Submitter : **Dr. JEFF ANDERSON** **Date: 02/20/2007**

Organization : **ANDERSON DRUGS**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-1271-Attach-1.DOC

#1271

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 and owner of Anderson Drugs a community retail pharmacy located at 725 Tennessee Ave. in Etowah, Tennessee. 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 my pharmacy, where 90% 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,

Jeff Anderson
258 County Road 876
Englewood, TN 37329

cc: Senator Lamar Alexander
Senator Bob Corker
Rep. John Duncan

Submitter : Mr. donald haynes **Date:** 02/20/2007

Organization : Don's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

definition of "retail class of trade" - removal of pbm and mail order pharmacies...excluding PBMs and mail order pharmacies recognizes that these are NOT community pharmacies whcre the heart of the commom people go to fill their prescriptions because of trust and face to face relationship comfort. This would be eradicated to the point that the "local pharmacy" would be out of business..The more extensive comments submitted by the Mississippi Independent Pharmacy Assn. has addressed diferentiation, consistency with federal policy, and thc benefits of excluding these data elements..This is in regard to DEFINITION OF RETAIL CLASS OF TRADE.. Next is the CALCULATION OF AMP- REMOVAL OF REBATES, CONSESSIONS TO PBMs AND MAIL ORDER PHARMACIES..AMP should reflect prices paid by retail pharmacies..To include these elements is counter to congressional intent.. Next(3) is REMOVAL OF MEDICAID DATA..Including these data elements "bootstrapping" the AMP calculation and does not recognize the Medicaid pricing is heavily regulated by the state and federal governments.. Next(4) is MANUFACTURER DATA REPORTING FOR PRICE DETERMINATION--Address market lag and potential for MANIPULATION...The actual implementation of the AMP could create and avenue for market manipulation. The risk of both price fluctuation 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 M.I.P.A. proposes a "trigger" mechanism whereby severe price fluctuations area promptly addressed by CMS...Next(5) is USE OF 11 DIGIT VS. 9 DIGIT NDC..We believe that CMS should use the 11 digit for the most commonly dispensed package size by retail pharmacies to calculatie the FUL for a particular dosae form and strength of a drug. the prices used to set the limits should be based on the most common size disp. by retail pharmacies..Current regulations specify that the FUL should be set on pkg size of 100 tablets or capsules (most commonly used in retail settings). These entities can oly be captured if the 11 digit pkg size is used.. In conclusion, I support the more extensive comments that are being filled by the Mississippi Independent Pharmacy Association regarding this proposed regulation.. I appreciate your consideration of these comments...

Submitter :

Date: 02/20/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1273-Attach-1.DOC

#1273

February 15, 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

1. You have the comments and suggestions filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We agree with and support the positions represented by NCPA and NACDS.

2. Generic medications average roughly 1/6th of the brand name cost. AMP as currently defined means that pharmacies are much better off dispensing brand name medications rather than losing money on generics. Instead of saving, there is a great chance of spending more. What a waste of tax payer dollars, when governmental policy is only focused on an aspect of cost savings that will ultimately cost more money in total.

3. Can CMS really ignore the report of the General Accounting Office (GAO) and proceed with releasing of AMP as currently defined?

4. The very existence of community pharmacy is at stake by the Federal Government setting such an irresponsible and inaccurate benchmark for community pharmacy cost of goods such as AMP currently is defined

5. The level of customer service and within rural and urban communities is seriously threatened when the AMP being used does not even cover wholesale cost of medication, let alone the cost of filling a prescription.

Please do the right thing for Medicaid Patients to be able to continue to get the medication they need.

Please do the right thing when spending tax payer dollars.

Please do the right thing for community pharmacy.

Sincerely,

Eric L. Graf, M.S., R.Ph.
President & Cheif Executive Officer
Ritzman Pharmacies, Inc.

Submitter : Mr. Nicholas Karalis **Date:** 02/20/2007

Organization : Elwyn Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Elwyn Pharmacy is a busy independent pharmacy the services our local community. We have over 40 employees and cater to needy patients. (i.e. elderly, mental health, and mentally handicap.) We provide services not found in the chain and mail order pharmacies. We deliver directly to the patient, we provide 24-hour emergency service, we offer special packaging, refill reminder programs, and we carry all medications including, injectables, specialty, and hard to find items. He carry a full-line of DME and surgical supplies. All these services are provided to all our patients, private-pay, third party, medicare, and medicaid. CMS's cost savings estimates does not consider the negative impact it will cause to these services. The Government Accountability Office (GAO) findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay open and offer these special services while experiencing a 36% loss on each and every transaction. The definition of "dispensing fee" does not reflect the true costs to pharmacists and pharmacies.

Collection of Information Requirements

Collection of Information Requirements

Calculations of AMP for the "Retail Class of Trade" should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants, and spermarket pharmacies. Mail-order is not a retail class, a patient can not go into a mail order pharmacy, nor can they expect same day service, face-face counseling, and interaction with local community people. CMS should also exclude rebates paid to PBMs from AMP calculations, since these rebates are not available nor shared with the Retail Pharmacy Class of Trade.

GENERAL

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CMS will simpley make community pharmacies unable to participate in the Medicaid program. We will loss patients, employees, and eventually our business. The hard-working, tax paying voters in our communities will become un-employed and bitter with Congress and this proposed Medicaid Deficit Reduction Act. Patients will loose the right to choose and their freedom of access to medications.

CMS must define AMP correctly to stop these actions:
1. Exclude all rebates and price concessions made by manufactures which are not available to retail pharmacy.
2. Exclude all mail order facilities and PBM pricing from AMP calculations. The same pricing is not available to retail pharmacies. Unless Congress controls this pricing and makes it equal for everyone, they should not consider it for AMP calculations.
3. Report AMP at the true and correct 11-digit NDC number to ensure accuracy.

These three simple steps will make for a fair AMP calculation, the only other factor will be to truely reimburse pharmacy for their actual dispensing fee.

Please take these points into consideration for this act will have one of the biggest impacts on community pharmacies.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

CMS must have a frequent pricing update model to accurately capture drug price changes. The monthly proposed reporting system is inadaquate and unfair if not illegal in its AMP calcutaion. AMP pricing must be reported on the 11-digit NDC number to ensure accuracy. Since Congress does not mandate the manufacturer to only make one size or price their medications according to unit of unit, it is again unfair to reimburse on a 9-digit NDC number. CMS and Congress has not made any attempts to save money from the Pharmaceutical Manufacturer (like every other country), who happen to have the largest lobbying organization on capitol hill, and who by far is the most profitable enities in healthcare.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS and Congress has not made any attempts to save money from the Pharmaceutical Manufacturers (like every other country), who happen to have the largest lobbying organization on capitol hill, and who by far are the most profitable enities in the healthcare industry. This action is a clear message that Congress takes care of the contributors. What independent pharmacy, the direct caregivers of our medicaid patients, is asking for is a fair ruling of AMP. When we voted our lawmakers in office, we expect them to do what is right for the people and not their own pockets. As clearly seen in this last election, the people will not stand for dirty politics and unfair policymakers. To propose a Medicaid Deficit Reduction Act that expects the community pharmacies to bear the burdon is unrealistic and will cause local business to close, unemployment to increase, and federal and state tax dollars to be lost. At the same time, the manufacturer will continue to enjoy the same high profit margins without any fear of government intervention.

Submitter : **Date: 02/20/2007**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1275-Attach-1.DOC

CMS-2238-P-1275-Attach-2.DOC

#1275

February 16, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

My name is Rebecca Poedy and I am the President and CEO of Planned Parenthood of Idaho (PPI), a not for profit outpatient healthcare organization with centers in Boise, Twin Falls, and Nampa, Idaho. PPI provides essential family planning and reproductive healthcare services to low income, uninsured and underinsured women, men, and teens. PPI serves over 8,000 patients in our three healthcare clinics by providing comprehensive family planning care to include annual exams, pap tests, breast exams, sexually transmitted infection testing and treatment, pregnancy testing, and birth control supplies.

Many of the patients we serve are uninsured or underinsured and could not afford the healthcare services we provided – particularly oral contraceptives. For over 33 years, Planned Parenthood of Idaho has served an unaided population of Idahoans who cannot normally afford contraception by providing them access to oral contraceptive pills at prices far lower than what is available in Idaho's retail market. PPI has been able to serve this underprivileged community because we have had the ability to purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal pricing. The very existence and viability of Planned Parenthood of Idaho is based on the ability to purchase oral contraceptives at less than 10% of the average retail price. Without these steeply discounted drugs, we will no longer be able to serve the most at-risk and in need population in Idaho. Idaho has the 37th highest teen pregnancy rate of any state and one out of six live births per day is to a teenager. In Idaho, 22% of women aged 15-44 have no health care coverage and are in need of publicly supported contraceptive services. These patients desperately need access to low cost or free oral contraceptives to prevent unplanned pregnancy – a service we desperately want to continue to provide.

As you know, the proposed rule -- published by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") -- preserves the ability of three kinds of providers (I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated nursing homes) to purchase drugs at best price ineligible nominal prices. Many of Planned Parenthood of Idaho's sister affiliate healthcare centers across the country are receiving Title X funding and therefore are 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. However, Planned Parenthood of Idaho is not state or federally funded. PPI

relies solely on other private foundation grants, individual contributions, and patient services which are offered on a sliding fee scale based on a patient's ability to pay for services. The vast majority of PPI's patients are not, and therefore receive their services at a steeply discounted or free rate. PPI is not a 340B covered entity eligible under the terms of the proposed rule for nominal prices.

Planned Parenthood of Idaho, along with many other non-340B providers of medical services to the poor, must rely on section 6001(d)(IV) of the DRA to permit its continued access to steeply discounted drugs. As you know, that section authorized the Secretary of the Department of Health and Human Services ("HHS") to define "other safety net providers" that would be eligible for the nominal pricing exception. We were deeply discouraged and disappointed when, in the proposed rule, CMS did not define or apply this fourth statutory exception. We very much hope that HHS will exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

The dilemma this poses to PPI and other similarly situated not for profit outpatient healthcare clinics across the nation should provide ample evidence to CMS that the other three categories of health services providers are not "sufficiently inclusive" and do not "capture the appropriate safety net providers." It is simply not the case that deserving, non-profit outpatient clinics like PPI are covered by the entities listed in 6001(d), subsections I, II and III. We and many others like us are left on the outside, looking in – which places our most at-risk populations in desperate need of low cost contraceptives at even greater risk.

