts.[17] While this would help to reduce wide month-to-month variations caused by lagged discounts, we believe that a 12-month smoothing methodology, similar to the methodology implemented by CMS in the ASP context,[18] would be preferable. Twelve-month smoothing would result in AMPs that have even less month-to-month fluctuation, and would thus help maintain stable federal upper limits.[19] Accordingly, Upsher Smith requests that CMS permit manufacturers to use a 12-month rolling average ratio methodology for the monthly AMP.

Twelve-month averaging of price reductions should be permitted for quarterly AMP also. This would minimize short-term variations in AMP. Moreover, under Medicare Part B, the Office of Inspector General of the Department of Health and Human Services is authorized to conduct surveys to compare ASP with AMP and to implement a rate substitution if the ASP exceeds AMP plus five percent.[20] Unless AMP uses the same smoothing methodology as ASP, the two prices may not be comparable in any given quarter. Without 12-month smoothing for AMP, there are almost certain to be many quarters when chargebacks or rebates cause AMP to be far lower than ASP, even though

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17 Id. at 77,198 (proposed 42 C.F.R. § 447.510(d)(2)).

18 42 C.F.R. § 414.804(a)(3).

19 71 Fed. Reg. at 77,187.

20 42 U.S.C. § 1395w-3a(d)(2).

the two are similar when averaged over a 12-month period. This could result in unwarranted rate substitutions for drugs that are covered under both Medicare Part B and the Medicaid Drug Rebate Program.

II. Reimbursement – Coordination of Benefits

Upsher Smith seeks clarification of how CMS intends to implement section 6002 of the Deficit Reduction Act of 2005, which requires state Medicaid programs to collect Medicaid rebates for physician-administered drugs. Given that federal law does not authorize states to collect rebates for the proportion of the payment for a drug made by the Medicare program, Upsher Smith calls CMS's attention to the special case that arises for dual-eligibles and Qualified Medicare Beneficiaries where Medicare is the primary payor for drugs provided in the physician-administered setting. Accordingly, Upsher Smith urges CMS to issue specific guidance stating that the rebate due for physician-administered drugs furnished to dual-eligibles and Qualified Medicare Beneficiaries is pro-rated for the portion of the Medicaid allowable payment that the state actually pays as a copayment or deductible on the claim paid by Medicare as the primary payor. In making this recommendation, Upsher Smith supports the position taken in letters from Charles E. Grassley, then Chairman, Committee on Finance, United States Senate, to Mark B. McClellan, then Administrator, CMS (Aug. 14, 2006) and from Jayson Slotnik, Director, Medicare Reimbursement and Economic Policy, BIO, to Deirdre Duzor, Director, Pharmacy Division, CMS (July 3, 2006).

* * *

We appreciate the opportunity to comment on this important proposed rule on behalf of Upsher Smith. If you have any questions about these comments, please do not hesitate to contact me at 202/737-7551.

Respectfully submitted,

Michelle L. Butler

MLB/dcp

Submitter : **Mrs. Jennifer Thurgood** **Date: 02/20/2007**

Organization : **University of Utah College of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

q The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
q Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
q To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

Community pharmacies cannot afford to provide service to medicare patients under the proposed reimbursement rates! Please do not force community pharmacies to turn these patients away! These proposed rates are rediculous, pharmacists should not be asked to choose between operating at a loss and turning their patients away.
Thank you
Jennifer Thurgood
PharmD Candidate 2009

Submitter : Mr. David Brown **Date:** 02/20/2007

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1326-Attach-1.DOC

Attachment 1346

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February 20, 2007

BY ELECTRONIC DELIVERY

Leslie Norwalk, 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 Norwalk:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding Medicaid price reporting (the "Proposed Rule").[1] GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

The Proposed Rule notes that Congress intended the Deficit Reduction Act of 2005 ("DRA") to result in the provision of actual pricing data to States, in the form of Average Manufacturer Price ("AMP"), for use in determining reimbursement rates for covered outpatient drugs under the Medicaid Program.[2] If AMP is to be used as a reimbursement metric, GSK believes it is essential that the AMP calculation methodology accurately incorporate the acquisition costs of providers and suppliers (hereinafter "provider"). Given the complicated nature of

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1 71 Fed. Reg. 77,173 (Dec. 22, 2006).

2 *Id.* at 77,178.

the AMP and Best Price calculations, GSK also believes the calculation and reporting requirements should be clearly articulated. Such clarity is particularly important if CMS finalizes its proposal to require manufacturers to certify their Medicaid price reports.

For these reasons, GSK is pleased that CMS has chosen to further clarify the rules surrounding the AMP and Best Price calculations, and we agree with many of CMS' proposals. GSK appreciates the opportunity to comment on the Proposed Rule, and below we provide comments on several specific issues addressed in the Proposed Rule.

I. GSK Asks That CMS Provide Further Clarifications Regarding Treatment of Certain Entity Types in Calculations of AMP and Best Price.

GSK appreciates that CMS has chosen to further clarify the definition of "retail pharmacy class of trade" for purposes of determining those sales to be included in the AMP calculation. Even with the clarifications provided by the Proposed Rule, however, certain categories of entities still remain unaddressed or would benefit from additional guidance. Specifically, GSK asks that CMS confirm that all price concessions to pharmacy benefit managers (PBMs) are included in AMP calculations. We also ask that CMS clarify that Health Maintenance Organizations ("HMOs") that do not purchase and take possession of drugs should be included in the AMP calculation. Additionally, GSK requests that CMS clarify that rebates paid in relation to the utilization of retiree dependents under Qualified Retiree Prescription Drug Plans are exempt from the calculation of Best Price. As to direct patient sales, GSK believes that it is inconsistent with the Medicaid drug rebate statute and the rebate agreement to include these sales in Best Price calculations and we urge CMS to revise its position in the Final Rule. Finally, GSK asks that CMS provide additional clarification on the treatment of Tricare utilization when the manufacturer has not paid rebates on this utilization and does not receive utilization data.

A. <u>CMS Should Clarify Whether All Price Concessions to Pharmacy Benefit Managers (PBMs) Are Included in AMP.</u>

The Proposed Rule includes in the calculation of AMP "[d]iscounts, rebates or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade."[3] CMS invited comment on this proposal in

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[3] *Id.* at 77,197 (proposed 42 C.F.R. § 447.504(g)(6)).

the preamble to the Proposed Rule, including whether the proposal is operationally feasible and the extent to which CMS should define which PBM discounts should be included in AMP.[4] GSK believes that it is important that CMS provide additional clarity to manufacturers regarding the treatment of PBM discounts. It is our understanding based on CMS' statements in the Proposed Rule that CMS intends for manufacturers to include *all* discounts to PBMs in their AMP calculations, without regard to whether the PBM passes on any portion of the discount to member plans or retail pharmacies, and without regard to whether the discounts relate to mail order utilization. We ask that CMS confirm this interpretation in its Final Rule.

B. CMS Should Clarify That Sales to Non-Possession Taking Health Maintenance Organizations ("HMOs") Are Included in AMP.

AMP refers to the average price received by manufacturers for drugs distributed to the "retail pharmacy class of trade."[5] Under the Proposed Rule, CMS has proposed to define the retail pharmacy class of trade as including "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[6] In calculating AMP, CMS also has proposed incorporating "the explicitly listed exclusions . . . in the national rebate agreement," thus excluding from AMP sales to certain entities such as HMOs and other managed care organizations.[7] In the Proposed Rule, CMS does not differentiate between those HMOs that purchase and take possession of drugs, and those that do not, and GSK therefore asks that CMS clarify that HMOs that do not purchase and take possession of drugs should be included in the calculation of AMP.

Certain HMOs take possession of drugs and directly distribute the drugs to their members, while other HMOs act as third party payers only. Sales to possession-taking HMOs should be excluded from AMP because these entities do not meet the proposed definition of retail pharmacy class of trade, i.e., they do not sell drugs to the general public, but to their own members only. Non-possession

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4 *Id.* at 77,179.

5 Social Security Act ("SSA") § 1927(k)(1).

6 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(e)).

7 *Id.* at 77,178.

taking HMOs, on the other hand, do not purchase drugs to distribute to their members, but instead allow their members to purchase drugs from retail pharmacies, and then act as a third party payer to the pharmacy. These entities act similarly to State Medicaid programs, state pharmaceutical assistance programs ("SPAPs"), and Medicare Part D prescription drug plans ("PDPs").

In the preamble to the Proposed Rule, CMS explained that Medicaid sales are to be *included* in the AMP calculation because "Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs."[8] CMS advised that these sales "should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade."[9] CMS utilized this same analysis to explain that SPAP sales and Medicare Part D sales also are to be included in the AMP calculation, but concluded that discounts associated with these commercially-negotiated arrangements should be included in the AMP calculation. Under the analysis set forth by CMS with respect to Medicaid, SPAP, and Medicare Part D sales, it would appear that non-possession taking HMO sales and discounts should also be *included* in the AMP calculation. Under the Proposed Rule, however, sales and discounts to all HMOs appear to be excluded from the AMP calculation.[10]

Sales to non-possession taking HMOs are more similar to SPAP and Medicare Part D sales, GSK therefore asks that CMS clarify that sales and discounts to these entities should also be included in the AMP calculation. Including sales to non-possession taking HMOs in AMP would also be more consistent with industry pricing practices. This approach also avoids inconsistent treatment of the same sales and discounts depending on whether the non-purchaser HMO contracts directly with the manufacturer for rebates or instead contracts with a PBM to do so. Under the Proposed Rule, if all HMO sales and discounts are excluded from AMP, regardless of whether the HMO is not a purchaser, then those sales and discounts would be excluded from the calculation of AMP where the HMO contracts directly with the manufacturer. Should the same HMO contract with a PBM to do so, however, those same sales and discounts would be included in AMP. The inclusion of non-purchaser HMOs in AMP will avoid this anomolous result.

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8 *Id.* at 77,180.

9 *Id.*

10 *Id.* at 77,197 (proposed 42 C.F.R. § 447.504(h)).

C. CMS Should Clarify that Rebates Paid In Relation to Utilization by Dependents of Retirees under Qualified Retiree Prescription Drug Plans Are Exempt from the Calculation of Best Price.

The statutory definition of Best Price exempts "any prices charged which are negotiated by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title."[11] GSK asks that CMS clarify that this exemption should be interpreted to apply to rebates paid both in relation to qualified retiree utilization as well as to utilization of dependents also covered by the qualified retiree plan. GSK contracts for rebates on qualified retiree plan utilization through its commercial PBM agreements, and those agreements do not provide for different rebate structures for retirees versus their dependents because there is no data available to distinguish the utilization of those two groups. The rebate claims submitted by the PBM do not separately quantify the utilization for retirees and their dependents, and, accordingly, manufacturers are unable to identify this utilization. It is GSK's understanding that even the PBM itself typically does not have access to data that separately quantifies these two categories of enrollees in many cases. Interpretation of the Best Price exemption to apply to both the utilization of retirees as well as their dependents will ensure that manufacturers have no Best Price related disincentive to offering significant discounts to qualified retiree plans.

D. CMS Should Exclude Direct Patient Sales from Best Price.

CMS has proposed that sales made directly to patients be included in manufacturers' calculations of AMP and Best Price.[12] GSK believes that this proposal is inconsistent with the definition of Best Price in the Medicaid drug rebate statute and asks that CMS include a provision in the Final Rule that excludes direct patient sales from Best Price. Section 1927(c)(1)(C) of the Social Security Act defines "best price" to mean "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."[13] The statute plainly does not include the prices of drugs sold directly to patients.

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11 SSA § 1927(c)(1)(C).

12 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. §§ 447.504(g)(7); 447.505(c)(7)).

13 SSA § 1927(c)(1)(C).

There also is no basis for including patients in the Best Price determination on the basis that they are "wholesalers" of drugs. The Medicaid drug rebate statute does not include a definition of "wholesaler", but the Medicaid drug rebate agreement defines it to mean "any *entity* (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug."[14] Similarly, the Proposed Rule defines wholesaler to mean "any *entity* (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug."[15] A patient is not an "entity." That term is commonly understood to mean a business or other organization or enterprise, not an individual. This is further evidenced by the examples of "entities" that are listed in the definitions – a pharmacy, chain of pharmacies, or a PBM – all of which are business entities that perform drug distribution services. Accordingly, GSK asks that CMS revise its proposal on direct patient sales and include a provision in the Final Rule excluding these sales from Best Price.

E. CMS Should Provide Additional Clarification on the Treatment of Tricare Utilization in AMP and Best Price.

CMS has adopted the provision of the Medicaid drug rebate statute exempting depot prices from the calculation of AMP and Best Price.[16] CMS explicitly identifies Tricare, the Department of Defense's (DoD) retail pharmacy benefit, as an excluded depot price.[17] As CMS is aware, the Tricare Retail Pharmacy Initiative, or TRRx, was invalidated by the Federal Circuit in September 2006, which held that DoD could not require the payment of rebates on TRRx utilization without formal notice-and-comment rulemaking.[18] The DoD has since ceased the Tricare program and there is currently no requirement for the payment of rebates on Tricare utilization.

GSK disagrees with CMS's position that Tricare utilization is a depot sale that is excluded from AMP and Best Price, for the same reasons outlined by the

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14 CMS Medicaid Drug Rebate Agreement § I(ee) (emphasis added).

15 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(f)) (emphasis added).

16 *Id.* at 77,197 (proposed 42 C.F.R. §§ 447.504(h)(3); 447.505(d)(4).

17 *Id.*

18 *Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306 (Fed. Cir. 2006).

petitioner in the case before the Federal Circuit.[19] If CMS nonetheless intends to move forward with its current proposal, we believe that it is critical that CMS provide guidance to manufacturers on how to treat Tricare utilization where no rebate has been paid. If it is CMS's position that Tricare utilization is a depot sale even where the manufacturer has not paid a rebate, we ask that CMS confirm that manufacturers are not required to remove Tricare utilization from AMP if they do not have the data needed to identify it. DoD is no longer providing manufacturers with the data that was previously used to quantify Tricare utilization. We therefore ask that CMS include a provision in the Final Rule that makes clear that a manufacturer is not required to remove Tricare utilization from AMP if it does not have the data necessary to identify such utilization.

Finally, while DoD has ceased the TRRx program, DoD currently does permit manufacturers voluntarily to pay rebates on TRRx utilization. GSK believes that any rebates paid on such utilization constitute "prices" to the Department of Defense and causes those sales and rebates to be exempt from the calculation of AMP and Best Price.[20] CMS should confirm this exemption in the Final Rule.

II. CMS Should Provide Additional Guidance On Its Revised Definition of "Bundled Sales" Prior to Finalizing the Definition.

The definition of "bundled sales" in the Proposed Rule differs significantly from the definition found in the Medicaid drug rebate agreement itself. Moreover, the Proposed Rule includes no explanation for this change in definition, nor does it explain how this definition change affects the actual calculation of AMP and Best Price. GSK requests that CMS wait to finalize the new definition until CMS provides an explanation for this change as well as guidance on the proper reallocation methodology to be used. This will permit stakeholders to understand the basis for the change and provide meaningful comments before CMS moves forward with a new definition that could have far-reaching impact on reimbursement rates.

The Proposed Rule's definition of bundled sale is substantially different than that found in the rebate agreement itself. The rebate agreement defines bundled sale in the following manner:

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19 *See, e.g.*, Reply Brief of Petitioner, *Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306 (Fed. Cir. 2006) (No. 05-7130); Brief of Petitioner, *Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306 (Fed. Cir. 2006) (No. 05-7130).

20 *Id.* at 77,197 (proposed 42 C.F.R. §§ 447.504(h)(1); 447.505(d)(1).

> 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.[21]

The Proposed Rule, by contrast, includes the following definition for bundled sale:

> Bundled Sale means *an arrangement regardless of physical packaging* under which the rebate, discount, or other price concession is conditioned upon the purchase of *the same drug* or drugs of different types *(that is, at the nine-digit National Drug Code (NDC) level) 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.*[22]

As is apparent, this definition differs significantly from the definition contained in the rebate agreement. The Proposed Rule itself gives no explanation for the changes nor does it explain how this change in definition affects the AMP or Best Price calculation. For these reasons, GSK asks that CMS provide further guidance on this revision before finalizing it.

With respect to the proposed definition of bundled sale itself, GSK submits that the expansion of the definition to include discounts conditioned on "some other performance requirement"[23] is over broad. Specifically, this language could be read to include standard commercial contract terms, such as insurance, credit-worthiness, and indemnification, and thereby transform nearly every commercial sales or rebate agreement into a bundled sale.