Moreover, we have been told by several manufacturers who have historically sold to us at nominal prices that we will have to pay full retail pricing for oral contraceptives going forward. This suggests that CMS's belief that inclusion of non-340B safety net providers in the nominal pricing exception will have an adverse effect on best price (and Medicaid rebate revenues) is misplaced. Eliminating PPI and other entities like it from the nominal price exception will not affect best price at all -- the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like PPI to serve our patients.

Planned Parenthood of Idaho is a non-profit outpatient healthcare facility that serves a critical function in the health and well being of over 8,000 uninsured and underinsured women, men, and teens in Idaho. PPI is able to provide these services and deeply discounted oral contraceptive medications to these women only because it can purchase oral contraceptives from drug manufacturers at nominal prices, as we have been doing for over 33 years. Carving safety net providers like PPI out of the nominal pricing exception would be devastating to our mission and to our operations -- without nominally priced drugs we will likely have to close our doors. PPI urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Warmest Regards,

Rebecca L. Poedy
President and CEO
Planned Parenthood of Idaho, Inc.

Submitter : Ms. RoseMarie Babbitt **Date:** 02/20/2007

Organization : Parkland Health & Hospital System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-2238-P-1276-Attach-1.DOC

#1276

February 15, 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 the Parkland Health & Hospital System, I am responding to the request for comments on regulations proposed to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Parkland Health & Hospital System is a 968 bed teaching hospital located in Dallas, Texas, 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 three principal concerns about the regulations are discussed below.

First, the proposed regulations would create undue financial and administrative burdens for our hospital by requiring the institution to report the NDC information for drugs administered in the hospital outpatient settings ("clinics"), for the following reasons:

a. Hospital electronic billing systems do not presently have the capability to include NDC numbers identifying clinic-administered drugs. It would require a very substantial investment to change the institution's electronic financial systems to allow inclusion of the NDC number and to perpetuate it throughout all the pathways required to achieve the CMS objective. However, every fiscal year CMS and government agencies decrease or discontinue funding for services needed to take care of the under and uninsured patients who depend on our institution
b. The clinics where the drugs are administered are located some distance from the offices where the UB-92 billings actually take place. There is no simple way to communicate the NDC number of the drugs being administered by the clinic staff, to the billing office.
c. Frequently, a multi-drug cocktail is administered and this has but one entry on the UB-92. Which NDC should be used?
d. The UB-92 billing document, mandated by the Federal Government, has no place on it where an NDC can be entered.
e. Outs, shorts and backorders of medications create frequent multiple NDC's system wide in different pharmacies. This in turn will create a high potential for error in any system creating a compliance nightmare.
f. The requirement appears pointless since 340B hospital clinic drugs are exempt from rebates (section 1927j (2) of the Medicare statute applies). If no rebates will be obtained, what is the point of all the expense and disruption which will occur in order to achieve no end?

g. Finally, in reviewing the 15-second CMS estimate to implement these changes, it appears this is a gross under estimation at best. Taking into consideration the many systems currently in place at each institution, clinic and physician office we doubt it can be accomplished in the 15 seconds recommended. Additionally, the complexity of Medicare regulations will cause hospitals to invest significantly in systems to support data requirements. In a hospital outpatient environment, manual solutions lead to greater errors. Any legislation that suggests a manual solution is helping perpetuate problems instead of helping solve them.

Second, these proposals could have a significant, negative impact on 340B hospitals including a potential loss of hundreds of thousands to millions of dollars annually to institutions and health systems. Again, section 1927j (2) of the Medicare Statute indicates that hospital-based clinics are exempt from rebates.

Third, the proposed changes to the rules related to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP") could raise 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 (e.g., Children's Hospitals) eligible for nominal pricing.

We hope the problems mentioned above will cause serious consideration to be given to the proposed regulations published on December 22 and they will be revised in such a manner as to not harm DSH hospitals and not invalidate the intention to assist indigent patients which Congress established when it passed the Veteran's Health Care Act of 1992 which established the 340B program.

Sincerely,

RoseMarie Babbitt, MA, RPh, CHC
Associate Director of Pharmacy Services

Submitter : Mrs. Stephanie Gilson **Date:** 02/20/2007

Organization : Johnson & Johnson

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1277-Attach-1.DOC

#1277

Johnson & Johnson

OFFICE OF
GENERAL COUNSEL

1350 EYE ST., N.W., SUITE 1210
WASHINGTON, DC 20005

February 20, 2007

Submitted Electronically to http://www.cms.hhs.gov/eRulemaking

Leslie Norwalk, Esq.
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

Re: Medicaid Program; Prescription Drugs (CMS–2238–P)

Dear Ms. Norwalk:

The Johnson & Johnson family of companies ("J&J") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Proposed Rule on Medicaid Program; Prescription Drugs (CMS–2238–P) (the "Proposed Rule"), 71 Fed. Reg. 77,174 (Dec. 22, 2006). J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. J&J has more than 200 operating companies in 54 countries around the world, employing approximately 110,600 employees and selling products in more than 175 countries. The fundamental objective of J&J is to provide scientifically sound, high quality products and services to help heal and cure disease and improve the quality of life. Many J&J Operating Companies participate in the Medicaid Rebate Program and as such, we have a strong interest in CMS providing the much-needed clarity on the definition of Average Manufacturer Price ("AMP") and other issues related to the Medicaid rebate program. We applaud CMS for its thoughtful work providing guidance on these issues and offer the following comments in the spirit of furthering these interests.

I. Definitions – Section 447.502

J&J supports CMS's efforts in trying to establish clear definitions for terms and concepts that are central to the Medicaid rebate program. As the agency works to finalize its position in the final rule, J&J offers these suggested refinements.

A. Bundled Sale: CMS's Proposed Definition is Overly Broad

Under the existing rebate agreement, manufacturers must take into account "bundled sales" in their calculations of average manufacturer price and best price ("BP") by allocating the value of the bundled discount proportionally among the items comprising the bundle. The Proposed Rule would redefine "bundled sales" for purposes of pricing calculations to mean arrangements "under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or drugs of different types [at the 9-digit NDC level] or some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discount 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". J&J believes that the new reference to and examples of performance requirements may result in the inappropriate treatment of some arrangements as bundled sales.

The purpose of the bundled sale requirements is to ensure that AMPs and BPs reflect accurate market prices for products. In an economic sense, the potential for distortion of these prices may be present where one product must be purchased at a higher price in order to obtain a lower price on a different product. As written, the proposed definition of bundled sales is overly broad because it may encompass arrangements where such a purchase requirement is not present. Specifically, the rule could be read to deem a bundled sale an arrangement in which multiple products are required to be listed on a formulary in order to be eligible for discounts. The mere requirement to place a product on a formulary, however, is not tantamount to a purchase requirement. Rather, the volumes of products purchased will ultimately depend on physician prescribing. If CMS were to deem such arrangements to be bundles, manufacturers and their customers may be forced into less efficient contracts and contracting processes.

Manufacturers engage in many types of contracting practices involving multiple products. For example, a formulary contract may address multiple products, with each product's discounts being determined independently based on volume, market share, and similar criteria specific to that product. Similarly, where a contract requires that multiple products be placed on a formulary as a condition to discounts, but the discounts are determined based on the individual products' performance, the formulary requirement does not act as a purchase requirement. On the other hand, allocating price concessions in cases where no specific contingency exists between products would result in artificial price points with no basis in the marketplace.

Furthermore, we find the provision in the Proposed Rule that requires an allocation of price concessions across the same drug or drugs of different types at the nine digit NDC level to be particularly problematic. Since virtually all contracts between manufacturers and customers are at the product family level and do not generally differentiate based on strengths or dosage forms, this Proposed Rule would in effect classify all contracts with products that have different strengths or formulations as bundled sales. Virtually every contract a manufacturer has would meet this definition and require an allocation of the price concessions. For example, assume a manufacturer has a product (Product A) with three strengths, 10mg, 20mg and 30mg. It is likely that the list prices for these put-ups are based on the relative clinical profile of the different strengths, pills per day, length of prescriptions, etc. When the manufacturer of Product A enters into a contract arrangement, the manufacturer is likely to provide varying levels of discounts across these strengths, again depending on marketplace characteristics, competition, indications for each strength, etc. The level of price concession on any single strength has no relation to or any contingency to any of the other strengths. A requirement to allocate the total price concessions across all three strengths provides no apparent benefit to the Medicaid program, likely distorts actual market based prices and creates a significant operational burden on the manufacturer.

In addition, we assume the allocation rule only applies to those parts of an arrangement involving a contingent, or bundled, discount or price concession. For example, assume Product A is discounted 10% when purchased independent of Product B and Product B is discounted 15%. If purchased together, an additional 2% discount is offered off of the gross sales of Products A and Product B. CMS should confirm that only the contingent, or bundled, discount, i.e., the overlay discount equating to 2% of gross sales, must be allocated.

In sum, J&J does not support the proposed change to the definition of bundled sales, and instead urges CMS to retain the current definition in the rebate agreement. Additionally, we urge CMS to exercise caution in defining the appropriate method for allocating discounts in bundled arrangements, specifically those special arrangements where monopoly, life-saving products are bundled with products that have competition. In these situations the current definition does not allow for the allocation of discounts to the intended product, which may ultimately jeopardize the integrity of AMP.

B. J&J Requests Guidance on the Definition of Customary Prompt Pay Discounts

J&J believes that CMS should clarify its definition of customary prompt pay discounts. CMS defines prompt pay discounts as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date." CMS should explain whether the term "routinely" includes temporary or one-time promotional offerings related to the discount for payment within a specified time period. J&J believes that the

exclusion should apply to temporary and one-time promotional offerings when consistent with normal business practices.