GSK also requests that CMS define the methodology for the reallocation of discounts involved in a bundled sale and clarify that only contingent discounts be subject to reallocation. In the preamble to the Proposed Rule, CMS directs manufacturers to adjust their AMP for bundled sales "by determining the total value of all of the discounts on all drugs in the bundle and allocating those

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21 National Drug Rebate Agreement § I(e).

22 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. § 447.502) (emphasis added).

23 *Id.* at 77,195 (proposed 42 C.F.R. § 447.502).

discounts proportionately to the respective AMP calculations."[24] This direction could be interpreted to require that all discounts involved in a given arrangement be reallocated, even if certain of those discounts are not subject to a purchase or performance requirement. For example, if a manufacturer were to provide a 10% discount on Product A with no related purchase or performance requirements, but also an additional 5% discount on Product A if the purchaser also buys Product B, CMS should clarify that only the additional 5% "contingent" discount requires reallocation, as only that discount is tied to the purchase of a different product.

Finally, if CMS proceeds to finalize the new definition of bundled sale in the Proposed Rule, GSK urges CMS to make clear that the effect of this new definition is to amend and supersede the current definition of bundled sale in the Medicaid rebate agreement. As the new definition would supersede that which currently is included in the rebate agreement, GSK believes that the new definition necessarily must be prospective only and strongly urges CMS to specify this in the Final Rule.

III. CMS Should Provide Further Clarifications Regarding the Proper Treatment of Manufacturer Coupons for Purposes of the AMP and Best Price Calculation.

GSK is committed to ensuring access to important therapies to patients, and one important means through which GSK is able to do so is through the use of patient coupon programs. GSK is concerned that the broad and unqualified direction contained in the Proposed Rule – that all coupons be included in the calculation of AMP and BP where not redeemed directly to the manufacturer – could have the unintended consequence of disincentivizing such programs.[25] The Proposed Rule seems to base this broad direction in the belief that the redemption process for a coupon, where it involves any entity other than the manufacturer, necessarily affects the price realized on the manufacturer product at issue by the intermediary redeeming entity. GSK believes that there are many circumstances in which coupons can be redeemed through an intermediary and not affect the price realized by that entity, detailed below, and urges CMS to provide additional guidance regarding coupons to provide that such arrangements need not be included in the calculation of AMP and Best Price.

Patient coupons can take several forms, including free goods coupons, mail-in manufacturer rebates, and copayment assistance coupons. Free goods

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[24] *Id.* at 77,177.

[25] *Id.* at 77,181, 77,183.

coupons typically permit an individual to present the coupon to a pharmacy in order to receive free drugs, with the manufacturer then reimbursing the pharmacy for the free drugs dispensed. Mail-in manufacturer rebates are typically like other mail in rebates, i.e., the individual purchases the drug product at the pharmacy, and then submits a mail-in rebate form with purchase documentation and receives the rebate payment in the mail from the manufacturer. Lastly, some coupons are in the form of point-of-sale copayment assistance (or out-of-pocket assistance if the patient is uninsured). These coupons allow an individual to receive some type of copayment assistance for the drug at the pharmacy, with the manufacturer reimbursing the pharmacy for the amount not received from the patient. GSK asks that CMS provide further guidance on the proper treatment of each of these coupon types in AMP and Best Price.

In the preamble to the Proposed Rule, CMS proposed including manufacturer coupons "redeemed by any entity other than the consumer in the calculation of AMP."[26] CMS explained that the "redemption of coupons by the consumer directly to the manufacturer is not included in the retail pharmacy class of trade."[27] This guidance suggests that mail-in manufacturer rebates are excluded from the AMP calculation. GSK asks that CMS clarify, however, that these types of coupons also are excluded from the AMP and Best Price calculation where a third party vendor that is not a purchaser administers the rebate program for the manufacturer. Although the consumer is not redeeming the coupon "directly to the manufacturer," but rather the manufacturer's designee, given that the vendor is working on behalf of the manufacturer and is not a purchaser, these types of transactions still would not affect any price realized by a purchaser and therefore should remain excludable from the AMP and Best Price calculations.

GSK also seeks guidance on the proper treatment of free goods and copayment assistance coupons. In the Best Price discussion of coupons in the preamble to the Proposed Rule, CMS stated that it "believe[s] that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy)."[28] In the case of co-pay assistance coupons, GSK asks that CMS clarify that these coupons are also excluded from the AMP and Best Price calculations so long as the manufacturer's reimbursement to the pharmacy is limited to the copayment amount not received by the patient plus a processing fee that meets the bona fide service fee definition. In such a case, the value of the coupon does not "ultimately affect[] the price paid by

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26 *Id.* at 77,181.

27 *Id.*

28 *Id.* at 77,183.

the [retail pharmacy]," and as such, it should not be included in the AMP and Best Price calculations.

GSK also seeks confirmation that free goods coupons should not be included in the AMP and Best Price calculations where the pharmacy receives replacement product or where the reimbursement formula utilized by the manufacturer to pay the pharmacy does not affect the price for the drug paid by the pharmacy. Where a manufacturer reimburses a pharmacy for free goods dispensed pursuant to a coupon with replacement product and a dispensing fee that satisfies the bona fide service fee definition, the coupon does not affect the price paid by the retail pharmacy for the drug and therefore should be excludable from AMP and BP In addition, where a pharmacy is reimbursed for the drug using a formulaic ceiling price intended to approximate acquisition cost, or is reimbursed its usual and customary price, the price paid the pharmacy for the drug also is not affected.

In 2002, CMS provided guidance on the proper treatment in AMP and BP of GSK's drug discount card (known as the Orange Card) as well as a multi-manufacturer drug discount card (known as the TogetherRX Card).[29] CMS advised that these discount cards would not affect the AMP and Best Price calculations where the formula utilized to derive the price for the drug products was based upon the lower of a formula used to estimate the pharmacy's acquisition cost, which included a dispensing fee, or the pharmacy's usual and customary price for the drug. GSK asks CMS to clarify that free goods coupons that utilize the reimbursement methodology defined in either of those letters, or another manufacturer-determined formula designed to estimate acquisition cost, need not to be considered in a manufacturer's AMP or Best Price because they can be presumed to not affect the price realized by the pharmacy for the products dispensed free of charge. [30] Lack of clarity regarding when and how free goods coupons are to be included in the AMP and BP calculation could cause manufacturers to limit or even cease offering these important mechanisms for ensuring patient access to needed therapies. The identification of permissible reimbursement methodologies for such programs will provide that needed clarity.

Lastly, GSK notes that the above-referenced letters from CMS regarding the Orange Card and TogetherRX Card provided for the exemption from AMP and Best Price of all transactions occurring in relation to those Cards. The Proposed Rule exempts from Best Price "Prices negotiated under a manufacturer's

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29 Letter to C. Fernandez from Administrator Scully dated Nov. 13, 2002; Letter to T. McKenna from Administrator Scully dated October 22, 2002.

30 *Id.* at 77,183.

Drug Discount Card Program,"[31] and GSK requests that CMS confirm that this exemption applies to these Cards. The Proposed Rule does not include a similar exemption from AMP, and GSK requests that CMS confirm that the exemption for these Cards from AMP provided by the CMS letters remains effective.

IV. CMS Should Revise Its Proposed Rule to Clarify that Fees Paid to Non-Purchasers Are Not Discounts For Purposes of Medicaid Price Reporting.

The Proposed Rule describes the current CMS guidance regarding administrative and/or service fees to be that such fees should be included in the calculation of AMP "if those sales are to an entity included in the calculation of AMP".[32] Accordingly, any fees paid to non-purchasers, such as group purchasing organizations ("GPOs"), have not needed to be included in the calculation of AMP or Best Price. CMS now proposes to revise this policy to include in the AMP and Best Price calculations all fees "except fees paid for bona fide services."[33] CMS proposed to adopt as its definition of a "bona fide service fee" the same definition of that term that CMS recently adopted by regulation in relation to the Average Sales Price ("ASP") calculation. This definition includes fees paid to entities "whether or not the entity takes title to the product."[34] It is unclear whether CMS now proposes that fees paid to non-purchasers are now to be included in AMP. In response to comments made regarding this definition for purposes of the average sales price ("ASP") calculation, CMS responded that it is "continuing to develop [its] understanding of the variety of agreements made with entities such as PBMs and GPOs," and that it believed it would be "premature . . . to provide specific guidance" on this topic.[35] GSK strongly opposes any change in policy that requires manufacturers to include service and administrative fees paid to non-purchasers in AMP.