II. Determination of AMP – Section 447.504

A. Retail Class of Trade: Further Refinements to this Concept are Needed

J&J generally agrees with CMS's definition of retail class of trade. However, J&J requests further clarification on what it means to "sell or provide [covered drugs] to the general public." Absent further guidance, J&J is concerned that manufacturers may interpret and apply this standard inconsistently. For example, J&J does not follow CMS's logic in excluding sales to nursing homes and long term care pharmacies from AMP on the basis that these entities are not in the retail class of trade. Although a long-term care facility does not resell the product to the "general public" at large, long term care facility patients are members of the general public, and these products are covered under the Medicaid outpatient drug benefit. Similarly, physician-administered drugs are ultimately provided to a physician's patients who are members of the general public. On the other hand, managed care mail order pharmacies may restrict their sales to those individuals who are members of their plan. This limitation may, or may not, determine whether mail order pharmacies distribute drugs to the "general public." Specialty pharmacies, hospital outpatient units, outpatient clinics, and many other types of entities also restrict their sales in various ways and, likewise, it is unclear whether they are within the definition of retail class of trade. J&J is concerned that the general definition of "retail pharmacy class of trade" does not clarify all matters for manufacturers, particularly in light of the seeming inconsistencies among the specific examples provided by CMS.

With regard to mail order pharmacies, long term care pharmacies, and Managed Care Organizations ("MCOs"), further complications arise. For instance, J&J agrees that mail order pharmacies should be included in the definition of retail class of trade, and accordingly their prices should be included in the AMP calculation. Similarly, although long-term care pharmacies are excluded from the definition of retail class of trade and therefore their prices are excluded from the AMP calculation, these types of entities frequently provide pharmacy services for home health care. Sales to long term care pharmacies are further complicated by the fact that some of these sales may be covered by Part D. CMS should clarify how rebates paid by the manufacturer to Part D plans for long term care beneficiaries should be treated in the AMP calculation.

Finally, the Proposed Rule does not specifically address price concessions provided to MCOs that are not "staff-model" HMOs. While a PBM may provide pharmacy benefits management to a number of managed care entities and other clients, many individual MCOs provide their own pharmacy benefit services for their plans through unaffiliated networks of retail pharmacies. These managed care plans are generally providing

benefits related to transactions that flow through the retail class of trade, much as PBMs do. J&J would assume that price concessions provided by manufacturers to these types of entities should be treated similarly to PBM rebates associated with retail utilization. However, J&J requests that CMS clarify the treatment of this significant segment of the marketplace.

In addition to providing guidance on what is meant by selling or providing drugs to the "general public," J&J requests clarification with regard to entities not specifically listed in the Proposed Rule. In other words, CMS should state whether it intends for any entity that is not expressly excluded from the retail class of trade (e.g., long term care, direct hospital sales, staff model HMOs), to be considered included in the definition.

B. J&J Requests that CMS Clarify Which "Prices" are Included in the Calculation of AMP

J&J requests that CMS clarify what types of "prices" it considers to be included in the AMP calculation. In J&J's view, the average revenue realized should reflect all discounts and price concessions paid on units that are sold through to the retail class of trade, regardless of to whom the discounts and price concessions are paid.
CMS appears to be taking a similar position by including discounts to PBMs, SPAP rebates, and Part D rebates in the calculation of AMP. We do not interpret the Proposed Rule to mean that CMS has identified PBMs as entities within the retail class of trade. Instead, we interpret the rule as including PBM rebates because the rebates are price concessions given, in CMS's view, on units that are sold through the retail class of trade. We request that CMS clarify that this interpretation is correct because it may be important for purposes of applying the definition of retail class of trade to future arrangements. One way it can do so is by, when referring to entities that are not in the retail class of trade, using the term "price concessions that are paid on units sold through the retail class of trade."

C. J&J Encourages CMS to Further Refine its PBM Rebate Guidance

J&J requests that CMS provide guidance concerning which PBM price concessions should be included in AMP. The Proposed Rule requires manufacturers to include all PBM rebates, discounts or other price concessions "associated with" sales of products to the retail class of trade in the calculation of AMP. The preamble to the Proposed Rule further discusses this requirement and requests comments on whether CMS should define which rebates, discounts, or price concessions should be included in AMP and how to best measure them. J&J supports the inclusion of PBM rebates in the calculation of AMP to the extent these price concessions are related to transactions that flow through entities covered under the definition of retail class of trade. However, J&J requests further clarification on the treatment of PBM rebates where a transaction flows through an entity that is not in the retail class of trade (e.g., long term care).

CMS has asked for comments related to how PBM price concessions should be reported to CMS to assure that appropriate price adjustments are captured and included in AMP. We do not believe that PBM price concessions should be reported separately to CMS. PBM price concessions are just one element of the AMP calculation. Based on statute, regulations and guidance, manufacturers must appropriately capture direct and indirect sales transactions, discounts and rebates to wholesalers and retailers and a myriad of other price concessions offered to a variety of entities (e.g. Part D plans, State Pharmaceutical Assistance Programs ("SPAPs"), PBMs). While PBM arrangements may be complex, many other aspects of the AMP calculation are equally, if not more, complex. We see no compelling reason why CMS would want this single element, PBM price concessions, reported separately. Given the amount of transaction data and total inclusions and exclusions required for an AMP calculation, reporting of PBM price concessions alone will not help CMS determine the appropriateness of any manufacturer's AMP calculation. Additionally, reporting of any individual elements of the AMP calculation will subject the manufacturer to additional unnecessary operational burdens to comply.

D. J&J Requests Clarification on Administrative and Service Fees

J&J requests clarification on CMS's treatment of administrative and service fees. CMS proposes "that all fees except fees paid for bona fide services should be included in AMP." CMS defines "bona fide service fees" to mean "fees paid by a manufacturer to an entity, which represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." CMS states that its treatment of administrative and services fees is consistent with the treatment of such fees for purposes of the ASP calculation. However, CMS does not address whether its guidance in the Medicare Physician Fee Schedule Rule concerning the treatment of these fees is incorporated into and applies to Medicaid rebate calculations. We request that CMS expressly incorporate this guidance in the final rule.

J&J further requests that CMS allow manufacturers to make reasonable assumptions concerning whether or not a service fee has been passed on in whole or part to an end user. The preamble to the ASP rule provides that "[i]f a manufacturer has determined that a fee paid meets the other elements of the definition of "bona fide service fee," then the manufacturer 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 any entity." Although this presumption is helpful in alleviating some of the administrative complications associated with monitoring and controlling whether an entity has passed on any portion of its fee to another entity, significant uncertainties remain unresolved (e.g., what quantum of evidence could "rebut" the presumption, and are amounts "passed through" as investment returns subject to the same rules as amounts passed through based on purchasing

performance?). J&J accordingly requests that CMS issue guidance providing that such arrangements do not constitute price concessions or discounts to purchasers.

J&J also urges CMS to adopt a clarification for GPO administrative fees. The standard should provide that fees that meet the GPO safe harbor regulation to the anti-kickback statute, 42 C.F.R. § 1001.952(j)(2), will not be considered to constitute price concessions unless they are passed on to the GPO's members as part of an agreement between a manufacturer and the GPO. We believe guidance to this effect is warranted to protect common business arrangements and is wholly consistent with the treatment of such fees in other contexts (i.e., under the anti-kickback statute). Further, a presumptive exclusion of GPO administrative fees recognizes their unique role in the supply chain and distinctiveness from price concessions.

E. Inclusion of Discounts and Price Concessions to SPAPs and SCHIPs Is Inconsistent with The Rationale for Their Exemption from Best Price

J&J is concerned that requiring the inclusion of discounts and price concessions mandated by States for their SPAPs and State Children's Health Insurance Program ("SCHIP") programs is inappropriate because these do not represent market-based pricing. These rebates typically are determined based on a State prescribed formula and are paid directly to the States. As such, including these rebates in the AMP calculation may not be consistent with the intent that AMP represents a net price based on market transactions.

F. CMS should Clarify the Treatment of Tricare Retail Pharmacy Sales

J&J requests that CMS clarify that voluntary rebates offered under the Tricare retail pharmacy program are excluded from AMP and BP based on the statutory exemption for "any price charged on or after October 1, 1992, to the Department of Defense."[1] The exclusion should not be based on the statutory exemption for depot prices because there is no procurement by the Department of Defense of the drugs that are sold through its retail pharmacy network.

G. J&J Requests that CMS Exclude Direct Patient Sales from AMP and BP

J&J requests that CMS reconsider its rationale for including direct sales to patients in the calculations of AMP and BP. CMS has explained that "retail pharmacy class of trade" includes entities that purchase drugs from manufacturers in order to distribute the product to the general public. However, patients who purchase drugs from manufacturers are not distributing to the general public, and are thus not within the retail

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1 SSA § 1927(c)(1)(C)(I).

class of trade. Moreover, patients are not among those entities listed in the definition of BP pursuant to section 1927(c)(1)(C)(i).