As CMS likely knows, GPOs generally are not themselves purchasers, but instead negotiate contracts with pharmaceutical manufacturers on behalf of their health care provider members. It is the GPO members and not the GPO itself that purchase the product. GSK recognizes that GPOs may choose to share with

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31 *Id.* at 77,198 (proposed 42 C.F.R. § 447.505(d)(7))

32 *Id.* at 77,180.

33 *Id.*

34 *Id.*

35 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006).

their members some portion of the fees paid by manufacturers.[36] This does not, however, make the GPO itself a purchaser or transform the fee paid into a discount.[37] In either situation, the manufacturer has no control over whether the fee is shared with the GPO's members, nor is the manufacturer typically aware of the GPO's arrangements with its members in this regard. Accordingly, even in these situations, administrative fees paid to the GPO should not be counted as a discount.[38]

If CMS moves forward with its proposal to include administrative fees paid to entities that do not take title to product as discounts, except where those fees meet the bona fide service fee standard, GSK asks that those fees paid that are consistent with the GPO safe harbor to the anti-kickback law be excluded from the AMP calculation.[39] The safe harbors were developed by the OIG to encourage competition in the industry, thus lowering prices, while at the same reducing the potential for abuse.[40] The OIG already has recognized that payment arrangements consistent with the GPO safe harbor are acceptable and non-abusive. Accordingly, CMS should not include as a price concession administrative and service fees that are compliant (in the case of GPOs) or consistent (in the case of PBMs) with the GPO safe harbor.

Lastly, GSK requests that CMS adopt as part of its final rule the preamble guidance on bona fide service fees provided in the 2007 Final Physician

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36 In an audit conducted by the Office of Inspector General ("OIG"), it noted that GPO practices differed regarding the passing on of administrative fees. *See* Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

37 Importantly, member-owned GPOs can satisfy the GPO definition found in the safe harbor to the anti-kickback statute. *See* 42 C.F.R. § 1001.952(j). The safe harbor excludes from its definition of a GPO those entities that own their members, but it has no similar prohibition against members owning the GPO. *Id.*

38 Such a proposal also would be unworkable. Manufacturers do not know when/whether the GPO has passed on the fee, the amount of any fee passed on, or as to which product the fee was generated. Such data is required if manufacturers are to include such transactions in the AMP calculation.

39 *See* 42 C.F.R. § 1001.952(j). The OIG, in its Compliance Program Guidance for Pharmaceutical Manufacturers, has explained that manufacturers can protect payment arrangements made with PBMs by structuring them so that they are consistent with the GPO safe harbor. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003).

40 *See* 54 Fed. Reg. 3088 (Jan. 23, 1989).

Fee Schedule Rule.[41] CMS noted in the Proposed Rule that the bona fide service fee definition it was adopting was the same as that adopted by Medicare Part B for purposes of the ASP calculation.[42] In the Final Rule adopting the definition for purposes of ASP, CMS provided significant guidance on the definition. GSK requests that CMS clarify that this guidance provided in the preamble to the final rule on the ASP calculation is equally applicable in the Medicaid context, except with regard to those circumstances in which a GPO's passing on of fees to members renders the amount passed on to be a discount from the manufacturer. CMS stated in the preamble to the Final Rule on ASP calculations that, once a manufacturer determines that a fee meets the other elements of the bona fide service fee definition, it "may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of the entity."[43] GSK does not believe that this "knowledge" test is an appropriate standard. A GPO's provision of some part of a manufacturer's fee to the GPO's members transforms the amount passed on into a discount from the manufacturer only when the provision of that amount to the members is part of the manufacturer's arrangement with the GPO. The fact that a manufacturer may know that a GPO passes on some amount of the fee to members is not enough to render that amount to be a manufacturer discount. GSK requests that CMS clarify this component of the preamble discussion and make clear that only those fees passed on as part of the manufacturer's arrangement with the GPO constitute discounts that must be accounted for in the AMP and Best Price calculations.

V. GSK Strongly Supports CMS' Proposal to Exclude Returns From the AMP Calculation.

GSK endorses CMS' proposal to exclude returns made in good faith from the AMP calculation. As CMS noted, including returns has been an administrative burden and has at times led to negative AMPs in a quarter. Moreover, we agree with the agency that the exclusion of returned goods will permit manufacturers "to calculate and report an AMP that is more reflective of its true pricing policies to the retail pharmacy class of trade in the reporting period."[44] For these reasons, we applaud this change in policy and we urge CMS to include it in the final rule.

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41 71 Fed. Reg. 69,624.

42 71 Fed. Reg. at 77,180.

43 71 Fed. Reg. at 69,669.

44 71 Fed. Reg. at 77,181.

VI. CMS Should Exclude from Best Price Goods Provided Under Patient Assistance Programs That Charge a Nominal Fee.

The Proposed Rule exempts from Best Price "[g]oods provided free of charge under a manufacturers' patient assistance programs."[45] Manufacturer patient assistance programs occasionally require payment of a nominal fee or copayment by patients participating in the program. GSK believes that where the patient pays such a nominal charge to the patient assistance program, the goods should nonetheless be considered "free of charge" and thus exempt from Best Price calculations.

VII. CMS Should Clarify Several Issues Surrounding Authorized Generics.

The Proposed Rule implements changes made to the Medicaid Drug Rebate statute by the DRA regarding authorized generics. Specifically, the Proposed Rule requires the manufacturer holding title to the original National Drug Application ("NDA") to include sales of the authorized generic in computing the AMP and BP for the branded drug.[46] GSK requests that CMS make several clarifications regarding the proposed regulation. First, we ask that CMS make clear that no transfer, royalty, and/or license payments paid from the authorized generic manufacturer to the primary manufacturer are to be included in the AMP or Best Price calculation. Next, we request that CMS specify that the primary manufacturer may utilize a weighted average approach to calculating AMP (i.e., obtain the AMP for the authorized generic from the secondary manufacturer and average it by weight with the AMP from the primary manufacturer). And, with respect to Best Price, we ask that the primary manufacturer be permitted to obtain the Best Price from the secondary manufacturer for the authorized generic and compare it to its own Best Price for the branded drug and submit to CMS the lower price point. Finally, we ask that CMS specify in the final rule that any certification provided by the secondary manufacturer hold the primary manufacturer harmless in relation to CMS for any inaccuracies later discovered in the authorized generic data.

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[45] *Id.* at 77,198 (proposed 42 C.F.R. 447.505(d)(9).

[46] *Id.* at 77,198 (proposed 42 C.F.R. § 447.506).

A. CMS Should Specify That Transfer, Royalty And/Or License Payments Of The Authorized Generic Need Not Be Factored Into the Medicaid Price Reporting For the Branded Drug.

The Proposed Rule directs that the manufacturer of the branded product include the sales of the authorized generic in its AMP and Best Price calculations. In the preamble to the Proposed Rule, CMS describes the authorized generic sales data that is to be incorporated into the branded calculations as the "sales of the authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs."[47] GSK interprets this language to refer to the secondary manufacturer's sales of the product to its own AMP-eligible and BP-eligible purchasers, and to not include any transfer, royalty, and/or license payments made by the authorized generic manufacturer to the primary manufacturer. This approach ensures that the blended AMP and Best Price figures reported by the primary manufacturer for the branded product tie to the AMP and Best Price figures reported for the authorized generic, so as to reflect the true market prices for the overall product. This approach also avoids the significant operational and compliance complexities presented by incorporating such inter-company transactions. GSK requests that CMS confirm the appropriateness of this interpretation in its final rule.

B. CMS Should Clarify That The Primary Manufacturer Is Permitted to Incorporate the AMP and Best Price of the Authorized Generic Into the Branded Drug's AMP and Best Price Rather Than Analyze the Authorized Generic's Raw Sales Data.

The text of the Proposed Rule directs that the primary manufacturer is to include the "direct and indirect sales" of the authorized generic in the branded product's AMP calculation, and the "price" of the authorized generic in the Best Price determination for the branded product.[48] GSK asks that CMS confirm that a primary manufacturer may implement these requirements by utilizing a weighted average approach to calculating its AMP and a single price point provided by the secondary manufacturer for purposes of Best Price, rather than utilize the raw sales data of the authorized generic. Such an approach should result in the same blended AMP and Best Price figures, while avoiding the extensive administrative burdens associated with the wholesale incorporation of a second manufacturer's data into

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47 *Id.* at 77184.