H. J&J Requests that Coupons Benefiting Only the Consumer Be Excluded from AMP and BP Regardless of How They Are Redeemed

J&J is concerned about CMS's proposal on the treatment of coupons for Medicaid AMP and BP calculations based only on from whom and how they are redeemed. CMS proposes that coupons redeemable directly from manufacturers by any entity other than the patient should be included in AMP and BP calculations because, CMS reasons, these coupons affect the pharmacy retail sale price or the price entities pay. J&J believes this interpretation may be too restrictive and discourage commonly established coupon practices that benefit consumers and promote access to life-improving medications.[2]

We recommend that CMS change its Proposed Rule to clarify that as long as coupons are only for the benefit of the patient, they should be excluded from Medicaid AMP and BP calculations. We believe that such an approach is consistent with the economics of coupon arrangements because patient coupons, even when redeemed by an entity other than a patient, are not price concessions that affect net price to the retailer.[3] For example, one such scenario is where a manufacturer contracts with a vendor to issue and redeem coupons on its behalf. Although the consumer technically redeems the coupon indirectly from the manufacturer, through the vendor, this is the substantive equivalent to redeeming it directly from the manufacturer. There are also other similar scenarios, even where consumers redeem coupons from retail pharmacies or other purchasers. In all of these cases, the benefit of patient coupons typically accrues only to the consumer. In instances where an entity (e.g. retail pharmacy) collects the coupon from the patient and redeems it, the entity is usually only being made whole for the value of the coupon. Minor handling fees paid to the entity accepting and processing the coupon are to cover the time and related costs of the coupon transaction. They are service fees, similar to dispensing fees paid to pharmacists, and do not impact the price of the drug. Furthermore, CMS's proposal to include patient coupons in AMP and BP calculations except in narrowly defined circumstances (i.e., when redeemed directly to the manufacturer) is inconsistent with the definitions of retail pharmacy class of trade and AMP. Again, patient coupons directly benefit individuals. Therefore, they should properly be characterized as being outside the retail class of trade and excluded from AMP. We request that CMS clarify its treatment of coupons in the final rule.

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2 We note that our discussion in this section is intended to apply not only to "traditional" consumer coupons redeemed at the retailer, but also to similar programs such as product trial "vouchers" and similar redemption vehicles.

3 Courts have recognized and held that consumer coupons should not be considered to constitute price concessions to the retail entity. See e.g., Indian Coffee Corp. and Penn-Western Food Corp. v. The Procter & Gamble Company and the Folger Coffee Company, 482 F. Supp. 1104 (Jan. 16, 1980).

I. J&J Believes that Guidance is Necessary with Regard to Good Faith Returns

J&J agrees with the proposal to exclude returns from the AMP calculation when returned in "good faith," pursuant to manufacturer policies that are not designed to manipulate or artificially inflate or deflate AMP. J&J requests that CMS clarify that a similar treatment is appropriate for the purpose of the BP calculation. Because a return is a reversal of a previous sales transaction, it would eliminate the existence of that transaction for the determination of BP. Additionally, the credit applied to a returned good should not be associated with other unrelated sales transactions as the credit would not be relevant to the price of any real sales transactions. Accordingly, returned goods should be excluded for the purpose of both calculations.

J. States Should Look Beyond the Scope of AMP to Assure Pharmacies and Other Providers are Adequately Reimbursed

In addition to the concerns that we raise above regarding the calculation of AMPs, as a general matter we believe the use of AMP as a basis for reimbursement causes conceptual concerns. The DRA explicitly establishes the Federal Upper Payment Limit based on 250% of AMP. Therefore moving forward, the regulations CMS issues for calculating AMP must serve the dual purpose of serving to calculate manufacturer rebates and limits on pharmacy reimbursement for covered drugs. Recognizing this reality, we urge that CMS ensure that States seek alternatives to assure pharmacists are adequately reimbursed for their product acquisition costs and the services that they provide in connection with dispensing covered drugs. Indeed, the federal law requires that States adopt rates that are sufficient to attract enough providers so as to ensure access to services for Medicaid patients, 42 U.S.C. §1396a(a)(30). This may be through advocating to the States that appropriate dispensing fees be paid to the pharmacies. We urge CMS to resist the temptation to alter the calculation of AMP from what has been proposed for the implicit purpose of covering other costs that pharmacists and other Medicaid providers may legitimately incur.

III. Determination of Best Price – Section 447.505

Many of J&J's concerns about the determination of Best Price under the Proposed Rule are discussed above in the comments on determination of AMP. Specifically, please see the AMP comments above for J&J's position on the following as it relates to both AMP and Best Price calculations: bundled sales, SPAP and SCHIP rebates, direct patient sales, coupons, and good faith returns.

A. Stacking

J&J requests that CMS clarify that manufacturers are not required to aggregate discounts offered to different entities when calculating BP. The Proposed Rule generally

defines BP as the lowest price available from a manufacturer to any entity that is not otherwise excluded from the BP determination. The Proposed Rule further provides that BP shall be calculated "to include all sales and associated discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount or other price concession is specifically excluded by statute." CMS should make clear that the references to "all sales and associated discounts" and "to any entity" are not intended to require a manufacturer to "stack" discounts offered at one level of the pharmaceutical delivery system (e.g., to a wholesaler) on top of discounts offered at a completely different level of that system (e.g., to a retailer or health plan). Unlike AMP, which clearly contemplates that prices be aggregated to determine an "average" amount, the BP is the single lowest price given by the manufacturer to a single customer. We believe that this clarification is consistent with CMS's preamble discussion of the BP definition. Moreover, this interpretation is sound from a policy perspective. Manufacturers are not in a position to determine end user prices. Requiring them to do so would require speculation and could introduce a high degree of uncertainty and inaccuracy in the BP calculation process. Accordingly, clarification concerning the scope of discounts included in BP (i.e., only those discounts associated with a sale to a single customer) is needed in the Final Rule.

IV. Authorized Generic Drugs – Section 447.506

A. J&J Requests Guidance on How Certain Implications of the Proposed Rule for Authorized Generics Will Be Addressed

J&J requests that CMS clarify how the Proposed Rule on "authorized generics" set forth in proposed 42 C.F.R. § 447.506 will apply in practice to several common types of transactions. J&J requests further guidance on the calculation of AMP and BP when both the brand and authorized generic manufacturer are selling the product. For example, this could apply to situations where two manufacturers have an agreement to co-market a product under a single labeler code. Because only one product is involved and, as such, it is not an authorized generic arrangement, J&J believes that all sales of that product should be considered when calculating AMP and BP and requests that CMS provide guidance in order to confirm this interpretation. Another situation on which the Proposed Rule is ambiguous occurs where the brand manufacturer licenses an authorized generic manufacturer to manufacture and distribute a generic version of the product for a fee. The Proposed Rule would require the brand manufacturer to account for the authorized generic manufacturer's sales in its AMP and BP calculations. It does not, however, specifically address how the license fee should be treated. Because these fees are paid in exchange for permission to market and sell the product, and are not sales prices, J&J believes that they should be excluded from AMP and BP. We request guidance to confirm that this interpretation is correct. Similarly, J&J believes that further guidance is necessary to confirm that a brand manufacturer that grants an authorized generic manufacturer permission to distribute a generic version of the product, but the brand manufacturer also produces the product for a fee pursuant to a manufacturing and supply agreement, would be not be required to account for the manufacturing fee or transfer

price as part of its pricing calculations. Because these contract manufacturing fees represent a contractual agreement between the parties, and are not sales prices, J&J believes that they should not factor into AMP and BP calculations. To require otherwise could also result in the manufacturing fee and sale price for a single unit of the product to be reflected in the BP calculation for two different quarters. Accordingly J&J believes further clarification from CMS is necessary to avoid such ambiguity.

J&J has questions concerning the mechanics of performing the required AMP and BP calculations. It is unclear whether the calculations should be a weighted average based on the units of the brand and authorized generic manufacturers or should be based on blended transactional data. J&J strongly favors using a weighted average approach and believes it provides the same degree of accuracy in the calculations. J&J also requests that CMS allow brand manufacturers to rely on the data reported to it by the authorized generic company. Brand manufacturers should not be in the position of reviewing an authorized generic company's AMP methodology or specific calculations and trying to conform them to the brand manufacturer's approach. In addition, the Proposed Rule's reporting requirement necessitating brand and authorized generic manufacturers to exchange detailed transaction data may implicate antitrust and trade issues. J&J thus requests that CMS coordinate and consult with the Federal Trade Commission and other agencies as appropriate so that such agencies may issue guidance addressing the regulatory concerns associated with the reporting and data-sharing requirements.

J&J requests that CMS clarify other arrangements that it considers to be outside the scope of the authorized generic provisions. One such arrangement involves drugs with redesignated NDCs and whether they should be combined and a single AMP calculated for all products codes at a nine-digit NDC level. CMS's previous guidance directed manufacturers to report these separately, and we believe this treatment should continue to apply. CMS also should provide guidance concerning the applicability of the authorized generic provisions in situations where products have been sold outright to another company and the original NDA owner still has inventory that is being sold. Again, in keeping with its previous guidance, CMS should direct manufacturers to continue reporting separate AMPs and BPs.

V. Requirements for Manufacturers – Section 447.510

A. J&J Requests that CMS Clarify that the Regulations Will Apply Only on a Prospective Basis and CMS Approval Is Not Necessary for Methodology Changes Necessitated by the Final Rule

J&J requests that CMS clarify that, other than as directed by the DRA, the regulations will apply only on a prospective basis. J&J understands that the regulations implement and provide guidance concerning some provisions enacted under the DRA (e.g., authorized generics, monthly reporting of AMPs) and that for many of these statutory-specific provisions the timeline for implementation is not within CMS's

discretion. However, there are many other provisions in the Proposed Rule that address matters outside of the DRA and indisputably reflect changes in the agency's approach in areas not addressed by the DRA itself. We believe that a prospective application of these provisions, when final, will be necessary to provide for consistency among manufacturers. Historically, the calculation of AMP has been ambiguous and, as reported by the OIG, manufacturers use different methodologies to calculate AMP. Applying the non-DRA specific final regulations on a retrospective basis could cause confusion as to whether manufacturers must recalculate and resubmit AMPs and BPs for prior quarters. A retrospective application also could create an unanticipated administrative burden for CMS if it is required to expend resources to review prior quarter changes to calculations. Accordingly, J&J recommends that CMS identify the timeline for implementing the regulations and that such timeline be on a prospective basis, only.

In a similar vein, J&J urges CMS to provide for a reasonable implementation time frame of at least four quarters following the promulgation of a final rule. As a practical matter, the rule is likely to require significant changes in systems across the industry which will need to be implemented and validated. Implementation in any lesser time will be dependent on the use of an increased number of assumptions and estimates in the calculation. These changes will need to occur at the same time as manufacturers are being required to implement monthly price reporting, and will ultimately be "competing" for the same resources as are required to implement numerous government price reporting obligations.

J&J also requests that CMS specify in the Final Rule that CMS approval of methodology changes is not required where the changes are being made to comply with new regulatory requirements. In a related vein, CMS should clarify how manufacturers should make corrections subsequent to the issuance of the Final Rule. For example, CMS should provide guidance on whether a manufacturer that makes a correction to the quarterly calculation of AMP also should make corrections to the monthly calculations that are a part of the quarter.

B. J&J Requests that CMS Reconsider it Proposed Certification Requirement

J&J requests that CMS reconsider its proposal to require a certification that comports with the language of the ASP certification. Unlike for ASP, we believe that there is no statutory or regulatory basis for requiring manufacturers to give certifications. Further, J&J questions the workability of such a requirement given the additional burden already being imposed on manufacturers for monthly calculations and the increased complexity of calculations. In particular, a certification requirement is not reasonable until the details of the AMP and BP calculations are resolved and pressure tested following the release of the final rule. Notwithstanding J&J's strong objections, insofar as CMS continues to require certifications, we request that CMS incorporate a knowledge

qualifier (e.g., "to the best of my knowledge and belief") to be consistent with the Medicaid statute's civil monetary penalty provision and provide a meaningful venue for manufacturers to obtain timely, reliable direction on how to handle unclear aspects of the calculation and unanticipated situations that may require a deviation from standard practice, e.g., negative monthly AMPs.

C. J&J Requests that CMS Clarify Several Aspects of the Proposed Rule Regarding Recalculation of Base Date AMP

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

D. J&J Requests that CMS allow Manufacturers to Use a 12-Month Rolling Average Methodology for Monthly and Quarterly AMP Calculations

J&J requests that CMS permit manufacturers to use a 12-month rolling average methodology for monthly and quarterly AMP calculations. We believe this is particularly important because monthly AMPs will be used for reimbursement purposes and, therefore, similar to the ASP calculation, it is important to minimize volatility. However, J&J does not believe that the use of a smoothing methodology should be absolutely required. In other words, in recognition of the additional computational burden imposed by using a smoothing methodology, manufacturers should be given the option of applying a smoothing methodology either on an NDC code or labeler code basis. If the agency permits smoothing, we request that CMS specify whether monthly or quarterly periods should be used to determine the percentage applied to AMP calculations and whether this will vary depending on whether a manufacturer is calculating a quarterly or monthly AMP. We believe the smoothed period and percentage should be the same for monthly and quarterly calculations to ensure greater consistency and minimize questions about differences between the calculations.

V. Further AMP Clarifications

A. J&J Requests that CMS Provide Guidance Regarding Price Concessions Offered by Generic Drug Companies

J&J supports CMS's efforts in the Proposed Rule to bring clarity and consistency to the Medicaid rebate program. However, to ensure manufacturers can implement a consistent methodology, J&J believes further guidance is required related to price concessions, payments and fees found primarily in the generic drug industry. The current Proposed Rule attempts to provide clarity into which price concessions and fees are included in AMP and BP, however the details, specifics and examples are primarily in the context of the marketplace for branded drugs. The generic industry business model is quite different from that of a branded manufacturer. Generic drug companies contract with and have arrangements with retail and wholesaler outlets to a significant degree while generally not contracting with PBMs, MCOs and other channels and payers in which branded drug companies interact.

As such, J&J requests that CMS provide guidance in the rule regarding price concessions offered by generic drug companies. Specifically, J&J recommends that all discounts, rebates, payments and fees (other than bona fide service fees), provided to entities in the retail pharmacy class of trade or related to sales flowing through the retail pharmacy class of trade, be included in the calculation of AMP and BP. This would include off-invoice discounts, rebates, payments for preferred product positioning, payments for the number of products carried or preferred, floor stock adjustments, new store credits, "meet-the-competition" price adjustments, and the like.

B. J&J Requests that CMS Coordinate with the OPA so that Manufacturers Must Only Perform and Report One Type of AMP Calculation

CMS should coordinate with the Office of Public Affairs within the Healthcare Systems Bureau of the Health Resources and Services Administration ("OPA") to ensure that manufacturers are required to calculate and report only a single AMP for the purpose of offering discounts to covered entities pursuant to the methodology specified in the Final Rule. Regardless of the DRA changes to the AMP calculation for purposes of the rebate program, OPA, in a January 30, 2007 letter, indicated that manufacturers that have signed pharmaceutical pricing agreements must continue to calculate 340B ceiling prices in accordance with the provision of the Social Security Act "as in effect on the date of enactment of this section." OPA letter (quoting 42 U.S.C. § 256B(c)). The OPA letter interprets this to mean that 340B ceiling prices must continue to reflect a reduction for prompt pay discounts.

Section 340B of the Public Health Services Act was enacted as part of the 1992 Veterans Health Care Act. Therefore, references to the Social Security Act should be based on the

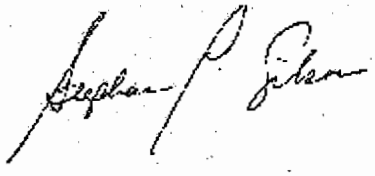
statutory provisions in effect at that time (*i.e.*, those provisions in effect under the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90")). Section 1927(k) of the Social Security Act then defined AMP to mean the average price paid to the manufacturer for drugs distributed to the retail pharmacy class of trade. A deduction for customary prompt pay discounts was not added until this provision was subsequently amended under the Omnibus Budget Reconciliation Act of 1993. According to OPA's interpretation, literally construed, the calculation of AMP for purposes of the 340B program should not include a reduction for customary prompt pay discounts and should never have. This treatment is fundamentally consistent with the post-DRA treatment of AMP which does not deduct customary prompt pay discounts from AMP. Moreover, following OPA's interpretation literally would require that manufacturers determine 340B prices using pre-OBRA 1993 Base AMP data in addition to creating a significant administrative burden without substantially changing anything in practice.

In addition to incorrect interpretation that the 340B AMP calculation requirements require a reduction for customary prompt pay discounts, J&J is concerned that OPA and CMS requiring two different AMP calculations will impose substantial administrative burdens. J&J disagrees with any requirement that manufacturers calculate two separate AMPs that is imposed for putative reasons. Such a requirement would simply inhibit manufacturers' ability to implement the DRA. Further, given the post-DRA importance of AMP and CMS's responsibility in defining key aspects of the calculation through its issuance of the Proposed and Final Rules, J&J requests that CMS coordinate with OPA and require, on a going forward basis, that manufacturers calculate only a single AMP that is consistent with the DRA.

* * * *

J&J appreciates the opportunity to comment on this Proposed Rule. Please do not hesitate to contact me at 202-589-1024 if you have any questions concerning the issues discussed herein.

Sincerely,



Stephanie P. Gilson
Assistant General Counsel

Submitter : Mrs. Megan Jolley Milne **Date:** 02/20/2007

Organization : University of Utah College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

As students at the University of Utah College of Pharmacy and future pharmacy health care professionals, we have an interest in the proposed changes to Medicaid reimbursement rates in the form of AMP. Our concerns are in line with the opinions of the National Community Pharmacist Association (NCPA), the American Pharmacist Association (APhA), and the Utah Pharmacists Association (UPhA). UPhA is a state pharmacy organization that represents over 450 Chain and independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBMs, regional and national health plans, and various governmental organizations.

Collection of Information Requirements

Collection of Information Requirements

Definition of Retail Pharmacy Class of Trade and Determination of AMP

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

Retail Pharmacy Class of Trade means that sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions (except prompt pay discounts) related to such goods and services. CMS proposes to exclude from AMP the prices of sales to nursing home pharmacies. CMS will include in AMP the prices of sales and discounts to mail order pharmacies. Inclusion of these lower mail order pharmacy prices would decrease AMP, thereby decreasing manufacturers current rebate liabilities the State Medicaid programs and other entities.

GENERAL

GENERAL

See attached petition and letter. The petition was signed by over 100 students of the University of Utah College of Pharmacy, or over one hundred future pharmacists. We are very concerned as to the potential detrimental effects the proposed regulations will have on our profession.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

A UPHA BOARD MEMBER WHO OWNS TWO PHARMACIES IN CEDAR CITY, UTAH DID THE FOLLOWING STUDY TO DETERMINE THE EXACT FINANCIAL IMPACT ON HIS GROSS AND NET PROFIT:

1. Medicaid represents 12.0% of the total prescriptions dispensed and 11.4% of the total prescription volume. 91% of the total business in these two stores is prescriptions.
2. 65.1% of all Medicaid prescriptions dispensed are generic.
3. Current average gross profit per Medicaid prescription is:
a. Brand Prescriptions $6.64
b. Generic Prescriptions $19.10
c. Brand and Generic Prescription overall average gross profit $16.75 which allows for a $4.36 profit on each Medicaid prescription using the Grant Thornton $12.39 average cost of dispensing calculation for Utah pharmacies.
4. Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:
a. $8.54(average acquisition cost on each generic Medicaid prescription) x 36%=$5.47 (average FUL per generic Medicaid prescription)
b. $5.47 x 250% =$13.68 (average AMP per generic Medicaid prescription)
c. $13.68 + $4.90 (current Utah Medicaid dispensing fee is $3.90 and it has been indicated to UPHA by the Utah State Medicaid Division that they are considering giving the pharmacies a $1.00 increase to cover AMP deficits) =$18.58 (average total reimbursement per generic Medicaid prescription)
d. $18.58-$8.54 (current average acquisition cost of each generic Medicaid prescription)=$10.04 (average gross profit per generic Medicaid prescription after AMP is implemented)
e. Brand and Generic Medicaid Prescription overall gross profit will be $8.85 per prescription after AMP is implemented. This will result in a net loss of $3.54 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study. This will result in a net loss of $116,667 in total profit to these two small pharmacies.