48 *Id.* at 77,198 (proposed 42 C.F.R. § 447.506).

primary manufacturer's price calculation system, which would otherwise require a formatting and validation effort that would strain the 30 day calculation period required by statute. Provision of summary data to the primary manufacturer also would minimize the amount of proprietary and confidential pricing information that the secondary manufacturer would have to share with its branded counterpart.

Under this approach, for purposes of Best Price, the authorized generic manufacturer would determine its Best Price, and the manufacturer of the branded product would report as its Best Price the lower of the branded product's Best Price or the authorized generic's Best Price. For AMP, the manufacturer of the authorized generic would separately calculate and report to the primary manufacturer the AMP and AMP-eligible units of the authorized generic, which would then be used by the primary manufacturer to derive a blended AMP using a weighted average of that data and the branded product's AMP and AMP-eligible units.

C. The Authorized Generic Manufacturer's Certification Should Serve To Hold The Primary Manufacturer Harmless Regarding Inaccuracies in the Authorized Generic's Pricing Data.

Finally, GSK asks that CMS specify that, to the extent the authorized generic manufacturer certifies its pricing reports in accordance with proposed regulation 42 C.F.R. § 447.510, the primary manufacturer is held harmless by CMS for any inaccuracies later discovered in the authorized generic's pricing data that affected the blended figures reported for the branded product. This approach provides a reasonable limitation on branded manufacturer liability for inaccuracies in reported blended figures that are caused by errors in the authorized generic data alone.

VIII. CMS Should Adopt the ASP Smoothing Methodology for Monthly AMP Submissions and Permit Manufacturers to Derive Quarterly AMP Figures from Monthly AMP Figures

The Proposed Rule requests comment regarding appropriate methodologies to be used for lagged data in monthly AMP calculations, which are not subject to restatement.[49] GSK urges CMS to adopt the same smoothing methodology for lagged price concessions in AMP as CMS has adopted for the ASP calculation. CMS has not required use of a particular methodology in ASP for lagged ineligible sales, and so GSK urges CMS to permit manufacturers to use in

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[49] *Id.* at 77,186.

their calculation of AMP the same approach employed by the manufacturer for ASP purposes. The Proposed Rule also directs that quarterly AMP figures are to continue to be subject to restatement for the 12 quarter period currently permitted by regulation. GSK urges CMS to permit manufacturers to choose to derive their quarterly AMP figures from their monthly AMP figures and to forego restatement of those figures as a result.

A. CMS Should Adopt the ASP Smoothing Approach for the Calculation of Monthly AMP.

CMS has expended significant resources in proposing, revising, and finalizing the methodology for estimating lagged price concessions in the calculation of ASP. GSK urges CMS to build on that learning by adopting the same approach for lagged price concessions in the calculation of monthly AMP. Such an approach would be the easiest to implement for those manufacturers with drug products subject to the ASP reporting requirement, as those manufacturers already have identified those of its transactions that are lagged and developed a calculation methodology that is compliant with the ASP regulation. Use of a different methodology will cause manufacturers of Part B drugs to have different methodologies for the different calculations, which will increase complexity, burden, and the risk of error. Use of the ASP approach also is appropriate to use in the calculation of monthly AMP figures because those figures will be used to set reimbursement rates, as currently is the case with ASP.

CMS currently does not specify the use of a particular methodology for the estimation of ASP-ineligible sales that are identified through lagged data, such as Federal Supply Schedule sales identified through chargebacks and State Pharmacy Assistance Program sales identified through rebates. GSK therefore urges CMS to direct manufacturers to estimate AMP-ineligible sales identified through lagged data using the same methodology that the manufacturer currently uses for its ASP calculation. Should CMS ever adopt a specific methodology for this purpose, manufacturers then would simply employ that methodology for the monthly AMP calculation as well.

The ASP methodology for estimating lagged price concessions calls for the development of 12-month rolling average ratio of ASP-eligible lagged price concessions to ASP-eligible sales, and then applying that ratio to the current period's ASP-eligible sales. For the monthly calculation of ASP, GSK requests that CMS permit manufacturers to develop a ratio for the most recent 12-month period ending before the quarter in which the month falls, and then to apply that ratio to each of the three months in a given quarter. For example, for January 2007, a manufacturer would develop an eligible lagged price concession ratio using the period January through December 2006, and would apply that ratio to the AMP-

eligible sales for January to estimate the AMP-eligible lagged price concessions for the January AMP calculation, again to the AMP-eligible sales for February to estimate the AMP-eligible lagged price concessions for the February AMP calculation, and lastly to the AMP-eligible sales for March to estimate the AMP-eligible lagged price concessions for the March AMP calculation. For each month in the second quarter of 2007, the manufacturer would apply a ratio using data for the period April 2006 through March 2007, and so on.

This approach will permit a manufacturer to update its 12-month rolling average on a quarterly rather than a monthly basis, which minimizes the complexity of the monthly AMP calculation and permits manufacturers to derive their ratios from quarterly data, which typically are subject to greater validation and reconciliation than monthly data. Use of a the same ratio for each month in a quarter also should work to minimize the volatility of monthly AMP figures, which is an important goal where AMP figures are used to set reimbursement rate. Lastly, this approach still permits quarterly updates to the ratio and therefore supports the overall statutory goal of providing States with up-to-date actual pricing figures to use in setting reimbursement rates.

B. CMS Should Permit Manufacturers To Calculate Quarterly AMP Utilizing A Weighted Average of Their Monthly AMPs.

The DRA requires manufacturers to submit both monthly as well as quarterly AMP figures. In the Proposed Rule, CMS proposed to not permit restatements of monthly AMP figures beyond 30 days after the month for which AMP is being reported, but to continue to permit restatements of quarterly AMP figures for the 12 quarter period currently permitted by statute.[50] GSK requests that CMS provide manufacturers with the option of deriving their quarterly AMP figures utilizing a weighted average of their three monthly AMPs, as to which late-arriving data have been included through a smoothing methodology, and then to forego restating the quarterly figure. Manufacturers still would be obligated to restate Best Price within the 12 quarter period as needed. A manufacturer choosing this option would be required to calculate its AMPs in this manner for all of its drugs, and would not be able to restate their quarterly AMPs more than 30 days after the quarter end, except where needed to correct errors.

Permitting manufacturers to utilize a weighted average of their monthly AMPs to compute their quarterly AMP will result in extensive administrative savings, as to manufacturers, the States, and CMS itself, as the

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50 *Id.* at 77,185.

need to process reconciliation statements due to AMP-driven changes in rebate amounts will decrease significantly. While changes in Best Price still would necessitate restatements, it has been GSK's experience that restatements to Best Price to account for late-arriving data are significantly less frequent than for AMP. Such an approach also will tie a manufacturer's rebate payments to the same AMP figures that determine reimbursement rates, and avoid significant disparities between the quarterly and monthly AMP figures, both of which will be public and subject to use for reimbursement. Finally, this practice is likely also reduce errors in both the monthly and quarterly AMP calculations by eliminating the need for a manufacturer to use different calculation methodologies for its monthly and quarterly calculations. For all of these reasons, GSK urges CMS to expressly permit this approach in the final rule.

* * *

GSK appreciates the opportunity to comment on these issues, and we look forward to working with CMS to ensure that the Medicaid price reporting system is fair and accurate, and that it protects Medicaid beneficiaries' access to critical drug therapies. Please feel free to contact me at (919) 483-2353 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

David Brown

David B. Brown
Director, Government Contracts and
Pricing Programs

Submitter : Mr. Gary Phillips **Date:** 02/20/2007

Organization : Phillips Pharmacy & U-Save-It Pharmacies

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1327-Attach-1.PDF

CMS-2238-P-1327-Attach-2.PDF

1327-2

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

February 20, 2007

Ms. Leslie Norwalk, ESQ:

I am contacting you in regard to the proposed changes relating to the Deficit Reduction Act of 2005 and how these changes could possibly ruin my business as well as countless others. I am writing on behalf of a small group of independent pharmacies, *U-Save-It Pharmacies* in & around southwest Georgia and my own store *Phillips Pharmacy* located in Albany, GA.