AS YOU CAN SEE FROM THESE CALCULATIONS THAT THE IMPLEMENTATION OF AMP AS IS CURRENTLY OUTLINED WILL HAVE A DISASTROUS EFFECT ON PHARMACIES, ESPECIALLY INDEPENDENT PHARMACIES. NCPA, APHA, UPHA, AND PHARMACIES IN UTAH ARE WILLING TO HELP IN REDUCING THE COST OF HEALTH CARE TO THE AMERICAN PEOPLE AND ARE WILLING TO FURTHER INCREASE GENERIC UTILIZATION AND THERAPEUTIC SUBSTITUTIONS THAT WILL DRASTICALLY DECREASE THE COST OF MEDICAID PRESCRIPTION DRUGS. IT IS OUR BELIEF THAT AMP WILL GREATLY DECREASE THE NUMBER OF RETAIL PHARMACIES IN UTAH AND

THE NATION AND THUS DECREASE PATIENT ACCESS TO HEALTH CARE. WE RESPECTFULLY ASK THAT CMS CONSIDER THE DETRIMENTAL OUTCOMES THAT WILL BE REALIZED IF AMP IS IMPLEMENTED AS CURRENTLY OUTLINED.

Regulatory Impact Analysis

Regulatory Impact Analysis

Comments:

Mail order pharmacies should be excluded for the following reasons:

1. All major mail order pharmacies in the U.S.A. are owned by PBM s. The alignment of the PBM, its customer,s and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies.

2. CMS states that the exclusion of mail order and PBM prices would substantially reduce the number of transactions included in AMP. Mail order pharmacies provide some prescriptions to Medicaid patients. PBM mail order companies provide approximately 20% of the prescriptions dispensed to the non-Medicaid market.

3. Mail order pharmacies favor the purchase in very large package sizes (NDC-11) yielding the lowest per unit price in the marketplace. These package sizes are not accessible to, nor feasible in a typical independent retail pharmacy due to smaller sales volume, inventory management and return on investment factors. It is not economically feasible for small independent pharmacies to purchase large package sizes as a standard of operations.

4. PBMs operate mail order facilities in the U.S.A. and they earn certain rebates, discounts, and other price concessions that are not available to retail pharmacies. Inclusion of PBM price concessions in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to our pharmacies.

5. PBMs do not distribute drugs except through their privately owned mail order facilities. Drugs dispensed and distributed through retail pharmacies are purchased and owned by the retail entities. PBMs credit their sales revenues as if they own the inventory, but they do not. Rebates earned by a PBM for sales of drugs at the retail pharmacy are not, in any fashion, shared with the pharmacy.

6. PBMs are not wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector.

As a result mail order pricing should NOT be considered in the AMP calculations.

Conclusion:

If the Final Rule permits the inclusion of mail order pricing in the calculation of AMP then these mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade-pg. 31-33
Inclusion in Best Price of PBM rebates, discounts and other price concessions-pg. 53

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 should exclude rebates pad to PBMs from AMP calculations: These rebates are not available to our retail pharmacies, and indeed, none of these funds are ever received by our pharmacies. 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.

How PBM price concessions should be reported to CMS-pg. 33

PBM Transparency is Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, neither at the federal nor 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. PBMs have been allowed, due to a lack of regulation, to keep most, if not all, of their information hidden; thus there is no transparency in the PBM Industry.

Use of the 11-digit NDC to calculate AMP-pg. 80

Response to Comments

Response to Comments

If the proposed definition of AMP is enacted, I can only see three possible outcomes:
1. Pharmacies refuse to sign contracts with Medicaid. Most of those who can afford to not sign contracts with Medicaid are in suburban, economically stable areas

with few Medicaid beneficiaries. Any Medicaid patients in their area will lose access to prescription benefits.
2. Pharmacies in rural areas where a majority of their patients are Medicaid beneficiaries will be forced to operate at a loss. They will be forced to close their doors, and Medicaid beneficiaries will have no other pharmacies to access their health care needs. The Medicaid beneficiaries will either have to drive hundreds of miles to the next nearest pharmacy, because their former pharmacy has been forced to close.
3. Pharmacies will have a perverse incentive to dispense brand prescriptions which cost ten times more than generic prescriptions affected by FUL. This will drive up the cost of Medicaid.
* Due to both #1 and #2, Medicaid beneficiaries will lose access to prescription coverage. These same patients who would be treated at a marginal cost with generic prescription drugs will now show up in emergency rooms, thus driving up the cost of Medicaid exponentially.

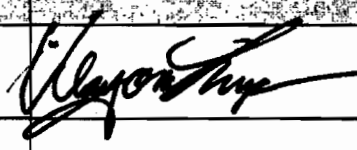
CMS-2238-P-1278-Attach-1.PDF

PETITION FOR CMS REGARDING MEDICAID REIMBURSEMENTS

	NAME	SIGNATURE	CONTACT INFO	DATE OF GRADUATION
1.	Megan Jolley Milne	Megan J Milne	megan.jolley@pharm.utah.edu	2009
2.	Melissa Thomas	Melissa Thomas	Melissa.Thomas@pharm.utah.edu	200
3.	Caitlin Oderda	Caitlin Oderda	katie.oderda@pharm.utah.edu	2009
4.	JAMES DAVIS	James Davis	james.davis@pharm.utah.edu	2009
5.	Rebecca Youngberg	Rebecca Y	rebecca.palmer@pharm.utah.edu	2009
6.	Ann Lingard	Ann Lingard	ann.lingard@pharm.utah.edu	2009
7.	[illegible]	[illegible]	[illegible]	[illegible]
8.	Angeleena Beutler	[illegible]	angeleena.beutler@pharm.utah.edu	2009
9.	Mike wright	mike wright	Mike.d.wright@hsc.utah.edu	2009
10.	Jared Jensen	Jared	jared.jensen@pharm.utah.edu	2009
11.	Sara White	Sara White	sara.white@pharm.utah.edu	2009
12.	[illegible]	[illegible]	[illegible]	[illegible]
13.	Adam Davies	[illegible]	adam.davies@pharm.utah.edu	2009
14.	Nikki Milne	Nikki Milne	nikkimariem@hotmail.com	2009
15.	Jessica Upton	[illegible]	Jessica.Upton@intermountainmail.org	2009
16.	[illegible]	[illegible]	[illegible]	[illegible]
17.	NICK WEAVER	Nicholas Weaver	NICHOLAS.WEAVER@PHARM.UTAH.EDU	20
18.	Jamesan Rice	Jamesan R	jamesan.rice@pharm.utah.edu	2009
19.	Nina Ivanova	Nina Ivanova	nina.IVANOVA@pharm.utah.ed	
20.	Alisa Hughes	Alisa Hughes	alisa.hughes@hsc.utah.edu	2009
21.	Susan Morstadt	Susan Morstadt	susan.morstadt@pharm.utah.edu	2009
22.	Nick Sparrow	[illegible]	nicholas.sparrow@pharm.utah.edu	20
23.	Lance Lindberg	[illegible]	lance.lindberg@pharm.utah.edu	20
24.	Rochelle Christen	Rochelle Christen	rochmills@yahoo.com	2009

Name	Signature	Address & Contact Info	PharmD Candidate
16. Ryan Nielsen	[signature]	1419 Allen Park Dr. SLC, UT 84105 [illegible]	Class of 2010
17. Megan Glanville	[signature]	3495 W. 5735 S. Taylorsville, UT 84118	Class of 2010
18. Lorinda Anderson	[signature]	1805 S. 500 E SLC, UT 84105	Class of 2010
19. Amber Nelson	[signature]	115 University Village SLC 84108 801-347-7724	Class of 2010
20. Todd Seamons	[signature]	1302 Univ. Vlg SLC, UT 84108 801-585-4125	Class of 2010
21. [illegible]	[signature]	[illegible] South [illegible] W Riverton, UT [illegible]	Class of 2010
22. Sean Leavitt	[signature]	2078 [illegible] Ct. #204 Cottonwood Heights, UT 84121	Class of 2010
23. Koffi Amevor	[signature]	145 University Village SLC, UT 84108	Class of 2010
24. Rory Davies	[signature]	Rory.Davies@utah.edu	Class of 2010
25. Scott Yost	[signature]	scott.yost@utah.edu	Class of 2010
26. [illegible] Peterson	[signature]	thomas.peterson@utah.edu	Class of 2010
27. Julie Smith	[signature]	j[illegible].smith@utah.edu	Class of 2010
28. Maryn Risenmay	[signature]	m.risenmay@utah.edu	Class of 2010
29. Amber Diaz	[signature]	amber.n.diaz@gmail.com	Class of 2010
30. Amber MacArt	[signature]	4525 W. 5615 So. Kearns, UT 84118 amber.macart@utah.edu	Class of 2010
31. Ashley Campbell	[signature]	1065 [illegible] Lane Ogden, UT 84403 [illegible]@aol.com	Class of 2010
32. [illegible]	[signature]	[illegible] @[illegible]	Class of 2010
33. Erica Bushnell	[signature]	erica.bushnell@utah.edu	Class of 2010
34. Nikki Hendricksen	[signature]	nicole.hendricksen@[illegible]	Class of 2010

Name	Signature	Address & Contact Info	PharmD Candidate
35. Michael C Boyer		michael.boyer@utah.edu	Class of 2010
36. Mike Brown		michael.h.brown@utah.edu	Class of 2010
37. Eva Salazar		eva.salazar@utah.edu	Class of 2010
38. MATI PEPPER		matthew.pepper@utah.edu	Class of 2010
39. Jacob White		jacob.white@utah.edu	Class of 2010
40. Sonja Kowsoum		s.kowsoum@utah.edu	Class of 2010
41. Matt Higley		matt.higley@utah.edu	Class of 2010
42. Alvin Nichols		[illegible]	Class of 2010
43. Loren Davis		[illegible]	Class of 2010
44. Nathan Gosney		ng77@yahoo.com	Class of 2010
45. LILLA NEPSTAD		lilla.nepstad@utah.edu	Class of 2010
46. Brandon Bellows		brandon.bellows@utah.edu	Class of 2010
47. [illegible]		[illegible]	Class of 2010
48. Koby Taylor		Koby.Taylor@utah.edu	Class of 2008
49. Andrea Chan		Andrea.chan@utah.edu	Class of 2008
50. [illegible]		[illegible]	Class of 2008
51. Crystal McCoy		crystal.mccoy@utah.edu	Class of 2008
52. Joanne Chapman		joanne.chapman@utah.edu	Class of 2008
53. BRETT MARKHAM		brett.markham@utah.edu	Class of 08

Name	Signature	Address & Contact Info	PharmD Candidate
54. VILAYVONE THIPSOUVAN		vilayvone.thipsouvan@utah.edu	Class of 2009
55.			Class of _____
56.			Class of _____
57.			Class of _____
58.			Class of _____
59.			Class of _____
60.			Class of _____
61.			Class of _____
62.			Class of _____
63.			Class of _____
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65.			Class of _____
66.			Class of _____
70.			Class of _____
71.			Class of _____
72.			Class of _____
73.			Class of _____
74.			Class of _____
75.			Class of _____

Name	Signature	Address & Contact Info	PharmD Candidate
95. Wade Poulson	Wade R Poulson	(801) 389-0267	Class of 2008
96. Ben Campbell		(801)-972-2886	Class of 2008
97. Kandis Brunson	Kandis Brunson	801-735-4423.	Class of 2008
98. Amberlie Stoddard	Amberlie Stoddard	(801)407-6327	Class of 2008
99. Erin Tibbs		801-682-8098	Class of 2008
100. Leslee Ash		(435) 590-4001	Class of 2008
101. Jason Olsen		(801) 292-5808	Class of 2008
102. BRYCE BITTON		(801) 721-1843	Class of 2008
103. Evan Draper		(801) 966-5852	Class of 2008
104. Jacob Lloyd		(801) 390-6330	Class of 2008
105. Dean Nielson		(801) 544-3715	Class of 2008
106. Ryan Steed		801-593-0650	Class of 2008
107. Katherine Wilkerson		(801) 585-4252	Class of 2008
108. Angie Flint		(801) 867-4534	Class of 2008
109. Lindsay Phillips	Lindsay Phillips	(801) 309-6264	Class of 2008
110. Lindsay Spear	Lindsay Spear	(801)763-0971	Class of 2008
111. Julie Bostick	Julie Ann Bostick	(801)544-2489	Class of 2008
112. Fred Henrion		801 581 8089	Class of 2008
113. Phung Nguyen		(801)631-7434	Class of 2008

Name	Signature	Address & Contact Info	PharmD Candidate
114. Kenneth Brown	Kenneth Brown	Kenneth.Brown@utah.edu	Class of 2008
115. Jacob Smith	Jacob Smith	jacob_b.smith@utah.edu	Class of 2010
116.			Class of _____
117.			Class of _____
118.			Class of _____
119.			Class of _____
120.			Class of _____
121.			Class of _____
122.			Class of _____
123.			Class of _____
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127.			Class of _____
128.			Class of _____
129.			Class of _____
130.			Class of _____
131.			Class of _____
132.			Class of _____

Submitter : Mr. Laurence Fligor **Date:** 02/20/2007

Organization : Ritzman Pharmacies, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1279-Attach-1.DOC

#1279

February 19, 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

1. You have the comments and suggestions filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We agree with and support the positions represented by NCPA and NACDS.

2. Generic medications average roughly 1/6th of the brand name cost. AMP as currently defined means that pharmacies are much better off dispensing brand name medications rather than losing money on generics. Instead of saving, there is a great chance of spending more. What a waste of tax payer dollars, when governmental policy is only focused on an aspect of cost savings that will ultimately cost more money in total.

3. Can CMS really ignore the report of the General Accounting Office (GAO) and proceed with releasing of AMP as currently defined?

4. The very existence of community pharmacy is at stake by the Federal Government setting such an irresponsible and inaccurate benchmark for community pharmacy cost of goods such as AMP currently is defined

5. The level of customer service and within rural and urban communities is seriously threatened when the AMP being used does not even cover wholesale cost of medication, let alone the cost of filling a prescription.

Please do the right thing for Medicaid Patients to be able to continue to get the medication they need.

Please do the right thing when spending tax payer dollars.

Please do the right thing for community pharmacy.

Sincerely,

Laurence W. Fligor, R.Ph.
Chief Technical Officer
Ritzman Pharmacies, Inc.

Submitter : Mr. Laurence Fligor **Date:** 02/20/2007

Organization : Ritzman Pharmacies, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1280-Attach-1.TXT

#1280

February 19, 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

1. You have the comments and suggestions filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We agree with and support the positions represented by NCPA and NACDS.

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Please do the right thing when spending tax payer dollars.

Please do the right thing for community pharmacy.

Sincerely,

Laurence W. Fligor, R.Ph.
Chief Technical Officer
Ritzman Pharmacies, Inc.

Submitter : Mr. Thomas Arnold **Date:** 02/20/2007

Organization : Florida Medicaid

Category : State Government

Issue Areas/Comments

Background

Background

See attachment

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

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment

Response to Comments

Response to Comments

See attachment

CMS-2238-P-1281-Attach-1.DOC

#1281

FLORIDA MEDICAID

CHARLIE CRIST
GOVERNOR

ANDREW C. AGWUNOBI, M.D.
SECRETARY

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via Express Mail and Electronically to www.cms.hhs.gov/eRulemaking

Re: Proposed Rule CMS-2238-P
RIN 0938-AO20
42 CFR Part 447

Dear Ms. Norwalk:

The Florida Medicaid program respectfully submits the following comments regarding the proposed rule to implement the provisions of the Deficit Reduction Act of 2005 pertaining to prescription drugs under the Medicaid program.

Florida believes that the DRA takes an important step toward facilitating transparency and accuracy of prescription drug pricing data in the Medicaid program. Because of the shared responsibility that states have with the federal government in providing quality, affordable care to Medicaid beneficiaries, we agree that the DRA provisions and the supporting proposed rule are essential.

The proposed rule would impact reimbursements to both pharmacy and physician providers through changes to the Federal Upper Limits (FUL) and requirements for National Drug Code inclusion on physician claims, modify the definition of the Average Manufacturer Price (AMP) on which FUL pricing will be based, require CMS to share AMP data with states as well as make AMP data publicly available. It also implies that states will be expected to increase dispensing fees for pharmacy providers.

Making AMP data available to the states and providing more direction to manufacturers on how to report this information is beneficial to the states. AMP data will be used by states in various scenarios, including calculation of rebates and reimbursement to pharmacy providers, consequently impacting pharmacy expenditures. While there is no direction in the rule to expand AMP based pricing beyond the FUL for multiple source products there is widespread concern in the provider community that AMP based pricing for all drugs will evolve. Nonetheless, it is extremely important for states to continue to have flexibility in determining estimated acquisition cost (EAC) for use in their reimbursement methodologies, while using FUL as a maximum reimbursement ceiling for multiple source.

drugs. It is essential that the rule take into account those critical factors which would make AMP data most useful to the states.

Specific issues are individually discussed in detail below

Federal Upper Limit (FUL) Proposal

The Deficit Reduction Act requires CMS to establish federal upper limits for multiple source drugs purchased through the Medicaid program based on 250% of the lowest reported AMP. CMS has requested comments on those aspects of the rule related to implementation of the new FUL methodology.

Proposed sections 447.512 and 447.514 address establishment of the FUL list, including criteria for inclusion, aggregate upper payment limits and ensuring appropriate supplies of listed drugs. CMS specifically asked for comments on the proposal to use 9-digit NDC's for establishing the FUL and the proposal to not consider the lowest AMP for a product if it is more than 30 percent lower than the next lowest product unless that product was the only competitor to the originator brand.

Florida currently reimburses pharmacies' EAC using an algorithm with multiple options; the lower of AWP – 15.4%, WAC + 5.75%, the Federal Upper Limit (FUL) or State Maximum Allowable Cost (SMAC), each plus a dispensing fee of $4.23 or the provider's usual and customary charge (billed amount). Pharmacies eligible to access 340b pricing are required to bill actual acquisition cost plus a dispensing fee of $7.50.

A significant number of reported AMPs on single source products are between 12% and 16% below the current Florida Medicaid reimbursement levels, and there are some products with reported AMPs that are more than 50% below the current basis and another group with reported AMPs well above our current basis of WAC+5.75%. These wide variations in AMPs make them unusable as a basis for reimbursement.

Over the past nine months we have encountered instances in which pharmacies are having difficulty finding product at or below 250% of average AMP. Complaints emanated primarily from independent pharmacies, but many are high volume with good purchasing power and practices. In other situations, reimbursement at 250% of average AMP was unreasonable overpayment. We do not believe that the variances will be substantially different when the DRA methodology of 250% of the lowest AMP is applied. This may result in inappropriate reimbursement for some products and inaccessibility of other products. The issue of product access is particularly important in Florida since the State implemented requirements for drug pedigrees in 2006. The result is that many out-of-state wholesalers are no longer able to sell their lowest priced multiple source drugs to Florida customers. This may become a nationwide issue when pedigree requirements are instituted nationally.

We agree that the 30 percent level for defining an outlier to be excluded from the calculation is reasonable. By definition the use of the lowest AMP, even disregarding any

447.504 (b) Average Unit Price

CMS proposes to include in the calculation of AMP a manufacturer's quarterly sales less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

This definition seems to support our suggestion below regarding treatment of discounts to PBMs and Mail Order pharmacies. If the discount or rebate occurs in the quarter it should be included in the AMP calculation. To the contrary, if a discount or rebate is a retroactive end-of-year rebate or charge back it should be excluded. Because of the myriad of innovative arrangements that frequently result in end of year charge backs and retrospective rebates based on market share changes, we believe that allowing manufacturers to include these or even estimates of these in calculating AMP will result in significant twelve to eighteen month revisions to AMP data. This will render AMP data unusable for reimbursement purposes. More importantly, it would serve to stabilize collection of rebates without frequent and multiple prior quarter adjustments. We also believe that many of these price concessions are linked to long-term market share agreements that would result in the very late AMP revisions discussed in other sections and would serve to reduce the utility of AMP's for reimbursement by states or other health plans.

We propose that only those rebates and discounts applicable to the reporting quarter be used in reporting AMP. While this may produce a small financial penalty to the manufacturer in the form of slightly increased AMPs and rebates it will serve to stabilize the reported AMPs and make them more useful to states and other payers.