I see several short comings that urgently need to be addressed before CMS finalizes a program that will ultimately negatively affect pharmacies and their patients. Perhaps CMS would reconsider the rulings in their present form and re-evaluate to what extent small businesses will be impacted and possibly bring about their demise.

A level playing field would present itself only in an ideal world. However, when the people's government draft such restrictive and sumptuary regulations that further distort the playing field as in these proposals, it is the little guy that suffers the consequences while the mail order & large chain pharmacies and PBMs benefit to reap millions.

Please revisit the following bullets:

- Provide AMP data to all concerned so real projections may be calculated
- Provide significant increase to community pharmacies that fill the gaps of disparity of products and services relative to mail order pharmacies
- Launch an unbiased study to determine real cost of dispensing tied to reimbursement for services provided
- Do not include discounts and rebates that PBMs unfairly enjoy
- FUL calculations should be based on the 11 digit NDC
- Revisit the 70 percent difference between lowest AMP and next lowest AMP and bring into a more palatable range
- Commit in the regulation to a 48 hour response to redefine a FUL when prescription dispensed below acquisition cost

The above points surely seem reasonable in light of the pricing disparity between the behemoth pharmaceutical concerns and the small business pharmacy owners that have traditionally provided the backbone of America's quality pharmaceutical care. As the government goes, so goes the private sector... it will only be a matter of time.

Very truly yours,

Gary H Phillips, RPh
Phillips Pharmacy

Submitter : Dr. Allan Goldstein **Date:** 02/20/2007

Organization : Medical Association of the State of Alabama

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

On behalf of the Medical Association of the State of Alabama, I am writing in regards to the proposed rule (file code CMS-2238-P) that implements the provisions of the Deficit Reduction Act of 2005 (DRA) as it pertains to prescription drugs under the Medicaid program, particularly Section III. Collection of Information Requirements, FFP: Conditions Relating to Physician-Administered Drugs. (S. 447.520). Please accept the following comments to this proposed rule.

Collection of Information Requirements

Collection of Information Requirements

In surveying a select group of physician practices, practice managers indicated they have serious concerns with regards to reporting National Drug Codes (NDCs) for established HCPCS codes.

As you are aware, a single HCPCS could have many NDC's allowed because of different manufacturers and different packaging. In practice billing systems, there is currently a single field for the identification of this number. This does not pose a problem for unlisted codes because each is loaded individually. However, there is no mechanism to load multiple numbers nor could practices identify which was appropriate for each item provided. According to practice managers, the charges often are entered from a super-bill and they don't currently have a way to identify what the correct NDC is for routine drugs administered. Some practices have a very large volume of drugs of all types in many locations.

Practice managers report that their claims filing departments have discussed this reporting requirement and have not been able to identify a way to resolve this. They have reported to us that their vendors don t have a suggestion at this point.

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The proposed requirement will put a huge burden on physicians practice and is considered an unfunded mandatc on physicians. The Medical Association of the State of Alabama requests that the proposal for physician reporting of NDC numbers be withdrawn and reconsidered until the system can become less burdensome.

Thank you for this opportunity to provide comment.

Regulatory Impact Analysis

Regulatory Impact Analysis

In surveying a select group of physician practices, practice managers indicated they have serious concerns with regards to reporting National Drug Codes (NDCs) for established HCPCS codes.

As you are aware, a single HCPCS could have many NDC's allowed because of different manufacturers and different packaging. In practice billing systems, there is currently a single field for the identification of this number. This does not pose a problem for unlisted codes because each is loaded individually. However, there is no mechanism to load multiple numbers nor could practices identify which was appropriate for each item provided. According to practice managers, the charges often are entered from a super-bill and they don't currently have a way to identify what the correct NDC is for routine drugs administered. Some practices have a very large volume of drugs of all types in many locations.

Practice managers report that their claims filing departments have discussed this reporting requirement and have not been able to identify a way to resolve this. They have reported to us that their vendors don t have a suggestion at this point.

Response to Comments

Response to Comments

The proposed requirement will put a huge burden on physicians practice and is considered an unfunded mandate on physicians. The Medical Association of the State of Alabama requests that the proposal for physician reporting of NDC numbers be withdrawn and reconsidered until the system can become less burdensome.

Thank you for this opportunity to provide comment.

CMS-2238-P-1328-Attach-1.DOC

#1328

February 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
PO Box 8015
Baltimore, MD 21244-8015

To Whom It May Concern:

On behalf of the Medical Association of the State of Alabama, I am writing in regards to the proposed rule (file code CMS-2238-P) that implements the provisions of the Deficit Reduction Act of 2005 (DRA) as it pertains to prescription drugs under the Medicaid program, particularly Section III. Collection of Information Requirements, *FFP: Conditions Relating to Physician-Administered Drugs. (S. 447.520)*. Please accept the following comments to this proposed rule.

In surveying a select group of physician practices, practice managers indicated they have serious concerns with regards to reporting National Drug Codes (NDCs) for established HCPCS codes.

As you are aware, a single HCPCS could have many NDC's allowed because of different manufacturers and different packaging. In practice billing systems, there is currently a single field for the identification of this number. This does not pose a problem for unlisted codes because each is loaded individually. However, there is no mechanism to load multiple numbers nor could practices identify which was appropriate for each item provided. According to practice managers, the charges often are entered from a super-bill and they don't currently have a way to identify what the correct NDC is for routine drugs administered. Some practices have a very large volume of drugs of all types in many locations.

Practice managers report that their claims filing departments have discussed this reporting requirement and have not been able to identify a way to resolve this. They have reported to us that their vendors don't have a suggestion at this point.

The proposed requirement will put a huge burden on physicians practice and is considered an unfunded mandate on physicians. The Medical Association of the State of Alabama requests that the proposal for physician reporting of NDC numbers be withdrawn and reconsidered until the system can become less burdensome.

Thank you for this opportunity to provide comment.

Sincerely,

Allan R. Goldstein, M.D.

President

Submitter : Mr. Jeff Spade **Date:** 02/20/2007

Organization : NC Rural Health Center

Category : Hospital

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

CMS-2238-P-1329-Attach-1.DOC

Attach# 1329

February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Baltimore, MD 21244-8015

RE: Proposed rule for Medicaid Program, Prescription Drugs

Dear CMS Administrators,

I am writing on behalf of the North Carolina Rural Health Center, a resource center for rural hospitals and rural health organizations in North Carolina. The NC Rural Health Center has worked diligently over the past two years to help rural North Carolina hospitals achieve access to the 340B drug program. North Carolina's rural hospitals lead the country in 340B participation achieving the highest proportion of hospitals involved in 340B. North Carolina has nearly 50 disproportionate share hospitals enrolled in the 340B program, including 26 rural hospitals that serve indigent and low-income clients. Protecting the integrity of the 340B drug program is vitally important to help North Carolina's disproportionate hospitals in their burden of caring for their disadvantaged patients.

First, the proposed regulations would create enormous administrative and financial burdens for North Carolina hospitals by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. In general, North Carolina hospitals' electronic billing systems are not configured with the capacity to substitute NDC numbers as identifiers for clinic administered drugs. To create the capacity for NDC codes, North Carolina 340B hospitals would have to make significant changes to their billing and information systems, at considerable expense in terms of capital, staff resources and disruption of administrative operations.

Furthermore, many hospital information technology vendors do not have the capacity to include NDC codes in their pharmacy and billing modules. North Carolina 340B hospitals have indicated that entering NDC codes manually is unrealistic and cost prohibitive. Even more problematic, the Medicaid claims system for North Carolina (hardware and software operated for the State of North Carolina by EDS) is incapable of accommodating hospital patient claims with NDC codes, meaning rebates are technically unavailable to North Carolina Medicaid, defeating the original purpose of requiring NDC codes.

Second, CMS's proposed regulations would significantly decrease the savings North Carolina hospitals achieve through participation in the 340B program by imposing manufacturer rebate obligations on hospital outpatient clinic drugs that should instead be exempt from rebate requirements, forcing North Carolina hospitals to forego the benefit of 340B discounts. Much of the benefit that a hospital receives by participating in the 340B program derives from savings achieved by purchasing drugs for Medicaid beneficiaries at discounted 340B prices. If the outpatient clinic drug purchases for North Carolina hospitals were to be redefined as Medicaid rebates, our hospitals would lose access to these savings because the law prohibits subjecting manufacturers to "double discount" obligations. As a

result, application of rebate requirements to hospital clinic administered outpatient drugs would force the hospital to lose the benefit of 340B participation on all such drugs used to treat Medicaid patients. Many North Carolina hospitals estimate that the loss of Medicaid drugs discounts will cost hospitals a large proportion of its 340B savings, making it no longer be feasible to participate in the 340B program given the administrative and other compliance burdens associated with 340B participation.

Third, the proposed rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP) would drive up the prices North Carolina hospitals pay for outpatient drugs by adversely affecting the formula for calculating 340B prices. The proposed regulations should clarify that best-price-exempt nominal pricing for which a 340B participating hospital may qualify extends not only to the covered outpatient drugs subject to 340B pricing, but also to other drugs purchased by the hospital, including drugs purchased for inpatient use. Without this clarification to the proposed rule, North Carolina 340B hospitals will face substantial cost increases resulting from the loss of nominal price contracts on many pharmaceutical products.

Finally, CMS has not included in its cost estimates any recognition that any increase in AMPs utilized in the formula for computing 340B ceiling prices will necessarily result in higher drug price ceilings and correspondingly higher costs to 340B covered entities. The new rule should clarify that the new formula for AMP computation is not applicable in calculating 340B ceiling prices because the 340B statute expressly provides for continuing to utilize the statutory definition of AMP that existed prior to enactment of the DRA. Thus the changed treatment of prompt pay discounts in determining AMP, and the higher resulting AMP figures, should apply in determining the amount of Medicaid rebates, but not in calculating 340B ceiling prices. This needs to be made clear in the issuance of final regulations in order to avoid confusion and the possibility of undue and improper increases in the costs of drugs to safety net healthcare facilities.

Please give serious consideration to these significant issues that negatively impact North Carolina disproportionate share hospitals' involvement in the 340B drug program. We expect CMS to consider our concerns and those of 340B hospitals across the country in order to clarify and revise the proposed regulations, to protect the integrity of the 340B program and continue to support rural disproportionate share hospitals as they care for indigent and low-income patients.

Sincerely,

Jeff Spade

Executive Director
North Carolina Rural Health Center
North Carolina Hospital Association
PO Box 4449
Cary, NC 27519

Email: jspade@ncha.org

Submitter : Dr. Mike Keny **Date:** 02/20/2007

Organization : H & S Pharmacy #1

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1330-Attach-1.PDF

1330

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Strategic Operations & Regulatory Affairs

The attachment cited in this document is not included because of one of the following:

- The submitter made an error when attaching the document. (We note that the commenter must click the yellow "Attach File" button to forward the attachment.)
- The attachment was received but the document attached was improperly formatted or in provided in a format that we are unable to accept. (We are not are not able to receive attachments that have been prepared in excel or zip files).
- The document provided was a password-protected file and CMS was given read-only access.

Please direct any questions or comments regarding this attachment to (800) 743-3951.

Submitter : Dr. Larry Shepherd **Date:** 02/20/2007

Organization : Clen's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1331-Attach-1.RTF

HHach #1331

February 20, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Clen's Pharmacy, a community retail pharmacy located at 8622 Asheville Highway, Knoxville, Tennessee, 37924. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the "general public." These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually

determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Larry C. Shepherd, Pharm. D.
3025 Shropshire Boulevard
Powell, Tennessee 37849

cc: Senator Lamar Alexander
Senator Bob Corker
Representative John J Duncan

Submitter : Ms. Lina Feliciano **Date:** 02/20/2007

Organization : J&J Saint Michael's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-2238-P-1332-Attach-1.DOC

Attach #1332

J&J Pharmacy
527 Cedar Lane
Teaneck, New Jersey 07666
201 836 7003

VIA ELECTRONIC SUBMISSION

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacters' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.

Public Access Defines Retail Pharmacy Class of Trade

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in calculating the AMP.

"Retail pharmacy class of trade" definition should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.

Inclusion in Best Price of PBM rebates, discounts and other price concessions.

Treatment of Manufacturer coupons with regard to Best Price.

Inclusion of Direct-to-Patient Sales with regard to AMP.

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

PBM price concessions reporting to CMS.

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed - again through lack of regulation - to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.

Impact on small pharmacies demonstrated by (General Accountability Office (GAO) findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. **It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.**

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
    1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
    2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*
- Reporting AMP at the 11-digit NDC level to ensure accuracy.

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

Michael Fedida R.Ph.
J&J Pharmacy
527 Cedar Lane
Teaneck NJ 07666

Submitter : Ms. Melody Culton **Date:** 02/20/2007

Organization : Dendrite International, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1333-Attach-1.DOC

Attach # 1333

DENDRITE®

1405 US Highway 206, Bedminster, NJ 07921 USA

February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
Mail Stop C4–26–05,
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-2238-P
Medicaid Program; Prescription Drugs Notice of Proposed Rulemaking
Impact of Manufacturer Coupons on Calculations of AMP and Best Price

Dear Sir or Madam:

Dendrite International, Inc. ("Dendrite") welcomes this opportunity to comment on the proposed rule (the "NPRM") promulgated by the Centers for Medicare and Medicaid Services ("CMS") entitled *Medicaid Program; Prescription Drugs; Proposed Rule* (71 Fed. Reg. 77174 (Dec. 22, 2006)). Dendrite is a company that specializes in furnishing sales, marketing, compliance, and clinical support to pharmaceutical manufacturers. In this capacity, Dendrite has assisted pharmaceutical manufacturers in implementing marketing programs which include as a component the use of coupons. Since Dendrite believes that CMS is being unduly restrictive in interpreting the scope of manufacturer coupons excluded from average manufacturer price and best price calculations, Dendrite respectfully requests CMS' reconsideration of its proposed policy. Specifically, Dendrite requests that CMS exclude all manufacturer coupons from average manufacturer price and best price calculations, irrespective of how the coupon is redeemed, when the only entity benefiting from the coupon is the consumer.

Dendrite's Program

The rebate programs administered by Dendrite likely resemble a number of manufacturer programs. Typically the programs administered by Dendrite begin by enrolling individuals who use a particular drug. Sometimes this involves the issuance of a card to program enrollees, who present the card when they purchase a drug from a pharmacy. At the time of purchase, the pharmacy processes the transaction with a

fulfillment house designated by the drug's manufacturer. The fulfillment house applies the rules for determining the rebate amount determined by the manufacturer. This amount is then furnished either to the pharmacy, resulting in a corresponding offset to the patient's coinsurance, or to the enrollee's rebate program card, which can then be used to pay the coinsurance amount. In either case, the pharmacy does not retain any portion of the enrollee's rebate as a reduction against the cost of the pharmacy's drugs.[1] It is solely the enrollee who receives any reduction in liability for payment for the drugs. Payment to the pharmacy for participation in the program is limited to a per-rebate administrative fee, which is set at the fair market value for processing the rebate.

As we understand to be true of many similar programs, the programs administered by Dendrite are designed to allow participation by any pharmacy interested in participating. Processing a rebate with the fulfillment house requires no more information than is already required under HIPAA standards applicable to electronic transactions. No particular hardware or software need be purchased. Furthermore, initiating participation in these programs requires only that the pharmacy contact a call center, which results in the ability to participate in a given program almost immediately. If, notwithstanding the convenience of participation, a pharmacy opts not to process enrollee rebates, enrollees themselves can obtain the rebates by transmitting their pharmacy receipt, along with a rebate form, to the fulfillment house. When enrollees mail in their request for a rebate on their own, they receive the same rebate as they would at the pharmacy, albeit with somewhat greater inconvenience and a lag in processing time.

Purchases to be Included in Average Manufacturer Price and Best Price Calculations

The Medicaid drug rebate statute specifies that only certain sales are included in the calculation of average manufacturer price and best price. As stated in the statute, average manufacturer price is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." Social Security Act, § 1927(k)(1)(A). In other words, not all sales are included in the calculation of average manufacturer price. Rather, this price is intended to reflect only the price paid by retail pharmacies. Similarly, best price is based only on sales to "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" Social Security Act, § 1927(c)(1)(C)(i). As explained in the Conference Report accompanying the legislation enacting the best price statutory provision, the intent of this provision is to set best price at the lowest price offered to any "bulk purchaser." House Conference Report No. 101-964 (Oct. 27, 1990), reprinted in U.S.C.C.A.N., at 2108. Thus, sales to consumers are outside of the purview of both the average manufacturer price and best price calculations.