447.504 (d) Net sales

CMS proposes to define net sales as quarterly gross sales revenue less cash discounts allowed and all other price reductions which reduce the amount received by the manufacturer.

Again, we support this definition because it addresses quarterly gross sales revenue less discounts and price reductions which reduce the amount received by the manufacturer. This does not appear to permit manufacturers to include chargebacks or rebates from other quarters which we think should be excluded from the definition of "net sales" as well as AMP.

407.504 (h) Sales, rebates, discounts or other price concessions included in AMP

(10) Free goods, not contingent on any purchase requirement:

Exclusion of free goods from the AMP calculation effectively penalizes the manufacturer engaging in this type of marketing by not lowering the AMP which bases the federal

outlier AMP (more than 30% below the next lowest) will result in lower reimbursement than does our current methodology using 250% of the average of AMPs and may result in even more instances of inaccessibility. We believe CMS should include a provision for product specific exemptions or adjustments by state or region when products are unavailable in those markets at the FUL price. Finally, Florida, like many other states have been successful in negotiating substantial supplemental rebates on many multiple source products. Since reimbursement for multiple source drugs is measured in aggregate, we request that the rule be modified to acknowledge that states be permitted to demonstrate that payment for the originator brand product, after adjustment for federal and state supplemental rebates, may be the most cost effective option. Florida and other states can provide examples to demonstrate this.

With respect to using a 9-digit NDC number to calculate the AMP, rather than an 11-digit NDC number, Florida agrees that using 9-digit NDC's will not create undue disparities in reimbursement. Pharmacies will be compelled to purchase and dispense using the most cost effective product if reimbursement is not based on the most commonly used package size.

Determination of Average Manufacturer Price (AMP)

Section 447.504 (a) through (j) proposes revisions to various definitions and directions to manufacturers related to AMP calculation. Validity of CMS' considerations for inclusion or exclusion of factors in determining AMP is essential for obtaining data that accurately reflects drug pricing. The accuracy of this data is critical if states elect to use it in estimating true acquisition cost for use in future reimbursement methodologies.

We recommend that CMS adopt clear and specific policies to ensure consistency in the calculation of AMPs across all manufacturers. As stated previously, states will be impacted by the final AMP calculation in several ways; for rebates as well as provider reimbursement for multiple source drugs. In general, we agree with those factors CMS proposes to include/exclude in the calculation of AMP. We have addressed specific issues with several proposed factors below.

<u>447.504 (a) Determination of AMP</u>

Florida Medicaid supports a definition of that takes into account any discounts and rebates that would lead to a more accurate calculation of AMP.

The exclusion of customary prompt pay discounts from the AMP calculation will effectively increase the AMP resulting in incremental increases the state's rebate for these drugs. While this will incrementally increase the AMP and subsequent AMP based reimbursements it will also increase federal rebates comparably.

In the discussion of treatment for sales to PBMs and Mail Order pharmacies the language suggests including "All sales and associated discounts and other price concessions".

rebate on a higher value and by not lowering the spread between AMP and best price. We support the exclusion of free goods from calculation of AMP.

(11)Bona fide service fees:

We agree that certain service fees should be included in the calculation of AMP. Some wholesalers charge inventory service or stocking fees to certain manufacturers for carrying their products. Such fees should not be considered bona fide service fees as they do not meet the definition proposed. To the contrary these fees, as described and applied, effectively result in a discount that should be considered when calculating AMP. We are concerned that inventory service or stocking fees charged to manufacturers by wholesalers are not imposed uniformly and agree that these should be excluded from AMP to insure consistency between manufacturers.

447.505 Determination of Best Price

Section 447.505 addresses determination of best price and proposes to include in the calculation cash discounts, free goods that are contingent on any purchase requirement, volume discounts, PBM price concessions, chargebacks, incentives, administrative fees, service fees (except bona-fide service fees), distribution fees, and any other discounts or price reduction and rebates, other than Section 1927, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade. In general, we agree with this interpretation. As stated above, we recommend that CMS adopt clear and specific policies to ensure consistency in the calculation of best price across all manufacturers.

Similar to our comments related to AMP, we recommend that CMS adopt clear policies that require manufacturers to adjust data related to best price for a rebate period of cumulative discounts, if rebates or other arrangements subsequently adjust the prices actually realized

Effect of Proposed Rule on Reimbursement to Pharmacies

The Deficit Reduction Act addresses reimbursement to pharmacies for multiple source drugs using a specific formula for establishing federal upper limits (FUL) for those products. We believe that the statutory provisions are important in ensuring accuracy and transparency of AMP data. However, we recommend that CMS consider the impact of the proposed rule on reimbursement beyond those provisions related to multiple source products. While the rule does not require states to use AMP data for estimating the acquisition cost for reimbursement for single source products, we believe that the rule has some implications. This is particularly important in the discussion of dispensing fees.

It is important that CMS recognize the need to be flexible in determining reimbursement to providers in the state. CMS has indicated that states should consider the feasibility of

dispensing fees paid to pharmacies as new reimbursement methodologies might serve to lower ingredient costs paid to pharmacies. Florida like many other states has established pharmacy reimbursement in accordance with state budgetary requirements.

Every one dollar increase in dispensing fees for prescriptions dispensed to Florida Medicaid recipients would increase expenditures approximately $18 million. In order to offset this cost, the reduction to ingredient cost would need to be substantial. Contrary to the intent of the DRA, increasing dispensing fees to offset ingredient reimbursement reductions will not result in net savings to Medicaid agencies and state budgets.

Commercial insurance plans, Part D plans and other payers are somewhat insulated from pressure to increase dispensing fees; in fact pharmacies are prohibited from negotiating as a group to gain higher fees. We are concerned that only Medicaid will be compelled to address dispensing costs with increased fees per the DRA, effectively placing the burden of dispensing costs for all health plans on Medicaid alone.

Requirements for Manufacturers

Proposed section 447.510 of the rule would require manufacturers to calculate and submit AMP to CMS on a monthly basis and proposes that manufacturers be permitted to estimate the impact of end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS.
If manufacturers are allowed to submit estimates for end-of-quarter rebates and adjustments, they should be required to use the midpoint of potential rebate amounts rather than estimating maximum amounts.

We believe some consideration should be included for end-of-year rebates and allowances. If manufacturers engage in annual contracts with end-of-year settlements, they should be required to estimate these at minimum discount levels and not be permitted to retroactively adjust AMP values based on changes from annual contracts. Manufacturers will benefit from higher profits if annual contracts perform above the minimal standard and revising AMP values after the fact deems AMP unusable for setting reimbursement to pharmacies.

We agree that using a three month rolling average is complex and likely result in frequent errors on the part of manufacturers.

<u>447.510 (b) Timeframe for reporting revised AMP, best price, customary prompt pay discounts or nominal prices</u>

As discussed above, we are concerned that allowing manufacturers to retroactively revise their statement of AMP will result in significant payment errors and potential litigation should states base pharmacy reimbursement on the AMP supplied by manufacturers. We note there is at least an implied assumption that states will use AMP in some way to establish reimbursement to pharmacies for brand name drugs in addition to the DRA prescribed use to establish FULs. Permission of revisions for a period of

three years (twelve quarters) is excessive, and we suggest a maximum of one year (four quarters).

447.510 (e) Certification of pricing reports

We agree that each manufacturer's chief executive or financial officer, or delegate, should certify all reporting, and we request that CMS present a specific methodology for timely verification of the integrity and accuracy of calculations and price information reported by manufacturers.

447.510 (g) Data reporting formats

Although the proposed rule requires submission of data by manufacturers in an electronic format, data specifications and unit reporting are not provided in adequate detail. We recommend that CMS develop clear guidelines for the electronic format and standardized unit reporting.

Further, regarding CMS' comment on Section 600 (b) (2) (C) amending confidentiality requirements in section 1927 (b) (3) (D) to require public availability of monthly and quarterly AMP through website access, the format of the information supplied is critical to its use by states and public entities. This data should be presented in a format that can be downloaded by users into a spreadsheet or database rather than PDF files that are not easily usable by data analysis software.

Federal Financial Participation (FFP) Conditions Relating to Physician-Administered Drugs: Uniform unit reporting format by manufacturers for National Drug Code (NDC) and Dose

This provision would fully implement the requirement for providers to include the NDC number on reimbursement claims for physician-administered drugs for the state to receive federal participation funds for those claims. Florida supports requiring NDC reporting for drugs administered and billed by physician providers using procedure codes because this will facilitate invoicing for rebates from manufacturers and reduce disputes in this area.

There are two potential issues related to physician administered drugs. First, the physician must know prior to use of a product whether the manufacturer has a federal rebate agreement in place, so that claims can be reimbursed by Medicaid. If the product is not a covered outpatient drug, per section 1927(k)(2), the claim cannot be reimbursed by Medicaid unless the state is willing to fund the payment without federal participation. Florida will engage in educational outreach programs to notify providers about rebate eligible drug products and will deny payment for ineligible products.

Second, concerns have been raised by several states that some Medicare carriers are not prepared to provide the detailed NDC information on crossover claims to Medicaid

payors, even though the detail may have been presented on the original Part B claim. We have been assured that Florida Medicaid will get NDC information from Part B carriers if it is present on the Part B claim.

Florida has implemented invoicing for physician administered drugs by using a J-code crosswalk to identify claims for which rebates can be collected.

Finally, the UB xx claim form does not include a field for NDC reporting. Because dialysis centers can use this claim form we recommend that it be modified to permit NDC reporting. The electronic equivalent 837 x transaction does permit NDC reporting.

We commend the thoroughness and hard work put into the development of the proposed rule and we look forward to working with CMS staff on implementation of these important provisions. We would be pleased to meet with CMS staff at any time to provide additional information that may be useful in finalizing the rule. If you have any questions, please do not hesitate to contact me or Jerry Wells, Pharmacy Bureau Chief at (850) 488-1447.

Sincerely,

Thomas W. Arnold
Deputy Secretary for Medicaid