Rebates to Consumers via Pharmacies Should be Excluded from Average Manufacturer Price and Best Price

[1] Individuals covered under any Federal healthcare program, such as Medicare and Medicaid, are not allowed to participate in any of the programs administered by Dendrite.

These Rebates are Excluded by Statute from Average Manufacturer Price and Best Price

CMS' proposed treatment of manufacturer coupons would include many consumer rebates that fairly fall outside the proper scope of the statute. In its NPRM, CMS would allow manufacturers to exclude from both average manufacturer price and best price only those "coupons redeemed by the consumer directly to the manufacturer." 71 Fed. Reg. at 77181 and 77183. Since CMS views these coupon redemptions as affecting the price paid by consumers, and not any member of the retail pharmacy class of trade, CMS has proposed excluding them from average manufacturer price calculations. 71 Fed. Reg. at 77181. Likewise, CMS has proposed that these coupon redemptions be excluded from the best price calculation because they do not reduce drug prices for any of the entities whose purchases are included in best price calculations. 71 Fed. Reg. at 77183. Dendrite appreciates that CMS has accepted that consumer redemptions of coupons directly to manufacturers are properly considered reductions in consumer payments, rather than payments by any other entity. Dendrite agrees that these coupons are therefore outside the purview of the Medicaid drug rebate statute. However, CMS' proposed policy does not cover all rebates that reduce drug costs exclusively for the consumer. Accordingly, the proposal is still at odds with the statute, and it discourages many arrangements that provide tremendous benefit to consumers.

Economically, programs like the ones administered by Dendrite are identical to the type of manufacturer coupon programs that CMS would consider to fall outside the scope of average manufacturer price and best price calculations. As described above, in these programs, the enrollees alone receive a reduction in the price of their drugs. No portion of the rebated amount is transferred to the pharmacies processing the rebate. Thus, in no way can the rebate be considered a reduction in the price paid by the pharmacy for the drug at issue. Although pharmacies processing the rebates may receive a per-rebate fee, the amount of the fee is intended to represent the fair market value of the administrative services rendered. Essentially, the fees make the pharmacy whole for its services in facilitating distribution of the rebate to the program enrollee. Without any economic benefit conferred upon pharmacies that process enrollee rebates, there is no statutory basis for including these rebates in the calculation of average manufacturer price or best price. The reasoning underlying CMS' policies with respect to coupons redeemed directly to manufacturers applies with equal force to rebate programs where pharmacies serve as the processing agents but do not receive a share of the rebate.

It cannot be said that mere participation by a pharmacy in one of these rebate programs bestows any competitive advantage over other pharmacies. Dendrite's rebate programs are open to any pharmacy wishing to participate. Since there is no particular software or hardware that needs to be purchased to participate in any of the programs, there are no structural impediments for pharmacies seeking to become participants. Therefore, only the program enrollee, and not the pharmacy, obtains a benefit from these rebate programs.

Relying on Mail-in Rebate Programs as an Alternative Imposes Costs on Consumers and Manufacturers

While there is thus no economic benefit or advantage conferred on pharmacies participating in this program, the benefit to program enrollees can be substantial, when compared with programs relying on rebates mailed in directly to the manufacturer. For many consumers, there are considerable disincentives against seeking rebates through a mail-in program. Consumers ordinarily need to complete a rebate form, which then needs to be mailed. After waiting for some period of time, consumers receive in the mail a check from the manufacturer for the rebate amount, which needs to be deposited in the consumer's bank account. A significant portion of consumers rationally determine that receipt of the rebate does not justify the corresponding inconvenience. For these consumers, the cost of their drugs, in light of the foregone rebate opportunities, is effectively higher than the cost for consumers who can readily process their rebates at their local pharmacy.

Despite the favorable impact of pharmacy-based rebate programs on consumers' drug costs, many manufacturers would be strongly incentivized to discontinue these programs, should CMS finalize its manufacturer coupon policy substantially in its proposed form. Since all that would remain would be mail-in programs, this proposed policy would result in increased drug costs for consumers. This increase in costs could also result in a reduction in consumer compliance with prescribed drug regimens.

Mail-in rebate programs are also problematic for most pharmaceutical manufacturers. The primary line of business for a pharmaceutical manufacturer is the production and distribution of pharmaceutical products. Since administering a rebate program involves claims adjudication, which is outside of a manufacturer's core business, manufacturers would need to incur costs in developing and maintaining the capability to process paper rebate claims received from consumers. It is, of course, far more efficient for manufacturers to outsource this task to a fulfillment house with the requisite rebate processing expertise. Further efficiency is realized through engaging pharmacies to submit claims for rebates on behalf of program enrollees to the fulfillment house because, as pharmacies generally submit claims electronically, the burden of processing paper claims received from program enrollees is obviated.

Yet, notwithstanding the efficiencies inherent in relying on pharmacies and fulfillment houses to operate a manufacturer's program, many manufacturers would likely discontinue these pharmacy-based programs, should CMS' proposed policy be finalized without change. For those manufacturers that switch to a mail-in rebate program, the additional costs of administering such a program may lead them to significantly reduce the rebate amounts offered. Others may simply not replace their discontinued programs at all.

The Upper Limit Implications of CMS' Manufacturer Coupon Policy May Impose Hardships on Pharmacies

Maintaining current pharmacy-based rebate programs, notwithstanding the Medicaid drug rebate consequences to the manufacturer, could create a hardship for pharmacies in some cases. Pursuant to the Deficit Reduction Act of 2005, the upper limit for certain multiple source drugs is now set at 250 percent of the average manufacturer price of the least costly therapeutically equivalent drug. Social Security Act, § 1927(e)(5); 42 C.F.R. § 447.332(b). Thus, a reduction in the average manufacturer price under some circumstances could reduce the drug's upper limit. Because, under CMS' currently proposed manufacturer coupon policy, a manufacturer's continued sponsorship of a pharmacy-based rebate program would reduce the average manufacturer price for the manufacturer's drug, the drug's upper limit may also decline. Many State Medicaid programs would likely effect a corresponding reduction to the drug's Medicaid payment rate. This reduction in payment could work to the detriment of pharmacies, which may experience difficulty purchasing these drugs at a rate below the Medicaid reimbursement rate. Ultimately, this could reduce Medicaid beneficiary access to these drugs.

* * *

In light of the above, we request that CMS reconsider its manufacturer coupon policy. CMS should affirm that, when the only party receiving an economic benefit from the program is the consumer, the value of the coupon will not be included in the average manufacturer price and best price calculations. Thus, rebates should ordinarily be redeemable at the consumer's pharmacy without any Medicaid drug rebate implications. Further, CMS should affirm that delegation of the operations of a coupon program to a fulfillment house or other agent does not by itself cause the rebates to be included in average manufacturer price and best price calculations. Such a policy would encourage economy and efficiency by allowing pharmacies to submit claims for rebates on behalf of program enrollees to specialized entities engaged by a manufacturer to adjudicate claims in accordance with the manufacturer's policies. Not only would such modifications to CMS' proposed policy better reflect the pertinent statutory provisions, it would also ensure that consumers continue to benefit from these popular programs.

Thank you for your consideration of the above. Please do not hesitate to contact me at (908) 443-2203 with any questions you may have.

Sincerely,

/s/ Christine A. Pellizzari

Christine A. Pellizzari
Senior Vice President, General Counsel and Secretary

Submitter : Ms. Susan Hathaway **Date:** 02/20/2007

Organization : Brockton Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attached memo.

CMS-2238-P-1334-Attach-1.DOC

Attach # 1334

February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

To Whom It May Concern:

On behalf of Brockton Hospital, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Brockton Hospital is a 276 bed hospital located in Brockton, MA, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Included in these burdens would be the necessity of dedicated full time staff that would be earmarked solely to the change of our current billing system into one that utilizes the NDC code. Additional staff would also be necessary to ensure that any changes propagated by contract changes or by stock outs would be updated in a manner that would meet Federal regulations. Anticipated cost would be approximately $50,000 per year, and would not include the cost of updating the database the first time.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. This would markedly increase the cost of our outpatient and clinic drugs. Costs for these drugs would increase by approximately $500,000 per year, or 30%.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Susan Hathaway, RPh
Director of Pharmacy
Brockton Hospital